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Implementing and expanding vaccination services: An updated review for routine vaccinations

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Sept. 2, 2019 (expires Sept. 2, 2022)
Activity Type: Knowledge-based
To earn continuing education credit:
ACPE UAN: 0207-0000-19-009-H01-P;
ACPE UAN: 0207-0000-19-009-H01-T

Upon successful completion of this article, the pharmacist should be able to:

1. Review the importance of pharmacist-provided vaccination services and the roles that pharmacists and other pharmacy personnel play in delivering this service.
2. Identify key steps, supplies, documents, required documentation, and other resources for starting or expanding a pharmacy-based vaccination service.
3. Recall routine vaccine storage, handling, and reconstitution according to manufacturer specifications.
4. Apply routine vaccine recommendations given a patient specific case including specific vaccine formulations, dosing, routes of administration, and safety considerations.

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INTRODUCTION

Vaccinations are a critical health care service and are increasingly available in pharmacies nationwide. Pharmacists have become widely accepted as immunizers and provide an increasing proportion of vaccines annually. Despite these advances, vaccination rates in the U.S. still remain far below national public health goals and represent a significant opportunity in particular for community pharmacists, pharmacy owners, and pharmacy technicians.

Independent pharmacies are, in many ways, ideal settings for vaccination services. Compared with their chain pharmacy counterparts, independent pharmacists may be seen as more approachable and therefore may have stronger personal relationships with their patients. Pharmacy-based vaccination services represent an important shift in health care delivery toward providing more comprehensive patient care services in settings other than a physician's office. Vaccination services, when combined with other pharmacy-based services such as medication therapy management, wellness screenings, or medication synchronization, can further the value of comprehensive patient care that a pharmacy provides. Vaccinations may also be a lucrative endeavor, because starting a vaccination program or expanding existing vaccine offerings may increase revenue while maintaining competitiveness and helping to maximize patient satisfaction. Therefore, this article's purpose is to provide a practical approach for the reader in implementing a vaccination service or enhancing an existing one. Additionally, recent updates to routine vaccine schedules will also be discussed.

GETTING STARTED

For pharmacists to provide vaccination services to their patients, it is important to first check state board of pharmacy laws and regulations to understand how pharmacy-based vaccination services are governed in that particular state. While some states allow for a wide range of vaccines to be administered to a variety of patients, other states may be more restrictive either in the types of vaccines that pharmacists can administer, the age of patients that they can be administered to, or both. The American Pharmacists Association (APhA) publishes a comprehensive overview of pharmacist authority to immunize, a useful resource available at https://media.pharmacist.com/practice/IZ_Authority_012019_corrected_April_2019.pdf.

Pharmacists may also want to consider enrolling in Medicare Part B as a Mass Immunizer to submit roster billing claims for influenza, pneumococcal, and hepatitis B vaccinations to eligible Medicare patients. Information on doing so can be found at https://go.cms.gov/2LCfN8w

Marketing efforts will also help to increase public awareness of vaccination programs. Posters, flyers, bag stuffers, newspaper, television or social media advertising are all means of accomplishing this goal directly with patients. Pharmacists may also consider reaching out to local medical practices and other institutions to advertise their services to others. For example, a pharmacy could collaborate with a local nursing home facility to provide vaccinations for residents, or advertise its vaccination program to area physicians who may not have the ability to provide certain vaccines to their patients.

The following sections briefly discuss key steps that pharmacists should consider when planning for their vaccination services.

TRAINING

Prior to administering any vaccines to patients, pharmacists should ensure they are in compliance with any board of pharmacy requirements, most commonly that they receive training for vaccine delivery and cardiopulmonary resuscitation (CPR) or basic life support (BLS) and have registered to report immunizations administered to a vaccine registry. Most boards of pharmacy recognize the APhA Pharmacy-Based Immunization Delivery Certificate Training Program, but also may recognize other programs, so be sure to check with the board. For example, North Carolina allows other programs (https://www.immunize.nc.gov/providers/immunizingpharmacists.htm).

PROTOCOL DEVELOPMENT

While laws and regulations may vary from state to state and may not legally require pharmacists to develop their own protocols in order to provide vaccination services, pharmacists should consider doing so to follow best practices consistent with current evidence-based guidelines. These protocols or standing order documents should be consistent with the Advisory Committee on Immunization Practices (ACIP) vaccine recommendations and guidelines. ACIP serves to make national vaccine recommendations and guidance on the safe use of vaccines and is composed of national medical and public health experts. More information about ACIP, including current vaccine recommendations and schedules, can be found at https://www.cdc.gov/vaccines/acip/index.html.

Pharmacists may alternatively elect to use ready-made protocols available from other authoritative sources, such as the Immunization Action Coalition, available

at http://www.immunize.org. This website has helpful resources to find additional forms, such as vaccine information statements (VIS) which need to be provided to patients prior to vaccine administration. Regardless of the source of information used, it is important that protocols be up to date and based on ACIP recommendations. Additionally, it is important to establish policies and procedures for how to respond to and report adverse events (such as anaphylactic reactions) in case they occur and incorporate these into the existing vaccination or general emergency standard operating procedures. In addition to documentation maintained in the pharmacy, any adverse events must be promptly reported to the Vaccine Adverse Event Reporting System (VAERS), which is a passive national reporting system for consumers and health professionals. VAERS can be accessed at http://vaers.hhs.gov.

In some states, pharmacists may need to partner with a physician or other prescriber on a protocol to be able to administer vaccines. The following are some ways in which pharmacists may be able to partner with such individuals in order to establish a vaccination program.

Some strategies to partner with a physician or other prescriber:

1. Contact the local, county, or state health department. Public health departments are stretched in many directions to improve the health of the community on limited funding; prescribers involved in public health may be more inclined to collaborate with a pharmacist to improve the vaccination rates in their jurisdiction.
2. Partner with a prescriber though a local university or college of pharmacy. This may be advantageous if the pharmacist also serves as a preceptor for that university or college of pharmacy.
3. Reach out to prescribers who commonly prescribe medications that are dispensed at the pharmacy. These individuals may be more willing to sign off on a vaccine protocol given that there may be more history between the individual prescriber and pharmacy/pharmacist.

According to the APhA Immunization Certificate Training Program; items that should be included for any vaccine protocol include:

1. Statement of physician authorization for the pharmacist to administer vaccines
2. Qualifications of person(s) administering vaccines
3. Vaccine(s) covered in the protocol
4. Policies
5. Screening tools for identifying patient indications and contraindications
6. Information to provide to patients (such as a vaccine information sheet)
7. How to administer vaccine (such as dose, route, anatomic location)
8. Documentation requirements
9. Communication to physician and reporting requirements
10. Emergency precautions (such as use of epinephrine for allergic reactions) including specific protocol

VACCINATION SUPPLIES

It is important that all supplies and equipment for administration are available and easily accessible when providing vaccination services in the pharmacy. This includes syringes and needles, alcohol swabs, cotton swabs, gloves, adhesive bandages, sharps containers, and emergency supplies such as injectable epinephrine and diphenhydramine (see Table 1). Most vaccines, with the exception of yellow fever vaccine, are available to order through a full-service drug wholesaler. Vaccines may also be purchased directly though the manufacturer.

VACCINE STORAGE AND HANDLING

Appropriate storage and handling of vaccines is imperative to ensure stability and efficacy. Vaccines should be stored in a separate unit with a digital data logger or continuous temperature monitoring device and temperatures manually checked and recorded at least twice per day. Most vaccine products on the market require storage between 2-8 degrees Celsius, or 35-45 degrees Fahrenheit, and therefore should, ideally, be stored in a separate and dedicated vaccine refrigerator unit to help minimize temperature fluctuations. However, Zostavax (herpes zoster vaccine), Varivax (varicella vaccine), and ProQuad (combined measles, mumps, rubella, and varicella vaccine) require storage in a separate freezer unit with temperatures between -50 degrees and -15 degrees C (or between -58 degrees and 5 degrees F). Regardless, close attention should be paid to the storage requirements of all vaccines to ensure its efficacy and maximum benefit to the patient.

It is important to have standard operating procedures for vaccine storage in case of emergencies such as equipment or power failures. Working agreements with alternative storage facilities such as hospitals, long-term care facilities, fire stations, or other pharmacies should be established and on-site emergency power sources such as generators or backup batteries be considered. Cold packs should be stored in a separate refrigerator or freezer so they are immediately available if vaccine

product needs to be transferred to another facility. In an emergency setting when storage in a nonfunctioning unit occurs, vaccines can be considered viable for use in a qualified transport container as long as appropriate temperatures are maintained. All pharmacy personnel should be trained on policies and procedures for vaccine storage and handling in an emergency setting.

The CDC's recommendations for proper storage and handling of all vaccines is an excellent comprehensive resource to consult when considering storage requirements, and is available at http://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html. The CDC also provides additional online training focused on storage and handling of vaccines, which can be found at https://www2a.cdc.gov/nip/isd/ycts/mod1/courses/sh/ce.asp.

DOCUMENTATION AND IMMUNIZATION INFORMATION SYSTEMS

Documentation of vaccination activities is essential for medical record keeping and billing purposes, in addition to being a legal requirement. Pharmacists can also review past documentation to help better determine the current vaccination needs of their patients. On a larger scale, complete and accessible vaccination records are important in order to monitor vaccination rates and to inform plans for outbreak responses.

Immunization information systems (IIS), commonly referred to as "immunization registries," are secure, computerized databases that serve as a repository for vaccine administration information (such as vaccine name, lot number, expiration date, site of administration, VIS date, and initials of the administering pharmacist, intern pharmacist, or technician [in applicable states]) for patients in a given geographical area. IIS may vary widely between states in terms of their accessibility, capabilities, and interoperability with other systems and with other IIS. Additionally, states have varying legal requirements for pharmacists, including intern pharmacists, to report vaccine administration information to their state IIS that range from optional to mandatory. Pharmacists

TABLE 1: Key supplies for providing immunization services

Syringes with needles (23-25G)	• Size 5/8" needles should be used for subcutaneous injections. • Size 1-1.5" needles should be for intramuscular injections. Longer needles may be needed for larger individuals. • All syringes (including prefilled syringes) should have a safety device to prevent/minimize needle stick injuries and to be in compliance with OSHA (Occupational Safety and Health Administration).
Medical gloves	Latex free (such as nitrile or vinyl) are preferred in case of patient allergies.
Alcohol wipes	Use to clean the site of administration.
Bandages	--
Gauze pads or cotton balls	--
Epinephrine	• For emergency allergic management • Weight-based dosing for pediatric patients may be necessary • Prefilled syringes (such as Epi Pens) are preferred.
Diphenhydramine	• For emergency allergic management • Weight-based dosing for pediatric patients may be necessary. • Injectable preferred.
Sharps containers	• For disposal of sharps only • Pharmacy will need to contract with a biohazardous waste company for proper transport and disposal.
Biohazardous disposal bags	• For disposal of medical waste (bandages, gauze, etc.) • Pharmacy will need to contract with a biohazardous waste company, hospital, or other source for proper disposal.
Immunization record cards	• To document vaccines administered.

should consult with their state board of pharmacy for information regarding the legal requirements and regulations in their state for using IIS. Pharmacists may also wish to consult with the health department for additional information including technical support for IIS reporting and querying. State IIS websites and contact information can be found at https://www.cdc.gov/vaccines/programs/iis/contacts-locate-records.html.

EXPANDING SERVICES AND IMPROVING VACCINATION RATES

Pharmacists may be able to enhance their vaccination activity by more efficiently utilizing their technicians, interns, and other personnel. Pharmacy technicians and clerks frequently have the first interaction with patients, and therefore should be trained to initiate conversations regarding their vaccination needs. For example, patients who present with prescriptions for metformin could be asked if they remember receiving a pneumococcal vaccine, or for patients who are 50 years of age or older, could be asked about zoster vaccine. If the patient doesn't remember, the IIS data can help the pharmacist determine whether it is appropriate to recommend a vaccine or give the patient a pat on the back for being up to date.

Therefore, by assessing a patient's age or their prescription profile, indications for vaccines may be found and discussions could ensue that encourage vaccination for vaccine preventable diseases for which the patient may be at risk. Additionally, vaccine screening forms could be provided to patients to complete while they wait for a prescription to further identify vaccination needs. The CDC has developed one such form, available at https://www.cdc.gov/vaccines/hcp/adults/downloads/patient-intake-form.pdf, and the Immunization Action Coalition has develop another, available at http://www.immunize.org/catg.d/p4036.pdf.

Pharmacy technicians, interns, and other personnel are invaluable in reminder and recall efforts through phone calls or other forms of communication such as text messages, personal emails, faxes, or letters. This can be useful for appointment reminders for those vaccines requiring multiple scheduled doses (such as hepatitis A, hepatitis B). Additionally, intern pharmacists may serve as immunizers under pharmacist supervision in most states and notably, Idaho became the first state to allow pharmacy technicians to administer vaccines in 2017.

Unfortunately, however, adolescent and adult vaccination rates remain suboptimal for most vaccines and as a result, the country remains below stated Healthy People 2020 goals. Additionally, vaccine-preventable disease outbreaks have been ongoing, the most notable example being the current measles outbreak. Pharmacists are the most accessible health care provider in the United States. Additionally, the hours that community pharmacies typically are open (particularly when other health care settings are closed) allow the public to access services at more convenient times or days of the week. As a result, the impact that pharmacies and pharmacists can have on improving vaccination rates is great. Therefore, pharmacists should strongly consider expanding their vaccination service offerings to help ensure that their community is protected from vaccine-preventable diseases, and to increase pharmacy revenue and profits.

One notable example to help improve vaccination rates is for pharmacists to create an "immunization neighborhood" by coordinating, collaborating, and communicating with other health care providers. By leveraging an immunization neighborhood, pharmacists can build on the success of pharmacy-based influenza vaccine to improve community vaccination rates of other vaccines with generally low patient uptake. To do this, pharmacists should review their current vaccination practices, including what vaccines are currently kept in stock (or routinely ordered on demand) and how they are promoted and recommended to individuals. Pharmacists should also review possible reasons why patients may be referred elsewhere for their vaccination needs, and to whom they are being referred, to coordinate and communicate between those sites and the pharmacy. Lastly, pharmacists should identify any barriers to stocking and administering vaccines to better enable themselves to increase their vaccination offerings.

In a national survey of community pharmacies, vaccines that were least administered included hepatitis A (49.2 percent of pharmacies), meningococcal ACWY (40 percent), human papillomavirus (38.9 percent), travel vaccines (36.8 percent), and meningococcal B (32.6 percent). It is interesting to note that these vaccines are given in a series of multiple doses over a short period of time, as compared to the more commonly administered vaccines in pharmacy settings (influenza, pneumococcal, tetanus) which are given as single doses or have longer dose intervals.

This implies that for less commonly administered vaccines, having an effective patient reminder and recall system is vital to ensure vaccine series completion

and ultimately, improved vaccination rates. Options for reminder and recall systems may include manual outreach, community education, incentives, paper vaccination records, case management, text messaging, and various smartphone apps. For those pharmacies that offer medication synchronization, a similar system or process could be used for vaccinations. The ideal reminder and recall system however is one that has minimal impact to current workflow and processes. Pharmacists should also review the National Standards for Adult Immunization Practices published by the National Vaccine Advisory Committee (NVAC), available at https://www.cdc.gov/vaccines/hcp/adults/for-practice/standards/index.html as these standards also discuss the concept of reminder and recall systems.

One example where pharmacists could substantially help to improve vaccination rates is with the human papillomavirus (HPV) vaccine. From 2011 to 2015, about 42,700 HPV-associated cancers occurred in the United States each year: about 24,400 among women, and about 18,300 among men. Cervical cancer is the most common HPV-associated cancer among women, and oropharyngeal cancers (cancers of the back of the throat, including the base of the tongue and tonsils) are the most common among men. In general, HPV is thought to be responsible for more than 90 percent of anal and cervical cancers, about 70 percent of vaginal and vulvar cancers, and more than 60 percent of penile cancers. Despite the availability of an effective cancer-preventing vaccine, vaccination rates remain low for adolescents and below Healthy People 2020 goals.

Barriers to HPV vaccination abound and include parental concerns (safety and side effects, social, philosophical, and religious stigmas, and concern that vaccination may lead to sexual promiscuity) and lack of a strong provider recommendation for the vaccine. As a result, adoption of a comprehensive, multi-pronged approach to tackling these and other barriers to improve HPV vaccination rates is sorely needed. HPV resources are available at http://hpvroundtable.org/. Fava et al describes one such proposed model in detail which involves a vaccination team composed of physicians, pharmacists, and public health officials that functions according to the concepts of the immunization neighborhood. In this model, patients for who the HPV vaccine is indicated could receive the vaccine at their provider of choice, with that provider subsequently following up with others in the immunization neighborhood to increase the chances of series completion as that patient moves throughout the health care system to different providers or settings.

A great suggestion for pharmacies is to identify family practice providers and gynecologists who will give the first dose in their office and refer a patient to the pharmacy to complete the series. Those parents or patients that are vaccine hesitant, undecided, or refuse vaccination altogether could be referred to a "motivational specialist" or "community champion," otherwise known as a community pharmacist, within this neighborhood group to encourage vaccination and to follow up with the other providers in that group regarding the outcomes from such counseling efforts.

Other strategies that may help to improve HPV vaccination rates include establishing partnerships with cancer organizations, educating providers outside of their immunization neighborhood to strongly recommend HPV vaccine when also recommending meningococcal and Tdap vaccines (to adolescents), conducting a public communications campaign to educate their community, and utilizing IIS to identify opportunities for patient reminders. Regardless of the strategies used, ensuring consistent messaging to the public, accurate and evidence-based patient education, comfort with the vaccine (such as understanding safety and side effects), and access to trustworthy and knowledgeable vaccine providers, including pharmacists, are all elements that can improve HPV vaccine uptake.

FOCUSED VACCINE UPDATES

Pharmacy-based vaccination services have been shown to improve patient access to this vital preventative health care service. All providers who directly administer vaccinations and those who work with other health care practitioners to facilitate vaccination delivery should maintain an up to date knowledge base about rapidly changing clinical recommendations, information resources, and other best practices. The following updates provide additional detail of significant recent changes in specific vaccine recommendations and considerations for select vaccines. Furthermore, Table 2 provides a quick reference for adult and pediatric vaccine indications, dosage, administration, schedule, safety issues, and storage and handling.

Hepatitis A

Hepatitis A is a viral disease caused by the hepatitis A virus (HAV) that is spread via fecal-oral route, most commonly among close household contacts or, in some outbreak situations, through contaminated food and water. Most young children who are infected are asymptomatic, but jaundice, often along with fever, malaise, abdominal pain, anorexia, and dark urine, occurs in more than 70 percent of patients over 6.

The ACIP recommends that children be vaccinated starting at the age of 12 months, and it voted in June 2019 to specifically recommend a full catch-up series for patients between the ages of 2 through 18.* Travelers to the developing world should be vaccinated at least two weeks prior to departure, and all other high-risk individuals should be vaccinated as soon as risk is known.

The hepatitis A vaccine, a highly effective inactivated vaccine, was introduced in 1995 and added to the routine pediatric vaccination schedule in 1999. Along with routine vaccination of children, vaccination efforts also focus on high-risk groups. ACIP also recommends vaccination of any adult who wants protection regardless of specific risk. The following are considered to be high risk populations: those traveling internationally to developing countries, men who have sex with men (MSM), injection and non-injection drug users, persons with clotting factor disorders, those with potential laboratory/research exposure, close personal contacts of international adoptees, and persons experiencing homelessness.

Homelessness was added as a high-risk indication in 2019 in response to a number of serious outbreaks among homeless individuals in multiple states beginning in 2017. Poor sanitation and hygiene and congregate living conditions are associated with increased risk for disease transmission and are thought to have contributed to a recent viral spread. While the need for follow up to complete the two dose vaccine series may be difficult in this population, ACIP notes that a single dose can provide short-to-medium term individual protection and may contribute to herd immunity. Additionally, in June 2019, ACIP voted to recommend hepatitis A vaccine for all patients with HIV ages 1 and older.*

There are currently two hepatitis A vaccines available in the U.S. – Havrix and VAQTA, along with a hepatitis A-hepatitis B combination vaccine (Twinrix). A 0.5 mL dose of Havrix or VAQTA is indicated for patients under 19 years old, while those 19 and older should receive 1 mL. The vaccine is administered intramuscularly (IM) on a two-dose schedule at zero and six months for all groups. Havrix and VAQTA may be used interchangeably. Twinrix is FDA approved and ACIP recommended only for patients 18 and older, and is dosed as 1 mL IM at zero, one, and six months. Vaccination is contraindicated only in those with a history of severe allergic reaction to a previous dose of any hepatitis A-containing vaccine or any vaccine component (such as neomycin).

Hepatitis B

Hepatitis B is a viral disease caused by the hepatitis B virus (HBV). HBV is a blood borne disease transmitted via percutaneous or mucosal exposure, including via sexual contact. The virus can survive on surfaces for more than seven days. Many infected people are asymptomatic, but symptoms include fever, fatigue, loss of appetite, nausea, vomiting, abdominal pain, dark urine, clay-colored stools, joint pain, and jaundice. Children, especially infants, are significantly more likely to experience chronic hepatitis B infection compared to adults. Chronic infection can lead to cirrhosis, liver cancer and other hepatic complications.

Hepatitis B vaccination was first recommended by the CDC in 1982 and has been recommended for infants since 1991. Hepatitis B vaccine is included on the pediatric routine vaccination schedule as the first vaccine infants receive beginning within 24 hours of birth. As of January 2018, ACIP has removed permissive language for delay of the birth dose until after hospital discharge. It is also recommended for any adult desiring protection as well as several high risk groups: injection drug users, MSM, household contacts of those with chronic hepatitis B, developmentally disabled persons in long-term care facilities, those in correctional facilities, anyone at risk for occupational exposure (including health care workers), hemodialysis patients, persons with chronic hepatitis C infection or other chronic liver disease, travelers to endemic countries, persons with HIV, and persons with diabetes.

Until late 2017, two formulations of recombinant hepatitis B vaccine, Engerix-B and Recombivax HB, were available in the U.S. Both recombinant hepatitis B vaccines are dosed at zero, one, and six months for most patients. Children and adolescents age under 20 should receive 0.5 mL IM per dose, and adults 20 and older should receive 1 mL IM. Alternate dosing schedules may be considered for certain patients, such as those who need more immediate protection (such as international travelers) or those on hemodialysis, who are less likely to seroconvert. A high dose formulation of Recombivax HB is also available for hemodialysis patients. Finally, patients between ages 11 and 15 can receive a two-dose series of Recombivax HB at zero and four to six months. At the standard doses and on the standard schedule, Engerix-B and Recombivax HB are interchangeable.

In April 2018, ACIP included a newly approved adjuvanted hepatitis B vaccine, Heplisav-B, as an option for vaccination for adults 18 and older. Heplisav-B is formulated

TABLE 2. Adult and pediatric vaccines

VACCINE	ACIP RECOMMENDED USE	DOSE, ROUTE, SCHEDULE[a]	POTENTIAL ALLERGENS
Hepatitis A • Havrix, VAQTA	Routine vaccination of children 1 and older as well as adults seeking protection. Risk-based vaccination for persons with: • Chronic liver disease • Clotting factor disorders • MSM • Injection drug users • Homelessness • Occupational exposure (laboratory research) • International travel • Close contacts of international adoptees	***Pediatric dosing*** 0.5 mL IM x 2 doses starting at age 12 months, separated by 6-12 months (Havrix) or 6-18 months (VAQTA) ***Age ≥19 years*** 1mL IM x 2 doses at 0, 6-12 months (Havrix) or 6-18 months (VAQTA)	Neomycin Vial stoppers and prefilled syringe cap tips/plungers may contain latex
Hepatitis B • Engerix-B, Recombivax-HB • Heplisav-B	Routine vaccination of children beginning within 24 hours of birth as well as adults who want protection. Risk-based vaccination for persons with: • Hepatitis C infection • Chronic liver disease • HIV infection • Sexual exposure risk • Injection drug users • Percutaneous or mucosal risk for exposure to blood (including healthcare personnel, dialysis patients, <60 years with diabetes) • Incarcerated persons • International travel	***Engerix-B and Recombivax-HB*** *Age 0 months-19 years:* 0.5 mL IM x 3 doses at 0, 1, 6 months *Age ≥20 years:* 1 mL IM x 3 doses at 0, 1, 6 months See additional ACIP recommendations for alternative dosing for adolescents ages 11-15 years, dialysis patients and those requiring accelerated dosing. ***Heplisav-B*** *Age ≥18 years:* 0.5 mL IM x 2 doses at 0 and 1 month. Not approved for use in pediatric patients.	Yeast
Hepatitis A-Hepatitis B • Twinrix	See above recommendations for hepatitis A and hepatitis B vaccination in adults. Twinrix is not approved for persons under age 18 years.	1 mL IM x 3 doses at 0, 1, 6 months An alternative schedule of 0, 1, 2 and 12 months may be used in certain situations (see ACIP recommendations for further information)	Yeast, neomycin Prefilled syringe cap tips/plungers may contain latex

Please see page 66 for footnotes.

STORAGE & HANDLING[b]		
Storage temperature (in degrees)	**Reconstitution needed?[c]**	**Brands interchangeable?**
Refrigerated between 2-8 C (36-46 F) DO NOT FREEZE	No	Yes
Refrigerated between 2-8 C (36-46 F) DO NOT FREEZE	No	Engerix-B and Recombivax-HB: Yes when used at standard doses and on the standard 3 dose schedule Heplisav-B: No
Refrigerated between 2-8 C (36-46 F) DO NOT FREEZE	No	Should not be used interchangeably with single-antigen hepatitis A or hepatitis B vaccines

with a novel adjuvant system, and in head-to-head trials was shown to have a similar safety profile and better adult seroconversion rates of 90-100 percent, compared to 70-90 percent with Engerix-B. It is also administered on a two-dose schedule at zero and one month, as opposed to the lengthier three-dose schedule for traditional formulations. Heplisav-B is FDA approved and CDC recommended for patients 18 and older, and is administered IM as a 0.5 mL dose. Of note, the diluent solution for this vaccine contains the adjuvant component, so it is important that no other diluent be substituted.

Heplisav-B is not interchangeable with either of the other formulations, but guidance is available from ACIP regarding the completion of non-adjuvanted vaccine series using Heplisav-B. As of April 2019, ACIP does not state a preference for any hepatitis B vaccine formulation, and has not yet commented on the potential usefulness of Heplisav-B for revaccination of non-responders to the traditional vaccines.

Herpes zoster (shingles)

Herpes zoster, also known as shingles or zoster, is a viral disease caused by the varicella-zoster virus (VZV). Initial infection with VZV causes varicella, commonly known as chickenpox. Shingles is the result of reactivation of the latent VZV that remains dormant in the dorsal root ganglia typically for decades following primary varicella-zoster infection. That said, shingles can occur at any age after initial infection. In most cases, shingles presents as a painful, tingling and/or itchy rash with vesicles localized to the abdomen, chest, or face. The rash may be preceded by localized pain/itching and/or prodromal headache, photophobia, and malaise. Typically, the rash resolves within two to four weeks, but there may be permanent scarring or pigmentation changes, along with post-herpetic neuralgia (PHN; pain that persists for weeks to years following rash resolution).

The first zoster vaccine, Zostavax (ZVL), licensed in 2006, was a live attenuated vaccine with moderate efficacy and a number of other limitations. A recombinant adjuvanted zoster vaccine, Shingrix (RZV) was approved by the FDA in 2017 and subsequently recommended in 2018 by ACIP as the preferred formulation for the prevention of shingles for patients aged 50 and older. Shingrix is also recommended for revaccination of patients who have previously received Zostavax. ***Unimmunized patients who have a shingles outbreak should receive a full series of Shingrix after the rash resolves***.

TABLE 2. Adult and pediatric vaccines (continued)

VACCINE	ACIP RECOMMENDED USE	DOSE, ROUTE, SCHEDULE[a]	POTENTIAL ALLERGENS
Live zoster vaccine (VZL) • Zostavax *Live-attenuated vaccine*	Routine vaccination of adults age ≥60 years	0.65 mL subQ x 1 dose	Neomycin, gelatin
Recombinant zoster vaccine (RZV) • Shingrix	Routine vaccination of adults age ≥50 years	0.5 mL IM x 2 doses at 0 and 2-6 months	--
Varicella • Varivax *Live-attenuated vaccine*	Routine vaccination of children Routine vaccination of adults with no evidence of immunity. Evidence of immunity includes: birth before 1980, documentation of 2 doses of varicella vaccine, health care provider diagnosis of varicella or herpes zoster, laboratory evidence of immunity or disease.	***Pediatric dosing*** 0.5 mL subQ x 2 doses at age 12-15 months and 4-6 years ***Adult dosing*** 0.5 mL subQ x 2 doses separated by 4-8 weeks	Neomycin, gelatin

Please see page 66 for footnotes.

STORAGE & HANDLING[b]		
Storage temperature (in degrees)	**Reconstitution needed?[c]**	**Brands interchangeable?**
Antigen component: Frozen between -50 and -15 C (-58 to 5 F) Diluent: refrigerated at 2-8 C (36-46 F), or at room temperature 20-25 C (68-77 F)	Yes – reconstitute with included sterile diluent. Administer immediately; discard if not used within 30 min of reconstitution.	Not interchangeable with Shingrix
Antigen component and adjuvant suspension diluent: Refrigerated between 2-8 C (36-46 F) DO NOT FREEZE	Yes – combine lyophilized antigen component with adjuvant suspension. Do not reconstitute with any other diluent. Administer immediately or store refrigerated; use or discard within 6 hours of reconstitution.	Not interchangeable with Zostavax
Antigen component: Frozen between -50 and -15 C (-58 to 5 F) or up to 24 months refrigerated at 2-8 C (36-46 F). Diluent: refrigerated at 2-8 C (36-46 F), or at room temperature 20-25 C (68-77 F)	Yes – reconstitute with included sterile diluent. Administer immediately; discard if not used within 30 min of reconstitution	Not interchangeable with Zostavax.

Shingrix has several distinct advantages compared to Zostavax:

1. Improved efficacy in terms of herpes zoster prevention and PHN prevention in patients 50 and older (97 percent versus 64-70 percent for zoster, 91 percent versus 65 percent for PHN) as well as those 70 and older (91 percent versus 38 percent for zoster, 89 percent versus 67 percent for PHN).
2. Longer duration of protection - RZV is estimated to have substantial efficacy beyond the four-year period for which data is currently available, whereas ZVL has been found to have only minimal continued efficacy by about six years post-vaccination. Due to this, RZV is ACIP recommended for patients as young as 50, whereas ZVL is only recommended for those 60 and older. Additionally, RZV is recommended for previous vaccination with ZVL.
3. Better safety profile in immunocompromised patients – there have been documented cases of disseminated zoster and other severe complications in these patients with ZVL. As RZV is not live, it is more likely to be safe for immunocompromised patients. ACIP will discuss this issue and make a specific recommendation as additional research becomes available.
4. Greater cost-effectiveness related to better clinical efficacy.

Shingrix is dosed as 0.5 mL IM at zero and two to six months, whereas Zostavax is given as a single 0.65 mL SQ dose. The Shingrix antigen is reconstituted with a diluent suspension that contains the adjuvant component of the vaccine. Both vials must be refrigerated prior to use. It is essential to ensure that the correct adjuvant suspension is used as effectiveness of the vaccine is compromised if other, non-adjuvanted diluents are used. There have been multiple instances of medication errors involving Shingrix reported even in its short history. ***ACIP recommends delaying RZV administration until after resolution of active herpes zoster disease and waiting at least two months after a dose of ZVL to administer RZV***.

HPV

HPV infection is asymptomatic and clears spontaneously in most cases. However, HPV can cause genital warts and cancers (cervical, vaginal, vulvar, penile, oropharyngeal, and anal) that are typically diagnosed decades after the initial infection. Types 6 and 11 cause most cases of genital warts, while types 16 and 18 cause most HPV-associated cancers. HPV is the most common sexually transmitted infection in the U.S. and is so common that nearly all sexually active men and women get the virus at some point in their lives (https://www.cdc.gov/std/hpv/stats.htm).

TABLE 2. Adult and pediatric vaccines (continued)

VACCINE	ACIP RECOMMENDED USE	DOSE, ROUTE, SCHEDULE[a]	POTENTIAL ALLERGENS
Human papillomavirus (HPV9) • Gardasil 9	Routine vaccination of adolescents starting at age 11-12 (children as young as 9 years old may be vaccinated based on individual clinical decision). Routine catch-up vaccination of adults through age 26, and permissive vaccination based on shared clinical decision-making for individuals age 27-45 years.	***Age 9-14 years at initial vaccination*** 0.5 mL IM x 2 doses at least 6 months apart ***Age 15 years or older*** 0.5 mL x 3 doses at 0, 1-2, and 6 months.	Yeast
Haemophilus influenzae type b (Hib) • ActHIB, Hiberix, PedvaxHIB	Routine vaccination of children Vaccination of adults with anatomical or functional asplenia (including sickle cell disease) or HSC.	***Pediatric dosing*** *ActHIB and Hiberix:* 0.5 mL IM at ages 2, 4, 6 and 12-15 months *PedvaxHIB:* 0.5 mL IM at ages 2, 4, and 12-15 months ***Adult dosing*** *ActHIB and Hiberix:* 0.5 mL x 1 dose in asplenia or x 3 doses administered 6-12 months after HSCT with at least 4 weeks between doses. PedvaxHIB is not recommended for use in adults.	***Pedvax HIB:*** prefilled syringe cap tips contain latex
Inactivated influenza[d] • Various brands (such as Fluzone Quadrivalent, Afluria, Fluzone High Dose, Fluad)	Routine vaccination of children and adults age 6 months and older.	***Pediatric dosing up to age 8 years***[e] 0.25 mL or 0.5 mL IM x 2 doses separated by 4 weeks in the first year immunized (or second year immunized if only one dose received in first year), then 1 dose annually thereafter ***Pediatric ages 9-18 years and adult dosing*** 0.5mL IM x 1 dose annually	Neomycin, polymyxin, kanamycin (some formulations - see individual product package insert for additional information) History of egg allergy is not a relevant contraindication/ precaution for any influenza vaccine formulation

Please see page 66 for footnotes.

STORAGE & HANDLING[b]		
Storage temperature (in degrees)	**Reconstitution needed?[c]**	**Brands interchangeable?**
Refrigerated between 2-8 C (36-46 F) DO NOT FREEZE	No	--
Refrigerated between 2-8 C (36-46 F) DO NOT FREEZE Except Hiberix diluent should be stored at room temperature (2-25 C, 36-77 F)	***ActHIB:*** Yes – reconstitute with included 0.4% sodium chloride diluent. Administer immediately or store refrigerated; use or discard within 24 hours of reconstitution. ***Hiberix:*** Yes – reconstitute with included normal saline diluent. Administer immediately or store refrigerated; use or discard within 24 hours of reconstitution. ***PedvaxHIB:*** No	Yes, follow 3 dose schedule if ActHIB or Hibrix is used for any dose
Refrigerated between 2-8 C (36-46 F) DO NOT FREEZE	No	Yes, except Fluzone High Dose and Fluad. See approved age groups for specific formulations

The 9-valent HPV vaccine (Gardasil 9), which protects against high-risk types 6, 11, 16, 18, 31, 33, 45, 52, and 58, is the only currently available HPV vaccine in the U.S. Gardasil 9, as well as its predecessors, quadrivalent Gardasil and bivalent Cervarix, is generally administered IM on a three-dose schedule at zero, one or two, and six months. It is currently ACIP recommended for those ages 11-12 as a routine adolescent vaccine as well as for older adolescents and adults up to age 26. Children may begin the series as early as age 9. As of October 2018, Gardasil 9 is FDA approved for men and women up to 45, and in June 2019 ACIP voted for a permissive recommendation that vaccination of individuals between the ages of 27-45 years should be considered based on shared clinical decision making.*

In 2016, post-licensure studies and post-hoc analysis of pre-licensure data were used to assess the immunogenicity and clinical efficacy of a two-dose vaccination series in girls and boys between the ages of 9-14. This analysis showed that two doses at zero and 6-12 months are at least as effective at inducing seroconversion as a three-dose series. ACIP currently recommends the use of the two-dose series for male and female patients who receive the first dose before turning 15. Those who begin the series after turning 15, and patients of any age who have an immunocompromising condition should receive a three-dose series at zero, one or two, and six months. ACIP also recommends that anyone who previously received two or three doses of any HPV vaccine consistent with the above recommended schedules should be considered fully vaccinated. Gardasil 9 can also be used to complete a series that was begun with quadrivalent Gardasil or Cervarix.

Influenza

Influenza is a seasonal viral infection that circulates at elevated or epidemic levels annually from late fall through early spring during most years. The strains that circulate and predominate each season can differ as a result of major or minor viral genetic changes (shifts and drift, respectively). Symptoms are somewhat non-specific and can include fever, cough, muscle/body aches, nasal congestion, headache, fatigue, and sore throat. Certain patient groups, including children, elderly, pregnant women, those with chronic comorbidities including obesity, asthma, COPD, diabetes, and immunocompromised states are at greater risk of hospitalization and mortality from influenza.

There are a number of influenza vaccine formulations available in the U.S. These include both trivalent

TABLE 2. Adult and pediatric vaccines (continued)

VACCINE	ACIP RECOMMENDED USE	DOSE, ROUTE, SCHEDULE[a]	POTENTIAL ALLERGENS
Live attenuated influenza (LAIV4) • Flumist *Live-attenuated vaccine*[f]	Routine vaccination of children and adults ages 2-49 years (healthy, non-pregnant)	***Pediatric dosing up to age 8 years*** 0.1 mL spray in each nostril 2 doses separated by 4 weeks in the first year immunized (or second year immunized if only one dose received in first year) then 1 dose annually thereafter ***Pediatric ages 9-18 years and adult dosing*** 0.1 mL spray in each nostril x 1 dose annually.	Gentamicin, gelatin, arginine History of egg allergy is not a relevant contraindication/ precaution for any influenza vaccine formulation
Measles-mumps-rubella (MMR) • M-M-R-II *Live-attenuated vaccine*	Routine vaccination of children Routine vaccination of adults with no evidence of immunity. Evidence of immunity includes: birth before 1957, documentation of MMR vaccination, laboratory evidence of immunity or disease for each of measles, mumps and rubella.	***Pediatric dosing*** 0.5 mL subQ x 2 doses at age 12-15 months and 4-6 years (prior to beginning elementary school). ***Adult dosing*** 0.5 mL subQ x 1 or 2 doses (depending on risk factors).	Neomycin, gelatin, chicken egg protein
Meningococcal quadrivalent (MenACWY) • Menactra, Menveo	Routine vaccination of adolescents Risk-based vaccination for adults and younger children with: • Anatomical or functional asplenia including sickle cell disease, HIV infection, persistent complement component deficiency, eculizumab use • Travel to hyperendemic or endemic countries, microbiologists routinely exposed to N. meningitidis • First year college students living in residential housing (if not previously vaccinated at age ≥16 years) and military recruits	***Pediatric dosing*** 0.5 mL IM x 2 doses at 11-12 years and 16 years ***Adult dosing*** 0.5 mL IM x 1 or 2 doses depending on indication	--

Please see page 66 for footnotes.

STORAGE & HANDLING[b]		
Storage temperature (in degrees)	**Reconstitution needed?[c]**	**Brands interchangeable?**
Refrigerated between 2-8 C (36-46 F) DO NOT FREEZE	No	--
Refrigerated between 2-8 C (36-46 F). May store frozen at temperatures not lower than -50 C (-58 F). Diluent may be stored in refrigerator or at room temperature.	Yes – reconstitute with included sterile water diluent. Administer immediately or store refrigerated; use or discard within 8 hours of reconstitution.	--
Refrigerated between 2-8 C (36-46F) DO NOT FREEZE	***Menactra:*** No ***Menveo:*** Yes – meningococcal A lyophilized powder conjugate vaccine component must be reconstituted with the meningococcal CYW-135 liquid conjugate vaccine component. Administer immediately or store below 25 degrees C (77 degrees F); use or discard within 8 hours of reconstitution.	Yes, for persons older than 9 months. Only Menveo is approved for use in infants younger than 9 months.

vaccines that include two A and one B influenza strains, along with quadrivalent formulations that include an additional B strain. A high dose vaccine (Fluzone High Dose) and an adjuvanted vaccine (Fluad) are indicated specifically for patients over 65 years to illicit a stronger immune response and ensure seroconversion. These have been found to be more serologically and clinically effective in older patients, however, the CDC does not preferentially recommend any specific formulation in patients 65 and older. A live attenuated quadrivalent influenza vaccine formulated into a nasal spray (LAIV4, Flumist Quadrivalent) is also recommended as an option for healthy, non-pregnant patients between the ages of 2-49. With the exception of Flumist, all influenza vaccines are administered IM at 0.5 mL (0.25 mL for patients under 3 for certain formulations).

In 2016, ACIP recommended against the use of LAIV4 in all persons due to minimal effectiveness against H1N1 viruses in preceding seasons, specifically in children. This recommendation was then renewed for the 2017-2018 season. During this time, the vaccine manufacturer identified an influenza A(H1N1) pdm09-like virus, A/Slovenia/2903/2015, with better replicative fitness in human epithelial cell culture. It also showed improved seroconversion and viral shedding rates compared to the strain used previously. Because of the change in strain, additional efficacy testing to be employed each year, and the potential of a needle-free vaccine option to improve coverage, ACIP now recommends, as of the 2018-2019 season, that LAIV4 be considered an option for influenza vaccination. LAIV4 should be avoided in those who are immunocompromised (including HIV infection) or pregnant, children ages 2-4 with history of asthma or wheezing, those who have taken influenza antivirals within 48 hours, and those with close personal contacts who are severely immunocompromised.

CDC recommends annual influenza vaccination for all persons over the age of 6 months, unless contraindicated, with an age-appropriate vaccine. Children between the ages of 6 months and 8 years should receive two doses of vaccine during the first year they are vaccinated, administered four weeks apart, and one dose annually thereafter.

Influenza vaccines, aside from a recombinant vaccine (Flublok Quadrivalent) and a cell-culture based vaccine (Flucelvax Quadrivalent) contain inactive or live virus that is grown in chicken eggs. Because the amount of egg protein contained in final vaccine products is significantly less than that required to illicit an allergic response, as of 2016, CDC no longer includes egg

TABLE 2. Adult and pediatric vaccines (continued)

VACCINE	ACIP RECOMMENDED USE	DOSE, ROUTE, SCHEDULE[a]	POTENTIAL ALLERGENS
Meningococcal B (MenB)) • Bexsero, Trumenba	Vaccination of persons age ≥10 years at increased risk during meningococcal serogroup B outbreak Risk-based vaccination (permissive recommendation) for children and adults with: • Anatomical or functional asplenia including sickle cell disease, HIV infection, persistent complement component deficiency, eculizumab use, microbiologists routinely exposed to N. menigitidis Adolescents and young adults age 16-23 years not at increased risk may be vaccinated based on individual clinical decision	***Bexsero*** 0.5 mL IM x 2 doses at 0 and 1 month ***Trumenba*** 0.5 mL IM x 2 doses at 0 and 6 months or x 3 doses at 0, 1-2, and 6 months depending on risk See CDC vaccination schedules for additional information regarding booster doses.	**Bexsero:** prefilled syringe cap tips contain latex
Pneumococcal • PCV13: Prevnar13 • PPSV23: Pneumovax 23	**PCV13:** Routine vaccination of children as well as permissive vaccination based on shared clinical decision-making for adults ≥65 years who do not have an immunocompromising condition. **PPSV23:** Routine vaccination of adults age ≥65 years *See ACIP information for specific age and indication-based recommendations and dosing **PPSV23:** Risk-based vaccination of children and adults with: • Chronic heart, lung or liver disease • Diabetes • Alcoholism • Cigarette smoking **PCV13 and PPSV23:** Risk-based vaccination of children and adults with: • Immunocompromising conditions • Cochlear implant or CSF leak	***Routine pediatric dosing*** PCV13 0.5 mL IM x 4 doses at age 2, 4, 6, and 12-15 months ***Routine adult dosing for vaccine naïve and ≥65 years[g]*** PPSV23 0.5mL IM x 1 dose. ***Risk-based dosing*** See CDC vaccination schedule and ACIP recommendations.	--
Polio • IPOL	Routine vaccination of children	0.5 mL IM or subQ x 4 doses at age 2, 4, and 6-18 months and booster at age 4-6 years	2-phenoxyethanol, formaldehyde, streptomycin, neomycin, polymixin B

Please see page 66 for footnotes.

STORAGE & HANDLING[b]		
Storage temperature (in degrees)	**Reconstitution needed?[c]**	**Brands interchangeable?**
Refrigerated between 2-8 C (36-46 F) DO NOT FREEZE	No	No – a single vaccine product must be used for complete series
Refrigerated between 2-8 C (36-46 F) DO NOT FREEZE	No	No
Refrigerated between 2-8 C (36-46 F) DO NOT FREEZE	No	--

allergy (including more severe reactions like anaphylaxis) as a contraindication or precaution for any influenza vaccine formulation. Patients with egg allergies should be counseled on this recommendation change. Patients with severe egg allergies should still be monitored after influenza vaccine administration.

To allow time for production of adequate seasonal vaccine stock, the World Health Organization and CDC make recommendations based on epidemiologic predictions regarding the strains to be included early each calendar year. Vaccine is then typically available by September in the U.S. Providers should begin offering vaccination no later than October and may continue vaccinating patients until vaccine stocks expire or are depleted. However, vaccination can begin as soon as the vaccine is in stock as early as August.

The 2019-2020 Northern Hemisphere trivalent vaccines will contain the following strains: A/Brisbane/02/2018 (H1N1) pdm09-like virus, A/Kansas/14/2017 (H3N2)-like virus, and B/Colorado/06/2017-like (Victoria lineage) virus. Quadrivalent vaccines will contain those listed previously in addition to B/Phuket/3073/2013-like (Yamagata lineage) virus. Both A virus components were updated from the 2018-2019 vaccine, and both B virus components are the same as in 2018-2019.

The choice of which formulation(s) to stock should consider patient population and preferences. For example, pharmacies with large geriatric populations should plan to have FluZone High Dose or Fluad available, while those who serve younger families may also stock preservative-free pediatric doses.

Measles

Measles is a highly contagious airborne viral illness characterized by fever, skin rash, oral lesions, respiratory manifestations, and in rare cases central nervous system and systemic disease. The virus is often brought into the U.S. via travelers from countries with high circulation rates. Outbreaks are occurring in U.S. communities where vaccination rates fall below about 95 percent. Vaccination against measles is available as a combination vaccine together with mumps and rubella (MMR). MMR is dosed at 0.5 mL SQ for adults and children.

CDC recommends routine vaccination for children ages 1 or older with a second dose between four to five years, along with adults with no evidence of immunity. Evidence of immunity includes written documentation of adequate vaccination, laboratory evidence of immunity, laboratory confirmation of measles, or birth before 1957.

TABLE 2. Adult and pediatric vaccines (continued)

VACCINE	ACIP RECOMMENDED USE	DOSE, ROUTE, SCHEDULE[a]	POTENTIAL ALLERGENS
Rotavirus • Rotarix, RotaTeq *Live-attenuated vaccine*	Routine vaccination of children	***Rotarix*** 1 mL PO x 2 doses at age 2 and 4 months ***RotaTeq*** 2 mL PO x 3 doses at age 2, 4, 6 months Maximum age for initial dose is 15 weeks, 0 days, maximum age for final dose is 8 months, 0 days	***Rotarix:*** tip cap and oral applicator contain latex
Tetanus-containing • Tdap: Adacel, Booxtrix • Td: Tenivac • DTaP: Daptacel, Infanrix	Routine vaccination of children, adolescents and adults, including during pregnancy Tetanus prophylaxis in wound management[h]	***Pediatric dosing (age <7 years)*** DTaP 0.5 mL IM x 5 doses at ages 2, 4, 6, 15-18 months and 4-6 years. ***Pediatric dosing (age ≥7 years)*** Tdap 0.5mL IM x 1 dose at age 11-12 years ***Adult dosing*** Tdap 0.5mL IM x 1 lifetime adult dose then Td 0.5mL IM every 10 years thereafter ***Pregnancy*** Tdap 0.5mL IM x 1 dose each pregnancy, preferably in early part of gestational weeks 27-36	***Adacel, Boostrix, Tenivac, Infanrix:*** tip caps of prefilled syringes contain latex ***Boostrix:*** rubber plunger of prefilled syringes contain latex

[a] Alternate dosing schedules may apply in special situations and catch up vaccination in children. Please refer to ACIP recommendations for additional information.
[b] All vaccine products should be protected from light unless upon guidance from vaccine manufacturer.
[c] Use or discard vaccines not requiring reconstitution immediately upon transfer to syringe unless otherwise stated or upon guidance from vaccine manufacturer. Use or discard reconstituted vaccines within 30 minutes unless otherwise stated or upon guidance from vaccine manufacturer.
[d] Refer to individual package inserts for additional information on specific formulations.
[e] Influenza vaccine dosing in young children is formulation-specific. Please refer to relevant product package insert for additional information.
[f] Live vaccines are contraindicated in pregnancy and severe immunosuppression. See CDC immunization and ACIP guidance for additional information.
[g] See CDC immunization schedule for additional pneumococcal vaccine dosing information for non-vaccine naïve older adults.
[h] See ACIP guidance for information regarding dosing of tetanus containing vaccines in wound management.

Abbreviations: ACIP = Advisory Committee on Immunization Practices; IM = intramuscular; MSM = men who have sex with men; HSCT = hematopoietic stem cell transplant; subQ = subcutaneous; PO = oral.

STORAGE & HANDLING[b]		
Storage temperature (in degrees)	**Reconstitution needed?[c]**	**Brands interchangeable?**
Refrigerated between 2-8 C (36-46 F) DO NOT FREEZE	***Rotarix:*** Yes – reconstitute with included oral liquid diluent. Administer immediately or store refrigerated or up to 25 degrees C (77 degrees F); use or discard within 24 hours of reconstitution. ***RotaTeq:*** No	Whenever possible, the same brand of rotavirus vaccine should be used to complete the primary pediatric series. If any dose in the series was RotaTeq, a total of 3 doses should be administered.
Refrigerated between 2-8 C (36-46 F) DO NOT FREEZE	No	Whenever possible, the same brand of DTaP should be used to complete the primary pediatric series.

Importantly, verbal report of vaccination is not acceptable as evidence of immunity. At the time of writing, over 1,100 measles cases have been reported in 30 U.S. states. Pharmacists are encouraged to consult their local and state health departments as well as the CDC for up to date recommendations on measles vaccination. For more information on current measles outbreaks, please visit https://www.cdc.gov/measles/cases-outbreaks.html

Meningococcal disease

Meningococcal disease is caused by the bacterium Neisseria meningitidis. Approximately 10 percent of people carry N. meningiditis in their upper respiratory tract and can transmit the bacteria to susceptible individuals through saliva or spit, for example via coughing, kissing, or food sharing. Meningococcal disease can progress rapidly to meningitis and can kill within hours of initial infection underscoring the importance of vaccination. There are a variety of serogroups of N. meningitidis; vaccines exist to prevent A, B, C, W, and Y serogroups, with B, C, and Y being the most commonly observed in the U.S. Recently there have been several outbreaks of serogroup B meningococcal disease on U.S. college campuses, prompting increased vigilance and regulation.

Two types of meningococcal vaccines are available in the U.S. based on the serogroups they target, quadrivalent conjugate MenACWY, which includes MenACWY-D (Menactra) and MenACWY-CRM (Menveo), and monovalent MenB (2 brands: Trumenba or Bexsero). Of note, meningococcal polysaccharide vaccine (Menomune) was discontinued in February 2017 and is no longer available.

CDC recommends routine vaccination with MenACWY for those ages 11 to 12, with a booster dose recommended at 16. Additional indications for Men ACWY exist, including HIV, asplenia, travel to certain international destinations, and others. Booster doses are required in some cases as well. As a permissive recommendation, adolescents and young adults between ages 16 to 23 may be vaccinated with MenB in certain situations, including a meningococcal disease outbreak. Individuals with certain medical conditions or other risk factors, including complement deficiency and functional or anatomic asplenia may also receive MenB vaccination. Pharmacists should also be aware of meningococcal vaccination mandates for colleges and universities in their state (http://www.immunize.org/laws/menin.asp). It is important to note that administration errors of Menveo have occurred because the vaccine has two active components (the first MenA lyophilized powder,

the second MenCYW liquid) that must be mixed and administered together. The liquid component, which can be mistaken as diluent, cannot be substituted with any other solution as it contains active vaccine components. In contrast, Menactra is available as a single component liquid that does not require reconstitution. Finally, it is also important to note that Trumenba and Bexsero are not interchangeable. If a patient starts their series with one formulation, they must continue the series with the same formulation instead of switching to the alternate.

Pneumococcal disease

Streptococcus pneumoniae (pneumococcus) are pathogenic bacteria that colonize a large portion of the population and can cause invasive pneumococcal disease (IPD) that may manifest as pneumonia, bacteremia, or meningitis. Population effects related to high childhood vaccination rates have been a significant factor in recent declines in IPD, but the disease remains an important source of morbidity and mortality.

Two pneumococcal vaccines are available in the U.S. – a 13-valent conjugate vaccine (PCV13) and a 23-valent polysaccharide vaccine (PPSV23). Both are administered as a 0.5 mL IM dose in adults and children. PPSV23 can also be administered SQ.

ACIP recommendations for use of PCV13 and PPSV23 are complex and based on age and indication. PCV13 is recommended as a routine vaccine for all children as a four-dose series beginning at age 2 months. Additionally, adults 65 and older should receive PPSV23 as a routine vaccine. Until June 2019, it was also recommended that all older adults receive PCV13 along with PPSV23. However ACIP voted to change this to a permissive recommendation to be made based on shared clinical decision making.* Shared clinical decision making should include the patient's input in consideration of the pros and cons for permissive recommendations. This change was due to a lack of convincing evidence that PCV13 in this population had been effective and necessary at reducing IPD incidence since it was first recommended in 2014.

Additionally, ACIP recommends PPSV23 for children 2 and older as well as younger adults with certain cardiovascular, respiratory, or immunocompromising diseases, or diabetes. Please reference CDC vaccine schedules and ACIP publications for specific recommendations regarding indications and timing of administration (https://www.cdc.gov/vaccines/acip/recommendations.html).

Conclusions

Pharmacists and other pharmacy personnel (pharmacist interns, technicians) are well positioned to provide vaccination services, particularly in the independent community pharmacy setting, due to their accessibility to the public, established personal relationships with the community, and a growing acceptability as a vaccine provider. Establishing and/or enhancing a vaccination service involves a number of planning and operational considerations, but has substantial patient care, public health, professional development, and financial benefits. All independent pharmacists should strongly consider implementing vaccination services or expanding their current vaccine offerings to meet the needs of their patients and communities.

**Please note that ACIP votes do not become official CDC recommendations until they are published in the Morbidity and Mortality Weekly Report. These votes were not yet published at the time of writing.* ■

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CE
QUIZ

Continuing Education Quiz

Select the correct answer.

1. Shingrix (RZV) is the preferred vaccine for prevention of shingles because it:
a. Is more effective and offers a longer duration of protection than Zostavax (ZVL).
b. Only requires one dose as compared to two doses with Zostavax (ZVL).
c. Does not cause local injection site reactions.
d. Has a lower risk of administration errors because it does not require reconstitution

2. All persons over the age of _____ should receive an influenza vaccine every year, and children aged _____ should receive two doses in the first year they are vaccinated.
a. 4 months, 4 months to 12 years
b. 6 months, 6 months to 8 years
c. 1 year, 1 to 8 years
d. 2 years, 2 to 12 years

CASE 1: RH is a 47-year-old homeless male who was diagnosed with HIV in 2001 and diabetes in 2013. RH also has a severe allergy to eggs with a history of anaphylaxis. He completed his routine MMR, polio, and tetanus/diphtheria/pertussis vaccines as a child. A record of the vaccinations administered for this patient in your pharmacy is below.
June 21, 2007: Engerix-B 1 mL IM
April 4, 2014: Meningococcal ACWY 0.5 mL IM
June 14, 2014: Meningococcal ACWY 0.5 mL IM
Dec. 9, 2016: Influenza 0.5 mL IM

3. (CASE 1) Which of the following hepatitis B vaccines is considered to be directly interchangeable with Engerix-B?
a. Recombivax-HB
b. Heplisav-B
c. Twinrix
d. None of the above

4. (CASE 1) Which of the following vaccines would be specifically indicated for RH due to his homeless status?
a. Hepatitis A
b. Hepatitis B
c. Meningococcal ACWY
d. Influenza

5. (CASE 1) Which of the following influenza vaccines can RH receive?
a. High dose inactivated influenza vaccine (Fluzone High Dose)
b. Adjuvanted influenza vaccine (Fluad)
c. Trivalent inactivated influenza vaccine (Afluria)
d. Live attenuated influenza vaccine (Flumist)

6. TK is a 17-year-old female patient who will be starting college in a few months. She completed all of her routine childhood vaccines, but needs a meningococcal vaccine booster dose. Which formulation is most appropriate for this patient assuming that there are no current outbreaks and that she does not have any specific risk factors?
a. Bexsero
b. Menactra
c. Menomune
d. Trumenba

7. Which of the following individuals is an appropriate candidate for a two-dose series of HPV vaccine.
a. An 11-year-old female with type 1 diabetes
b. A 14-year-old male renal transplant patient taking immunosuppressive medications
c. A 21-year-old female with no relevant medical history
d. A 41-year-old male patient with asthma and hypercholesterolemia

CASE 2: HB is a 56-year-old male who was recently diagnosed with herpes zoster (shingles). The rash is beginning to resolve, but is still present.

8. (CASE 2) When should HB receive the first dose of Shingrix?
a. Today
b. After the rash resolves
c. After his 60th birthday
d. Herpes zoster vaccination is not necessary in patients who have had an episode of shingles.

9. (CASE 2) What is the dose/route for administration of Shingrix®?
a. 0.5 mL IM
b. 0.5 mL SQ
c. 0.65 mL IM
d. 0.65 mL SQ

10. Tdap vaccination is recommended for women during each pregnancy. Ideally, it should be administered between weeks _____ to provide optimal protection for the newborn after delivery.
a. 0-13
b. 14-26
c. 27-36
d. 36-40

11. A 62-year-old patient with diabetes well known to you arrives to your pharmacy to pick up his prescription for insulin. Given his history of diabetes, which vaccination would be important to determine his eligibility for?
a. Zoster
b. Pneumococcal
c. Measles-mumps-rubella
d. Meningococcal

12. A 32-year-old pregnant woman drops off a prescription for prenatal vitamins and folic acid. She says she read somewhere that she needs a "tetanus shot" for pregnancy but that she received a Tdap when she was pregnant two years ago. Which of the following is most appropriate for her?
a. She should receive a Td with this pregnancy.
b. She should receive a Tdap with this pregnancy.
c. She should receive either a Td or Tdap with this pregnancy.
d. No Tdap or Td is needed since she received a Tdap within the last 10 years.

13. Which one of the following vaccines should be stored frozen?
a. Adacel
b. Zostavax
c. Prevnar 13
d. Trumenba

14. The CDC maintains updated online resources for which of the following?
a. Vaccination schedules
b. Vaccine storage and handling
c. Vaccination information systems ("vaccination registries")
d. All of the above

15. A 65-year-old woman arrives at your pharmacy for her age-indicated pneumococcal vaccines. Assuming that she is eligible for both Prevnar 13 and Pneumovax 23, which of the following actions is the most appropriate?
a. Administer both Prevnar 13 and Pneumovax 23 today.
b. Administer Prevnar 13 today and Pneumovax 23 one year later.
c. Administer Pneumovax 23 today and Prevnar 13 one year later.
d. Any of the above is appropriate

16. You are discussing influenza vaccine with a 35-year-old patient who is concerned about his egg allergy. He says that he gets hives after eating cooked eggs. What is the most appropriate course of action to take?
a. Only intranasal vaccine may be administered
b. Only recombinant vaccine may be administered
c. Any age-appropriate vaccine may be administered
d. Do not administer any influenza vaccine.

17. Which vaccine DOES NOT require reconstitution?
a. Gardasil 9
b. Menveo
c. Shingrix
d. Varivax

18. Evidence of immunity includes birth before _____ for varicella, and birth before _____ for measles, mumps, and rubella.
a. 1974, 1962
b. 1952, 1995
c. 1965, 1972
d. 1980, 1957

19. A 67-year-old man arrives to your pharmacy asking about shingles vaccine. He says that he had already received Zostavax two years prior when he was 65. What of the following is the most appropriate action to take?
a. He should receive a booster dose of Zostavax.
b. He should receive Shingrix, but only one dose is required since he received Zostavax.
c. He should receive two doses of Shingrix at zero and between two and six months.
d. He does not require any further vaccination for shingles since he received Zostavax.

20. A 70-year-old woman arrives to your pharmacy inquiring about influenza vaccine. Which of the following is true regarding Fluzone High Dose and Fluad in patients 65 and older?
a. Illicits stronger immune response. Recommended preferentially over other formulations by CDC.
b. Illicits stronger immune response. Not recommended preferentially over other formulations by CDC.
c. Does not illicit stronger immune response. Recommended preferentially over other formulations by CDC.
d. Does not illicit stronger immune response. Not recommended preferentially over other formulations by CDC.