WELCOME TO THE ACP GUIDE TO ADULT IMMUNIZATION

You are among 50,000 physicians, physician assistants, residents, nurse practitioners, nurses, medical assistants and office managers who have received a complimentary copy of the ACP Guide to Adult Immunization. Produced by faculty of ACP’s Quality Improvement Programs and members of the ACP Adult Immunization Advisory Board, the ACP Guide to Adult Immunization will help you develop systematic processes for incorporating immunization in your day-to-day practice.

A committee of leading experts has worked hard to create a book that is accessible, featuring a flexible binding that allows you to flip to a helpful page or two and make copies for other members of your care team.

The Guide is divided into four sections:

Section 1: Quality Improvement Principles in Immunization
Section 2: Resources for Practical Application
Section 3: Recommended Adult Vaccines and Their Indications
Section 4: Special Populations (Pregnant Women, Immunocompromised, etc.)

Our intention is that this Guide will be read by and shared among the entire office team. You may find that Sections 1 and 2 are more beneficial to administrators and office staff, while physicians, physician assistants, nurse practitioners, and nurses may want to concentrate on Sections 3 and 4. Attending physicians and their residents will find residency clinic-specific information in Section 2. An electronic copy of the entire guide is available at www.immunization.acponline.org to facilitate sharing.

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IMMUNIZATION AND THE CHRONIC CARE MODEL

The primary care office system currently produces vaccination rates that fall well below the objectives outlined in the Healthy People 2010 goals from the U.S. Department of Health and Human Services. According to the latest national statistics, rates for influenza and pneumococcal vaccinations fall short of the 90% Healthy People goal for all patients, most dramatically for persons of color and persons of Hispanic origin. (See Figure 1, p. 2.) Rates for tetanus/Tdap, herpes zoster, and other vaccines for adults also fall short of national goals with significant racial and ethnic disparity.
Immunization and the Chronic Care Model

There are a number of reasons why immunization rates fall short of the Healthy People goals. The intention of this guide is to concentrate on steps that staff in the typical primary care office—including physicians, physician assistants, nurse practitioners, nurses, medical assistants and office managers—can take to improve rates of immunization. This guide will lead the primary care office staff through an examination of the practice’s immunization rates, as well as the actual processes of vaccine delivery in the office. The focus is on improving the way that immunization services are provided, which ultimately will help to improve immunization rates.

It is not just a matter of “doing more,” or “working harder.” In order to improve performance in a meaningful and sustained way, the primary care office needs to undergo transformation in how it operates—from the time the patient makes an appointment and enters the office, to the time the patient walks out the door, to the time the patient returns for follow-up.

The idea of vaccinating patients is straightforward enough: Patients who require certain immunizations should receive them during any appropriate office visit.

As the latest national immunization rates show, vaccination is not so simple. A practice needs to establish clear, well-defined processes for a variety of immunization-related tasks: ordering and storing vaccines, educating patients, and discussing vaccination during each visit. It is well established that a recommendation for immunization by a physician or other staff member can greatly increase the likelihood of a patient being vaccinated; however, practices need to develop processes designed to trigger that recommendation. Development of such processes requires a great deal of communication.

### FIGURE 1: Immunization Rates, 2009

<table>
<thead>
<tr>
<th>VACCINE (AGE AND/OR RISK STATUS)</th>
<th>NON-HISPANIC WHITE (%)</th>
<th>NON-HISPANIC BLACK (%)</th>
<th>HISPANIC OR LATINO (%)</th>
</tr>
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<tr>
<td>Tdap (19-64 years)</td>
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<td>54</td>
<td>49</td>
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<tr>
<td>Pneumococcal (65 years and older)</td>
<td>65</td>
<td>45</td>
<td>40</td>
</tr>
<tr>
<td>Pneumococcal (19-64 years, high risk)</td>
<td>18</td>
<td>18</td>
<td>12</td>
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<tr>
<td>Shingles (60 years and older)</td>
<td>11</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Influenza (65 years and older)</td>
<td>69</td>
<td>51</td>
<td>51</td>
</tr>
<tr>
<td>Influenza (50-64 years)</td>
<td>42</td>
<td>37</td>
<td>31</td>
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and coordination among physicians, staff, and patients.

A framework for such communication and coordination required in delivering immunizations in the office setting can be found in the Chronic Care Model (CCM).

The CCM, developed by Edward H. Wagner,2,3 outlines all the components necessary for practices to achieve optimal outcomes for treating chronic conditions such as diabetes and asthma, and delivering preventive services such as vaccinations.

Figure 2 above shows the prevalence of chronic conditions among Medicare beneficiaries and the relationship between chronic conditions and Medicare expenditures. Sixty-three percent of Medicare beneficiaries make up 95% of Medicare expenditures. And most of these people need to be immunized!

Figure 3 (see p. 4) illustrates the CCM and the components of care essential to achieving the best functional and clinical outcomes. The easiest way to understand the model is to start at the bottom and work up from there.

- **A prepared, proactive practice team** has the relevant information about the patient, uses decision support tools, is appropriately staffed and organized, and has the equipment and time to deliver evidence-based clinical management and self-management support.

- **An informed, activated patient** understands the disease process and his or her role as the daily self manager. The patient’s family is engaged in his or her self-management too. These two elements combine to form a productive interaction.

- **Productive interaction** occurs when staff - assesses each patient’s clinical status and also each patient’s self-management skills and confidence; - tailors clinical management by stepped protocol; - facilitates goal setting and problem solving with the patient to result in a shared care plan; and - provides active, sustained follow-up.

---

**FIGURE 2: Medicare Beneficiary Chart**

<table>
<thead>
<tr>
<th>NO. OF CONDITIONS</th>
<th>% OF BENEFICIARIES</th>
<th>% OF EXPENDITURES</th>
</tr>
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<tbody>
<tr>
<td>0</td>
<td>18</td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td>19</td>
<td>4</td>
</tr>
<tr>
<td>2</td>
<td>21</td>
<td>11</td>
</tr>
<tr>
<td>3</td>
<td>18</td>
<td>18</td>
</tr>
<tr>
<td>4</td>
<td>12</td>
<td>21</td>
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<tr>
<td>5</td>
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<td>18</td>
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<tr>
<td>6</td>
<td>3</td>
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<td>7+</td>
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The productive interaction is supported by a health care delivery system (i.e., at the practice level, or a larger health care network or system) that includes the following:

1. **Self-management Support**: Patients who are actively involved in their own care generally have better clinical outcomes. Self management requires patients—and to the extent possible—their family and/or caregivers, to understand clinical recommendations and guidance pertaining to their care. Knowledge about their condition and their plan of care allows patients to more fully participate in joint decision making with their health care team, enhances adherence to agreed-upon treatment plans and goals, leads to better lifestyle choices and action plans, and allows patients to become advocates for the delivery of evidence-based health care.

There are many ways the primary care office can systematically support patients in their quest for self management. In addition to supporting patient self management, the activities outlined as follows have also been shown to increase vaccination rates:

- Providing educational brochures
- Dispensing an “information prescription” (i.e., directing patients to trusted, reliable websites, such as ACP (www.acponline.org/patients_families/immunization/) or CDC (www.cdc.gov/vaccines/spec-grps/adults.htm))
- Providing office-based education with dedicated nurses or other members of the office team
- Providing access to educational videos or other tools in the office
Delivery System Design: Optimally designed primary care offices recognize that the responsibility for excellent clinical outcomes does not reside solely with the physician. Team-based approaches to providing services for patients often improve efficacy and allow all health care professionals to practice at the top of their license, skill, and abilities.

Decision Support: The complexity and burden of illness seen in ambulatory care is increasing on an almost daily basis. Decision support tools help the team manage this complexity by translating medical literature, consensus statements, and guidelines into actions at the bedside. These tools work best when they are configured to fit within the office’s workflow and are accessible and utilized in real time. Examples include care flowsheets, algorithms, computer alerts, and drug-drug/drug-allergy interaction software for electronic prescriptions. When creating any tool that will be provided to patients, such as information sheets, it can be helpful to receive feedback about them from one or two patients; this also provides an opportunity to address health literacy and cultural competency in the practice.

Clinical Information Systems: Using registries integrated within the office’s information system provides a path to population management. Registries let the practice create specific lists of patients who have conditions of interest. After staff enters patient-specific clinical data, registries can be configured to alert the practice to patients who need additional services or who are in danger of developing complications. Registries also allow for pre-visit planning for upcoming patient visits. In addition to facilitating

**SELF-MANAGEMENT EXAMPLE**

Develop a one-page education sheet about the benefits of the Tdap vaccine. Include an easy-to-read list of scenarios where Tdap vaccination is recommended.

**DELIVERY SYSTEM EXAMPLE**

- During influenza season, front-office staff ask patients if they have been vaccinated against influenza. If a patient has not, that staff member places a sticker on the progress note for the day, noting that the patient is a candidate for influenza vaccine.
- The medical assistant (MA) who escorts the patient sees the sticker indicating influenza vaccine candidate, and hands the patient an education sheet about the influenza vaccination. If the patient agrees to get the vaccine, the MA leaves the flu vaccine order form for the doctor to sign.
- The physician signs the flu vaccine order at the end of the visit or puts in place a standing order for influenza vaccine to be administered to all patients indicated for this preventive intervention.
- For an example of a PDSA cycle focusing on patient refusals, see p. 19, Residency Setting.

**DECISION SUPPORT EXAMPLE**

- Program an electronic health record (EHR) alert for patients 65 and over who have not had a pneumococcal vaccine.
- Laminate age-specific vaccine recommendations and information sheets and place them on the table in each exam room. The patient may read while awaiting his or her visit and then review the information with the physician during the visit.

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Ideally, a primary care practice will tackle one element of the Chronic Care Model at a time: **Self-Management Support, Delivery System Design, Decision Support, or Clinical Information Systems.**

Care, they also can be queried for data regarding practice performance, and identifying opportunities for further improvement. Although many practices continue to rely on paper registries or homegrown computer programs using Microsoft Excel or Access, some EHR programs/software can perform these registry functions.

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**CLINICAL INFORMATION EXAMPLE**

Create a registry of female patients up to age 26. Query the registry to find those patients who still need to receive the initial HPV vaccine, and those needing the follow-up doses.

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**COMMUNITY RESOURCES EXAMPLE**

Increase patient awareness of the various alternative sites for vaccination in the community, such as community clinics or drug stores. Coordinate with these sites to ensure information sharing.

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Community Resources: As part of the model, practices must become aware of local resources that they can offer to patients. Collaborating with community agencies, support groups, and other providers allows physician practices to be integrated with other societal efforts intended to promote wellness, disease prevention, and chronic disease management.

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Ideally, a primary care practice will tackle one element of the CCM at a time. The PDSA (Plan-Do-Study-Act) Cycle for Improvement, discussed in the next chapter, is a tool for initiating a quality improvement project once a particular area of focus has been identified.

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PDSA and Rapid Cycles of Change

Once a primary care office determines which part of the CCM to emphasize, the PDSA Cycle for Improvement helps navigate the quality improvement process.

The PDSA (Plan-Do-Study-Act) Cycle is based on the premise that small incremental changes taking place over time can result in significant change. The PDSA Cycle does not require expensive training or upfront costs. The cycles for improvement occur within the daily workflow of the practice.

This section discusses the key components of practice change based on the Institute for Healthcare Improvement’s (IHI) model for change. (See Figure 1, p. 8.)

**SETTING AIMS**

At the beginning of a quality initiative, the physician practice needs to identify a gap in performance (area to target for improvement). This is usually identified during a chart audit. ACP recommends conducting a baseline chart audit of 25 charts. From this baseline data, select a measure where a gap exists between current and desired performance levels. Establish an **AIM statement** defining the practice’s goals for improving performance by a certain percentage over a defined time period. This firmly established and agreed-upon target contributes to a sense of urgency and shared vision that unites team members.

**SELECTING MEASURES**

Practices seeking to improve are typically most concerned about clinical outcomes. Patients value these measures because they represent the care delivery that most directly affects their health. However, in order to attain desired clinical outcomes, the practice may need to improve process measures first. **Process measures are those steps within care delivery that are necessary to achieve the clinical outcomes (e.g., discussing vaccination with a patient vs. actually administering the vaccine).** As a practice typically has more control over process measures, it is helpful to concentrate on them during the initial stages of each quality improvement cycle. Once addressed, improved process measures can lead to improved outcomes measures over time.

**MEASURES EXAMPLE**

- **Process measures:** Use a tracking form that shows the percentage of patients for whom the practice provided an influenza vaccine information statement.
- **Clinical outcomes:** Calculate the percentage of patients who received the influenza vaccine.

SELECTING CHANGES

The next step is to determine which change to attempt first. It is important to recognize that not all change leads to an improvement. At the outset, attempted changes should be small and easily implemented in the practice (i.e., with as little as one practitioner and one staff member during one patient care session). Determine which section of the CCM the practice wants to work on first—Self-Management Support, Delivery System Design, Decision Support, or Clinical Information Systems. The PDSA cycle is then used to improve the chosen area for change.

The four steps of the PDSA cycle are: Plan, Do, Study, and Act.

1. **Plan**: The team must plan what change it hopes to see at the end of the cycle. Planning and preparing for change is an important first step prior to implementing change. In order to gain momentum, the change should be small and easy to implement by willing staff.

2. **Do**: Next, carry out the plan. **Continue the redesign process long enough to ensure that the practice gets enough experience and obtains sufficient data points to judge its impact on patient care.** A common error is to continue a plan that is ineffective for too long, which can delay forward progress. On the other hand, ending a PDSA cycle too soon could lead to underestimating the impact of the change and thus processes that are not beneficial. View each process change as (hopefully) an incremental improvement—not a solution to the entire problem.
Study: It is important to set aside time to analyze the data and study the results. Complete the analysis of the data, compare the data to the predictions, and summarize and reflect on what was learned.

• Use a measurement strategy to determine if the change is an improvement. (See next chapter.)
• Plot the data on a run chart at the end of each week (or a more appropriate interval of time, as deemed by the practice) to sample the performance. (See p. 11 for details on how to create a run chart.) After the run chart is updated, analyze the data. Consider whether progress is being made toward the goal.
• Practices with EHRs can create or use existing reports that query the care rendered, thus streamlining and simplifying the data collection. This is especially valuable for creating lists of individuals who were actually administered a vaccine during a particular interval in time.

Act: After considering the data, determine whether or not the cycle of change was an improvement. There are three possible outcomes of this analysis:

• Adopt the change. Selected when a sufficient amount of data points to sustained improvement. By adopting the change, the practice develops a new standard operating procedure.
• Adapt the change. Selected when the last cycle of change has not led to sustained improvement in outcomes but has shown promise. Additional changes or tweaks to the prior change are planned, thus initiating a new PDSA cycle.
• Abandon the change. Selected when the team determines that the concept behind the change will not lead to sustained improvement and the practice needs to undertake a completely different tactic.

The next step is to chart the progress of the PDSA cycle on a regular basis. The following chapter, Measuring Change in Your Practice, will introduce the concept of simple run charts, and how they can keep the entire office practice engaged in the improvement process.

PDSA EXAMPLE

**Plan:** Provide Tdap Vaccine Information Statements (VIS) to all patients before receiving the vaccine.

**Do:** MA provides the VIS to “Dr. Jones’” patients at Tuesday clinic.

**Study:** Percentage of immunized patients provided with a VIS before receiving vaccine. Low success rate (30% first week and 20% the next).

**Act:** Adapt and modify current design. Further review revealed that because the VIS were kept in the drawers, the MA often forgot to give them to patients.

**Plan:** Provide Tdap VIS to patients before receiving vaccine.

**Do:** MA provides the VIS to “Dr. Jones’” patients (now kept on counter) for three weeks.

**Study:** 40% the first week, 60% the next.

**Act:** More patients are receiving the VIS. The practice decides to continue the current design for several more weeks until they reach 100% of all patients indicated for Tdap receiving VIS.
AIM STATEMENT WORKSHEET

An AIM statement should describe the target goal in quantifiable terms, the intervention, and the timeframe.

For example: 80% of patients who smoke will receive an information sheet about the pneumococcal vaccine in the next six months.

AIM:

Use these prompts to develop and track your AIM statement:

What change:

Who will do it:

Where:

When:

What measurement:

When/how/by whom will the measurement be done:

Where will the run chart be located/updated by whom:
Measuring Change in Your Practice

It is impossible to measure change over time without a tracking mechanism. A run chart—a simple visual display of data—can illustrate a practice’s progress in improvement over time. Run charts are simple to create, relatively easy to interpret, and help physician practices stay on track towards their goal. This section provides a brief overview of how to create run charts and incorporate them into a practice’s PDSA Cycle.

**LIMITS OF TRADITIONAL DATA DISPLAY**

Traditionally data are displayed in tables and bar graphs. These formats collapse individual data points into aggregate or summative data. These types of data are beneficial for representing performance during a given time period. However, these types of data can make it more difficult to detect and react to patterns and outliers, thereby minimizing the potential lessons learned. Interpretations based on summative data may then lead to incorrect conclusions about performance.

Run charts tell a more complete story than traditional data displays. The traditional data display in Figure 1 shows an average pre-intervention performance of 70 minutes and post-intervention performance of 35 minutes. (The intervention and the measure are used for demonstration purposes only.) But when each individual data point is plotted on a run chart, a different picture emerges—even though all three units have identical “before” and “after” averages. Unit 1 demonstrates improved performance that began immediately after the intervention; Unit 2 shows improvement even before the intervention; and Unit 3 reveals immediate improvement after the intervention with eventual worsening of performance with each ongoing measurement.

**CREATING RUN CHARTS**

Appropriately configured run charts contain the following key elements:

*Creating the run chart:* Simple run charts can be developed on blank pieces of paper. The size should be large enough to accommodate multiple data points with annotation. Most practices simply begin with a white 8.5 x 11 sheet of paper. Excel or other computer programs can also be used to create the charts. Because regularly updated run charts are most useful, manually created charts that are easy to update may be most valuable.

*Axis labeling:* The “x” axis is used to display the passing of time. Intervals should be even and clearly labeled. The “y” axis is used to display performance. For quality improvement initiatives the “y” axis is usually labeled from 0% to 100%. In order to more clearly demonstrate improvement, start the axis near the baseline performance point.

**RUN CHART SET-UP**

If baseline vaccination rates are 50%, and the desired goal is 90%, the “y” axis labeling could begin near 50%.
Note the real story the run charts demonstrate below.
Goal line: To keep the team focused and aligned toward the goal, it is important to place a horizontal line at the level of desired performance. The line serves as a constant reminder of the gap in current performance.

Goal date: The run chart includes the date by which the desired goal needs to be met; this creates a sense of urgency and the visual cue helps reduce complacency among staff.

Process changes: When implementing substantial changes in process it is important for the run chart to emphasize when the practice initiated the change efforts. This is seen in Figure 1 as the black arrow. In this example, only one change occurred in the data set. If multiple changes occur (as is often the case with quality improvement initiatives), add details of the change to the chart as space allows. This will allow staff to make connections between the data and newly implemented process changes that have affected performance over time.

UPDATING RUN CHARTS
It is imperative for the team to select a staff member to update the run charts. This individual does not need to be the same person who acquires data (through sampling). The charts should be updated immediately after data are obtained.

REVIEWING DATA
Sharing project data fosters a culture of improvement. Begin sharing data in an ongoing, real-time manner by placing the data in a visible location in the office. A quality improvement project can become derailed if the project champion keeps the data in his or her office, filed away, or elsewhere out of view, and fails to discuss it with others. Many practices also will post run charts in patient waiting areas. This serves to apply additional pressure on the staff to perform while also involving patients in the effort.

However, it is not enough to simply post data and expect staff to review it in an ongoing and meaningful manner. Get staff to actively interact with the data by including quality improvement as a standard agenda item at practice meetings. These meetings are an opportunity to remove the run chart from its usual location and review it in front of the group. A committed and well-respected champion becomes an essential driver in maintaining momentum for improvement. This person needs to lead a dialogue about the data to ensure everyone understands the team’s progress to the goal and the need for further change.

ADVANCED USE OF RUN CHARTS
Most office-based quality improvement efforts can effectively use simple run charts and track progress toward the goal. More advanced uses of run charts exist. These uses can help the practice spot excessive variation, new trends, and shifts in performance over time. For further information on advanced run chart use see www.ihi.org/IHI/Topics/Improvement/ImprovementMethods/Tools/Run+Chart.htm.
Most office-based quality improvement efforts can effectively use simple run charts and track progress toward the goal.
Incorporating Run Charts Into Daily Practice

A run chart is a simple way to display how a process improvement performs over time. It is usually presented as a line graph, with data points plotted in chronological order. Here is an example of an intervention that is tracked over time with the use of run charts.

Dr. Quality of Fantastic Internal Medicine decides to perform a process improvement with her nursing staff using an immunization review sheet provided to patients. Her hunch is that use of the review sheet will improve vaccination rates.

When patients check in, the front desk staff provides them with an immunization review sheet entitled, Do I Need My Vaccination Today? The sheet presents a series of questions about pneumococcal and Td/Tdap vaccination history. The patients bring their sheets with them into the exam room, where the nurse and patients review them together. Because the practice uses standing orders, the nurses are authorized to administer the vaccine if appropriate. The immunization review sheet is then placed in the medical record.

At the end of each day, Dr. Quality samples 2 charts to see if the immunization review sheet is present, and if so, whether it was used appropriately (i.e., vaccine given). At the end of the week, she creates a run chart to record the progress. (A hand-drawn run chart works just fine, see right.) The number graphed for the week would be the number of charts with a review sheet used appropriately divided by total number of sampled charts.
After week 1, Dr. Quality “huddles” with her nursing staff to get their input and show them the results (only 30%). They explain that many times the review sheet cannot be appropriately addressed because it is written in a confusing manner with too much medical jargon. Dr. Quality rewrites the sheet for Week 2. After Week 3, the nursing staff notes that urgent care patients are not interested in addressing the review sheet. Dr. Quality decides only non-urgent visits will be involved with the project beginning Week 4. After Week 4, Dr. Quality treats her entire office to a pizza party lunch to celebrate their success! She continues sampling to ensure the improvement is sustained, but after Week 6 decides to pursue another hunch. In 6 months, she will perform a random sample chart review to determine if immunization rates are indeed improved.

Run charts do not have to be elaborately drawn on a computer to be effective. They need to be simple, visible, and kept up-to-date!
DOES YOUR STAFF NEED TRAINING IN IMMUNIZATION?

See pages 27-28 for a list of immunization training programs for nurses and other members of the office practice team.
Applying the Chronic Care Model and PDSA Cycle to Any Immunization Setting

Patients receive vaccines in many different settings. Each setting is unique and the success of vaccination strategies is affected by each particular setting.

In this section, two types of vaccination settings are described—the Residency Clinic and the Private Practice. These discussions provide examples that may be used as a resource when embarking on immunization practice improvement projects. Please keep in mind that these examples are provided to illustrate the practice improvement process, and that actual efforts devised by physicians and their team may differ based upon individual needs.

Some examples pertain to any practice setting and are thus noted. Regardless of the setting, these examples can be used as springboards to guide the planning of any immunization quality improvement project.

Residency Clinic Settings
Residency is an ideal time to teach quality improvement skills and apply them to situations in the “real world.” Residency establishes the learning processes that physicians will continue to apply over the course of their careers. Residency provides an opportunity to develop good habits when residents are most open to learning new concepts and working in teams—both key to practice improvement.

The Accreditation Council for Graduate Medical Education requires internal medicine residencies to provide training in a continuity clinic setting. While practice improvement can be exercised in many different aspects of residency training, the continuity clinic is ideal for several reasons. Typically, many residents spend at least one-half day per week in this setting, allowing for the development of an ongoing relationship with the faculty that supervise their clinic practice over the duration of their training.

Additionally, residents typically have the opportunity to follow assigned patients on a regular basis, thus providing a sense of continuity for both the patients and their doctors.

IDEAS FOR GETTING STARTED
The CCM can be used to design a practical system of care delivery in any setting. When getting started, it is always best to start with basics. Here are some key elements to focus on first:

1 Form a team.

Practice Setting
Designate a non-physician champion to provide leadership and direction on a day-to-day basis. Because it can be difficult for team members to attend scheduled meetings, consider communicating through weekly e-mail updates or quick “huddles” on a regular basis.

Residency Setting
Designate a physician champion to provide leadership and direction, such as a faculty physician who oversees residents in the outpatient clinic. Get administrative buy-in from the hospital leadership. Include a resident from each clinic day who is enthusiastic and influential among his or her peers as well as a member from the nursing, scheduling, and medical records staff.
2 Evaluate current performance.
Perform an initial chart review to provide a baseline snapshot of current performance. Be prepared to be surprised. Use the data from a baseline assessment to identify an area needing improvement to tackle first.

Paper Charts Example
If the baseline chart audit took weeks longer than expected because of poorly organized charts and a lack of consistent documentation of vaccinations by providers, start with a chart organization tool or a new immunization worksheet that will organize the patient’s vaccination history at a glance. The first PDSA cycle may be to make sure that this sheet is placed in every chart, is updated when the charts are pulled and prepped for the day, and then is updated again by everyone in the practice who orders or gives vaccines.

EHR Example
Ensure that all staff are aware of the correct fields to use for documentation of vaccination status. If a flow sheet for vaccines is not evident, contact the IT department or the EHR vendor for additional support.

Many EHRs have the ability to run reports. These “queries” of the system can be used to gain awareness of performance during the PDSA interval.

3 Set the aim.
Set a well-defined goal and a specific time-frame.

Any Setting
To attain an influenza vaccination rate of at least 80% in patients with asthma within the next year.

4 Plan the practice’s first PDSA.
Pick one idea that seems straightforward and break it down into smaller steps.

Practice Setting
Plan: Provide influenza VIS to 100% of patients before receiving the vaccine.

Do: MA to provide VIS to all Dr. Jones’ patients who agree to receive the vaccine on Tuesday. The MA will document on the chart that the VIS was given.

Study: Office manager will sample 10 charts (determined by billing codes), compute the percentage of patients provided with a VIS, and display the data on a run chart in the break room.

Act: Implement or adapt as needed.

Residency Setting
Plan: Reduce patient refusals for influenza by 25% in six months.

Do: When a patient refuses a vaccine, the patient care technician who is placing the patient in a room makes a note and, if possible, the reason for refusal, in the patient’s medical record to promote discussion between the patient and the resident.

Study: At the end of the day, records of all noted patients will be checked by the patient care technician to determine whether the vaccine was given. A simple table is kept with “Given,” “Not Given” and “Reason Refused” for all relevant charts. The percentage of vaccines given over the course of each week is displayed on a visual run chart in the resident conference room. If the number of refusals is low (i.e., less than three per week), the data can be displayed every two weeks, or even every month, on the run chart.

Act: Revise PDSA or move on to another vaccine.
Maintain momentum

Once the practice or residency clinic finishes the first PDSA, take what is learned and plan the next cycle. Do not be afraid to scrap ideas that did not work well. Show appreciation to the team and all involved parties. Administration’s recognition of practice improvement can be a great motivational tool; this can be as simple as sending an e-mail to the department praising the quality improvement team.

Any Setting

Using the VIS example in the Practice Setting above, if the practice was reporting only 60% success on the run charts, a “huddle” (as opposed to a formal sit-down meeting) with the MA may be in order to try to determine the barrier. For example, if the MA reports that documenting the information onto the chart is proving cumbersome, a PDSA cycle concentrated on documentation would be a natural next step. Education on the federal requirements of VIS distribution may also be necessary.
CASE STUDY—PRIVATE PRACTICE

Wellington Medical Practice is a small practice with two physicians, an office manager, two MAs, and two support staff. The office is located in a diverse community, and has a payer mix that is one-third private insurance and/or Medicare and two-thirds HMO or medical assistance. The practice has just completed its chart audits. The data suggest a large gap: only 60% of the practice’s diabetic patients have received the pneumococcal vaccine.

To develop its first PDSA cycle, the staff first set a goal of vaccinating 80% of their patients with diabetes with the pneumococcal vaccine in the next six months. It is late August and they feel this vaccine could easily be given at the same time as the seasonal flu vaccine. They need to design a way to educate patients about the need for this vaccination and then implement a systems change that will capitalize on every opportunity for vaccination.

A team meeting is scheduled. In attendance is one physician champion, the office manager, an MA, and a member of the support staff. They decide to have the physician write standing orders that include vaccine administration for every patient with diabetes. They then begin to identify opportunities for every team member to improve this vaccine rate among these patients. Because they have already attached yellow labels to the edge of all applicable charts, they decide to first look at these charts for patients who have not had a pneumococcal vaccine. Office staff will hand these patients vaccine brochures at check in. When the MA calls the patient back to the exam room, he will begin a dialog with the patients who have not been vaccinated. By the time the physician enters the exam room, patients who have reservations or questions are prepared to talk about vaccination. The visit will be used as an opportunity to bring these patients up to date before they leave the office. The team also decides that staff will utilize the standing orders for all patients with diabetes who will receive reminders to visit the office for a flu shot.

They decide to pick two charts a day to audit their progress. At the end of each week, they update a run chart to ensure that the system they have designed is working and keep it posted in the kitchen. They agree to meet monthly to assess their progress and to make adjustments as needed to help stay on track with their goals. Plans are put in place to meet sooner if the chart audits reveal they are falling short of their goals.
CASE STUDY—RESIDENCY SETTING

Dr. Jones at Smithville Hospital wants to help her residents understand the rewards of participating in quality improvement. She regularly points out the long-term gains in terms of knowledge, lifelong practice, etc., but knows it will be easier if the residents experience it firsthand. Rather than making a dictum that residents be involved, Dr. Jones taps into their natural competitiveness and sets up a “Which clinic day is performing best?” challenge. She also displays run charts in the break room and keeps them updated. In addition, she offers short-term incentives such as pizza parties and visible recognition such as “Resident of the Week” status for obtaining PDSA goals.

Dr. Jones knows that efficiency is key in a residency clinic. She initiates the use of flowsheets to help keep information organized. She makes sure that the flowsheets are readily available and easily updated to ensure that the process of keeping vaccination records is easy and efficient.

Dr. Jones knows that the tasks associated with PDSA—reviewing charts, keeping statistics, and reporting results—are time-consuming. However, she explains to her residents that the process of reviewing charts can reveal differences between the self-perception of care and what is actually documented in the chart. Physicians, however, do not need to perform the data collection; in fact, some programs may benefit from having other team members provide the ongoing measurement.

Dr. Jones incorporates data collection into the daily work flow. For example, she asks each resident to review one chart each week for documentation of flu vaccination during the course of his or her continuity clinic. The resident can choose to do the review either while waiting for a patient to be roomed, while waiting to present to an attending physician, or at the end of the panel. Dr. Jones assigns one resident to update the run charts. The charts are displayed in the conference room where all residents can track their progress.

Both Private Practice and Residency examples meet all of the criteria of a great PDSA cycle because the staff have:

1. Identified the gap;
2. Set a timely goal to accomplish their progress;
3. Chosen a team that represents each process of the office during a patient encounter;
4. Engaged patient feedback about information materials;
5. Delegated responsibilities across team members equally so no one member is overburdened; and
6. Evaluated their progress on an ongoing basis, and shared the results in a visible format to help ensure the team stays on track with its goals.
Practice Management Issues

In the practice setting it is important to design a program for delivering immunization services that can be sustained long-term. The key to system redesign is to incorporate change into everyone’s job, often little changes that do not overburden anyone. Below are some tips for increasing efficiency with immunization procedures in the office setting.

STANDING ORDERS
Standing orders help vaccination rates by involving team members other than physicians, thereby reducing the pressure on the already time-pressed physician-patient encounter. Standing orders ensure that every team member can identify an opportunity to vaccinate every patient.

PATIENT EDUCATION
A simple first step may be to begin in the waiting room with a modest investment for a display rack offering brochures about vaccines that patients can peruse while they are waiting. When the front desk staff pulls charts for visits, they could include standing orders that allow the nurses or MAs to give the vaccine. By the time the physician sees patients, they will either have been given the vaccines or they can raise any reservations or concerns about the vaccines with the physician.

PAIRING VACCINES
Pick times of the year to encourage patients to get certain vaccines. For example, for influenza season—from October through March—focus on influenza and pneumococcal. In the spring, focus on tetanus/Tdap and herpes zoster. Audit vaccines at yearly physicals particularly noting childhood catch-up, hepatitis A and B, HPV, and meningococcal vaccines. Automatically audit charts and run labs at the visits for patients in a high-risk category such as diabetes. Use every patient visit as an opportunity for educating the patient and providing vaccinations.

VACCINE ORDERING
Vaccines are a large financial burden on medical practices so it is important to seek every opportunity for saving money with every vaccine purchase. One way is to take advantage of vaccine manufacturers’ December discounts for ordering vaccines in bulk for the upcoming year. Whenever possible, arrange to be billed once the vaccines are shipped. The practice may be able to receive additional discounts if payments are made within 30 days of shipment. Track vaccine purchases and administrations on an Excel spreadsheet to assist with estimations for actual costs incurred, revenue generated, and ordering in subsequent years.
SAFE VACCINE STORAGE
Best practices include separating vaccines in a refrigerator solely dedicated for medication and vaccine storage. One strategy is to use inexpensive, brightly-colored plastic bins labeled with the vaccine’s name. This will separate vaccines that look or sound similar and help eliminate a chance for medical errors in the administration process. Another way to prevent errors is to add “STOP, take time out” stickers on every shelf to remind staff to stop, use two identifiers for the patient, and verify the vaccine and the dose ordered by the physician. This storage process offers the added benefit of keeping inventory at the forefront of the visual display. Assign a staff member the task of periodically examining the vaccine stocks to track expiration dates and lot numbers.

Given how much the practice invests in vaccines, it is critical to put safeguards in place to protect the investment. For less than $1,000 the practice can purchase systems that will constantly monitor the temperature inside the vaccine refrigerators. These programs record the temperature hourly or daily, and send a log to a desktop computer or designated mobile device by e-mail. If the temperature inside the vaccine refrigerator falls outside of the pre-determined acceptable range, an alarm will sound and the manufacturer will notify staff members whose contact information has been provided in the event of any system failure in the vaccine storage refrigerator.

INVENTORY CONTROL
Count the practice’s vaccines daily and match the number given out with the number billed. Just ten missed charges of herpes zoster or HPV vaccines in a month, for example, can cost the practice thousands of dollars.

VACCINE RECALLS
If the practice doesn’t have an EHR to track recalls, keep a manual log of every vaccine administered. Date the log at the start of every day. Before giving the vaccine, update the log with the patient name, date of birth, manufacturer name, vaccine name, lot number, injection site, and the initials of the staff member administering the vaccine. Keep these logs in a binder. If there is a recall, someone can go back through the logs highlighting any suspect vaccines to identify patients that need to be notified.

ADVERSE EVENTS
To report adverse events, go to http://vaers.hhs.gov/index. A link there connects to the reporting form. The information the practice will need to report an adverse event should be in the vaccine logs.
Use every patient visit as an opportunity for educating the patient and providing vaccinations.
RUNNING A VACCINE CLINIC

Setting up an influenza vaccine clinic to vaccinate as many patients as possible is relatively simple if the practice is well organized. Below is a step-by-step list of how to set up and run a clinic:

1. Set dates, times, and a maximum number of patients the clinic will serve. A well-organized clinic can vaccinate as many as 300 or 400 patients in a few hours.

2. Advertise your clinic by making flyers and displaying in every exam room. If you have a website, add a message that gives information about your vaccine clinics or add a banner to every patient statement. Offer appointments early and encourage patients to sign up.

3. Begin accepting appointments at least two months prior to the vaccine clinic date. Most clinics can accommodate as many as eight patients every 15 minutes with one support staff and one tech working.

4. Pull charts and print encounter forms three days before the clinic.

5. Verify insurance of every patient when the appointment is made. Those without insurance or those whose insurance does not cover the vaccine need to know the cost and payment process they can expect at the time of the visit.

6. Make sure physician orders for each patient are complete and up to date.

7. Copy up-to-date vaccine information statements for vaccines that will be distributed. Find these at [www.cdc.gov/vaccines/pubs/vis/default.htm](http://www.cdc.gov/vaccines/pubs/vis/default.htm).

8. If different doses are being administered of the same vaccines, the practice must have a system that clearly identifies and separates each dose.


10. Make labels for charts. Be sure to include: date given, vaccine name, manufacturer, lot number, expiration date, site, and a place for the initials of the tech administering the vaccine.

Practices using an EHR should ensure that all staff participating in the vaccination clinic are competent in correctly documenting the vaccination.

11. Prepare vaccine logs so the documentation requirement is easy for staff to complete.

12. Make sure a table is set up to receive the patients in the registration process and a place is designated to keep charts.

13. Have a table ready for the vaccine supplies and a chair available to allow your patients to sit in order to administer the vaccine safely and comfortably.

After the clinic is complete, charge out encounter forms. Call no-show patients to schedule new appointments.
Immunization Resources

STARTING AN IMMUNIZATION PROGRAM FROM SCRATCH?
Check out the *Adults Only Vaccination: A Step-by-Step Guide*, produced by the Immunization Action Coalition (IAC) and available at www.immunize.org/guide/aovguide_all.pdf.

The IAC is a practical resource for user-friendly immunization information. The website houses all of IAC’s informational handouts, which are available free of charge, and users are encouraged to reproduce and redistribute the materials. This website also makes available all VIS published in the United States in up to 50 languages and some alternative formats.

IMMUNIZATION TRAINING PROGRAMS FOR NURSES AND OTHER PROVIDERS

**ANA Bringing Immunity to Every Community initiative**

The American Nurses Association and Every Child By Two (ECBT) have partnered to produce an innovative continuing education webcast for nurses on vaccine safety and patient communication. Combining a nurse-panel presentation with patient-nurse video vignettes, this course offers practical knowledge and skills to increase immunization competency.

Developed for the nurse in any role or specialty, this course will cover:
- Impact of vaccines on society
- How the nursing profession is vital to the promotion of immunizations
- Benefits of vaccination to nurses (and health care workers)
- Vaccine safety and adverse event reporting
- Common questions and vaccine myths
- Risk communication methods to reduce concerns and increase vaccine acceptance

**Faculty**
- Mary Beth Koslap-Petraco, DNP, PNP-BC, CPNP
- Katie Brewer, MSN, RN

Content presented during this program was developed by a national Advisory Panel with documented expertise in immunization advocacy and education.

To access the program, visit www.anaimmunize.org/webcast

**The Nurse Training on Immunization Project (NurseTIP)**

NurseTIP recognizes that nurses play an integral role in the success of immunization programs. Nurses are often the first point of contact at any health care visit and can have considerable influence on the public health practices of a community.
Goals: Increasing the knowledge and competency of nurses in immunization by offering relevant content in a variety of distance-learning approaches.

Engaging nurses in program planning, dialogues with other nurses, and exploring strategies to promote immunization.

Target audience: Nurses working in medical offices, clinics, community health centers as well as other settings.

All programs are archived and offered free of charge and CNEs, CMEs and CHEs are available. NurseTIP is funded through a cooperative agreement with CDC #1U01IP000374.

www.nursetip.org

NIP-IT

The Nursing Initiative Promoting Immunization Training (NIP-IT) is made possible by a cooperative agreement between the University of Oklahoma College of Nursing, a National League Center of Excellence in Nursing Education since 2006, and the Centers for Disease Control and Prevention. This innovative and creative web-based curriculum about immunizations and vaccine preventable diseases is intended to inform and educate nursing students and nurses nationwide.

www.nip-it.org

IMMUNIZATION.AC PonLINE.ORG

Visit this ACP web page for:

Electronic assess to the Guide to Adult Immunization. The Guide will be available in both PDF format and will also be downloadable to electronic readers such as iPads, Kindles, and Nooks. In addition, the site will provide updates to the Guide with respect to future ACIP and FDA recommendations and announcements.

Immunization Mobile Application. A program that allows the user to search for adult vaccines and their indications will be created for download to mobile phone devices and updated regularly. (Available Fall 2011)

Content and Practice Tools. The web page will also include presentations of content and practice tools from ACP’s quality improvement program Closing the Gap.

Immunization related-RSS feeds. Sign up for a number of immunization-related RSS feeds with latest immunization-related news, including updates from the CDC’s Advisory Committee on Immunization Practice (ACIP).

Links to the ACP Medical Home Builder. Learn how this Guide can help your practice become a medical home.
Since 2006, ACP has endorsed the ACIP Immunization Schedule, a collection of the recommended age groups and medical indications for which administration of currently licensed vaccines is commonly indicated for adults ages 19 years and older. The latest schedule (as of January 1, 2011) appears on the following page.

Each January, the ACIP Immunization Schedule is published in ACP’s Annals of Internal Medicine, along with an editorial highlighting the updates since the previous year. (www.annals.org)

Many practices display the ACIP Immunization Schedule throughout the office and in exam rooms, where staff and patients can refer to them easily.

In addition, the Immunization Action Coalition has developed a more patient-friendly version for practices to share with their patients:
### Recommended Adult Immunization Schedule

#### UNITED STATES - 2011

Note: These recommendations must be read with the footnotes that follow, containing number of doses, intervals between doses, and other important information.

#### Recommended adult immunization schedule, by vaccine and age group

| VACCINE | AGE GROUP | 15-26 years | 27-49 years | 50-64 years | 65 years | 65 years+
<table>
<thead>
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</thead>
<tbody>
<tr>
<td>Influenza</td>
<td>1 dose annually</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Tetanus, diphtheria, pertussis (Tdap)</td>
<td>Substitute 1-time dose of Tdap for Td booster; then boost with Td every 10 yr</td>
<td>Td booster every 10 yr</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Varicella</td>
<td>2 doses</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Human papillomavirus (HPV)</td>
<td>3 doses (males)</td>
<td>3 doses (females)</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Zoster</td>
<td>3 doses</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Measles, mumps, rubella (MMR)</td>
<td>1 or 2 doses</td>
<td>1 dose</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pneumococcal (polysaccharide)</td>
<td>1 or 2 doses</td>
<td>1 dose</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Meningococcal</td>
<td>1 or 2 doses</td>
<td>1 dose</td>
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<tr>
<td>Hepatitis A</td>
<td>2 doses</td>
<td></td>
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<tr>
<td>Hepatitis B</td>
<td>3 doses</td>
<td></td>
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</tbody>
</table>

*Covered by the Vaccine Injury Compensation Program.*

For all persons in every category, except the age 65 and older who have medical contraindications, and those who have no evidence of previous infection:

**Recommended if age <65 and: a) older than age 50, b) smoker, c) chronic medical condition (e.g., diabetes, heart disease, chronic kidney disease, chronic liver disease).**

No recommendation for those who have received three doses of a hepatitis B vaccine by age 18 and have no evidence of subsequent infection.

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### Vaccines that might be indicated for adults based on medical and other indications

<table>
<thead>
<tr>
<th>VACCINE</th>
<th>INDICATION</th>
<th>Preemies</th>
<th>Immune-compromising conditions</th>
<th>Chronic lung disease</th>
<th>Diabetes, heart disease</th>
<th>Chronic liver disease</th>
<th>Chronic kidney disease</th>
<th>Kidney failure, chronic renal replacement therapy</th>
<th>Healthcare personnel</th>
</tr>
</thead>
<tbody>
<tr>
<td>Influenza</td>
<td>1 dose TIV annually</td>
<td>3 doses IV or LAIV annually</td>
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<tr>
<td>Tetanus, diphtheria, pertussis (Tdap)</td>
<td>Td</td>
<td>Substitute 1-time dose of Tdap for Td booster; then boost with Td every 10 yr</td>
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<tr>
<td>Varicella</td>
<td>Contraindicated</td>
<td>2 doses</td>
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<tr>
<td>Human papillomavirus (HPV)</td>
<td>3 doses through age 26 yr</td>
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<tr>
<td>Zoster</td>
<td>Contraindicated</td>
<td>1 dose</td>
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<td>Contraindicated</td>
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<td>Pneumococcal (polysaccharide)</td>
<td>1 or 2 doses</td>
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For all persons in this category except those who are <65 and older who have medical contraindications, and those who have received three doses of a hepatitis B vaccine by age 18 and have no evidence of subsequent infection:

**Recommended if age <65 and: a) older than age 50, b) smoker, c) chronic medical condition (e.g., diabetes, heart disease, chronic kidney disease, chronic liver disease).**

No recommendation for those who have received three doses of a hepatitis B vaccine by age 18 and have no evidence of subsequent infection.

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These schedules outline the recommended age groups and medical indications for which administration of currently licensed vaccines is commonly indicated for adults ages 10 years and older as of January 1, 2011. For vaccines being recommended on the adult immunization schedule, a vaccine series does not need to be repeated, regardless of the time that has elapsed between doses. Contraindications to vaccination may be used as a reason to delay or withhold a vaccine dose until appropriate medical evaluation and management can occur. It is important to fully assess patients’ medical history, past history of immunization, and current health status before any vaccine is administered. This schedule does not apply to immunization requirements for travel, military personnel, or other special populations or purposes.

The recommendations in this schedule were approved by the Centers for Disease Control and Prevention’s (CDC) Advisory Committee on Immunization Practices (ACIP), the American Academy of Family Physicians (AAFP), the American Academy of Pediatrics (AAP), the American College of Obstetricians and Gynecologists (ACOG), and the American College of Physicians (ACP).
Vaccinations for Adults
You’re NEVER too old to get immunized!

Getting immunized is a lifelong, life-protecting job. Don’t leave your healthcare provider’s office without making sure you’ve had all the vaccinations you need.

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>19–49 years</th>
<th>50–64 years</th>
<th>65 years &amp; older</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Influenza</strong></td>
<td>You need a dose every fall (or winter) for your protection and for the protection of others around you.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Pneumococcal</strong></td>
<td>You need 1–2 doses if you smoke cigarettes or if you have certain chronic medical conditions.*</td>
<td>You need 1 dose at age 65 (or older) if you’ve never been vaccinated.</td>
<td></td>
</tr>
<tr>
<td><strong>Tetanus, diphtheria, pertussis (whooping cough) (Td, Tdap)</strong></td>
<td>Be sure to get a 1-time dose of “Tdap” vaccine (the adult whooping cough vaccine) if you are younger than age 65 years, are 65+ and have contact with an infant, are a healthcare worker, or simply want to be protected from whooping cough. You need a Td booster dose every 10 years. Consult your healthcare provider if you haven’t had at least 3 tetanus- and diphtheria-containing shots sometime in your life or have a deep or dirty wound.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Hepatitis B (HepB)</strong></td>
<td>You need this vaccine if you have a specific risk factor for hepatitis B virus infection* or you simply wish to be protected from this disease. The vaccine is given in 3 doses, usually over 6 months.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Hepatitis A (HepA)</strong></td>
<td>You need this vaccine if you have a specific risk factor for hepatitis A virus infection* or you simply wish to be protected from this disease. The vaccine is usually given as 2 doses, 6–18 months apart.</td>
<td></td>
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</tr>
<tr>
<td><strong>Human papillomavirus (HPV)</strong></td>
<td>You need this vaccine if you are a woman who is age 26 years or younger. One brand, Gardasil, can be given to men age 26 years or younger to prevent genital warts. The vaccine is given in 3 doses over 6 months.</td>
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<td></td>
</tr>
<tr>
<td><strong>Measles, mumps, rubella (MMR)</strong></td>
<td>You need at least 1 dose of MMR if you were born in 1957 or later. You may also need a 2nd dose.*</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Varicella (Chickenpox)</strong></td>
<td>If you’ve never had chickenpox or you were vaccinated but received only 1 dose, talk to your healthcare provider to find out if you need this vaccine.*</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Meningococcal</strong></td>
<td>If you are going to college and plan to live in a dormitory, or have one of several medical conditions*, you need to get vaccinated against meningococcal disease. You may also need additional booster doses.*</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Zoster</strong> (shingles)</td>
<td></td>
<td>If you are age 60 years or older, you should get this vaccine now.</td>
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</tr>
</tbody>
</table>

* Consult your healthcare provider to determine your level of risk for infection and your need for this vaccine.

**Do you travel outside the United States?** If so, you may need additional vaccines. The Centers for Disease Control and Prevention (CDC) provides information to assist travelers and their healthcare providers in deciding the vaccines, medications, and other measures necessary to prevent illness and injury during international travel. Visit CDC’s website at www.cdc.gov/travel or call (800) CDC-INFO ([800] 232-4636). You may also consult a travel clinic or your healthcare provider.
The information presented in this section reflects the most recent recommendations of the Advisory Committee on Immunization Practices (ACIP). As you refer to the vaccine information on the following pages, please keep in mind that the world of immunization is dynamic and immunization recommendations are always changing as our medical knowledge grows. Any changes or updates to the information provided here will be offered on ACP’s immunization web portal, immunization.acponline.org.

The latest ACIP recommendations are always available at www.cdc.gov/vaccines/pubs/acip-list.htm.
Weighing Vaccine Benefit vs. Risk

In a perfect world, all patients would be vaccinated according to the ACIP guidelines, which are often considered the “gold standard” of immunization recommendations. But of course that is not always possible, as some patients refuse some or all vaccines for personal or religious reasons. Still other patients question certain vaccinations or want to better understand the risks and benefits of vaccines.

Physicians and their staff are the best advocates to help patients navigate what can sometimes be a confusing relationship between the goals of public health and individual benefit and risk. A physician’s (or other office staff member’s) recommendation for vaccination is a powerful tool for influencing even a hesitant patient to be vaccinated. But for some patients, a recommendation might not be enough. They might need practical guidance about how and why vaccines are important in their day-to-day lives. That’s where the physician practice team comes in. Taking the time to ask questions that assess a patient’s personal situation may be helpful. For example:

- Are you working in close contact with children, such as in a day care setting?
- Are you around the following people on a regular basis, such as young babies, immuno-compromised people or people who absolutely should not get the flu or some other disease for whatever reason?
- Are you planning any international travel in the coming year?

Vaccine Information Statements (VIS) are another helpful resource for communicating risks and benefits of vaccination. To ensure that patients receive the most up-to-date version, a staff person should download and print them on the day of vaccine administration.

VIS can be found at:
http://www.cdc.gov/vaccines/pubs/vis/default.htm
and http://www.immunize.org/vis/ in a variety of languages.

Vaccination in time of disease outbreak illustrates how the relationship between risk and benefit can rapidly change. In some cases, recommendations offer guidance for routine circumstances, others address disease outbreak situations. The 2010 pertussis outbreak in California is a good example.

The FDA licensed Tdap for use in people ages 18 to 64. However, in 2010, California experienced 10 infant deaths (nine in infants younger than age two months) and more than 6,400 confirmed, probable, and suspected pertussis cases. In light of this, the State of California urged people older than 65 to be vaccinated with Tdap, because the risk for spread of disease to infants was so great. The ACIP soon followed with its own recommendation:

Adults age 65 years and older who have not previously received Tdap, and who have or who anticipate having close contact with a child younger than age 12 months, should receive a single dose of Tdap to reduce the likelihood of transmitting pertussis to an infant. Other adults age 65 years and older who have not previously received Tdap may be given a single dose of Tdap.
ACIP RECOMMENDATION AND FDA LICENSING: WHAT’S THE DIFFERENCE?

The Food and Drug Administration’s (FDA) Center for Biologics Evaluation and Research is responsible for regulating vaccines in the United States. The FDA licensing process involves four phases of clinical study required to ensure that the vaccine is safe and effective, to establish appropriate dosage, and to document benefits and risks of the vaccine for specific patient populations.

ACIP recommendations represent the standard of care for vaccination practice in the United States. The ACIP provides advice for the control of diseases for which a vaccine is licensed in the United States. ACIP guidance includes the appropriate use of the licensed vaccine, and in some special circumstances, may also indicate the use of unlicensed vaccines.

For each recommended vaccine, the ACIP examines:
- population groups and/or circumstances in which a vaccine or related agent is recommended;
- appropriate route, dose and frequency of administration of the vaccine, associated immune globulin, or antimicrobial agent;
- recommendations on contraindications and precautions for use of the vaccine and related agents and providing information on recognized adverse events.

There is usually very close agreement between FDA licensing and ACIP recommendations. Occasionally, ACIP may use different data to formulate its recommendations or try to add flexibility to its recommendations. This can result in wording that differs from that presented on the package insert for the vaccine. (Package inserts for vaccines must be approved by the FDA.) In addition, ACIP sometimes makes recommendations based on expert opinion and public health considerations. In general, to determine recommendations for use, one should follow ACIP’s most recent recommendations rather than the information in the package insert.

For a list of vaccines where ACIP recommendations and FDA licensing do not correspond, see Table A on the following pages.

MORE RESOURCES AVAILABLE

www.cdc.gov/vaccines/recs/vac-admin/contraindications.htm
www.cdc.gov/vaccines/recs/vac-admin/contraindications-misconceptions.htm
### TABLE A: DIFFERENCES BETWEEN ACIP RECOMMENDED VACCINES AND FDA LICENSING

<table>
<thead>
<tr>
<th>VACCINE</th>
<th>BRAND NAME</th>
<th>ACIP RECOMMENDATION</th>
<th>FDA LICENSE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Influenza</td>
<td>Afluria</td>
<td>For active immunization of persons ages 5 years and older against influenza disease caused by influenza virus subtypes A and type B present in the vaccine</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Agriflu</td>
<td>Active immunization of adults 18 years of age and older against influenza disease caused by influenza virus subtypes A and type B present in the vaccine</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Fluarix</td>
<td>For active immunization against influenza for individuals 3 years of age and to include the data from pediatric clinical studies with revision of the prescribing information for Fluarix&lt;sup&gt;®&lt;/sup&gt;</td>
<td></td>
</tr>
<tr>
<td></td>
<td>FluLaval</td>
<td>Active immunization of adults 18 years of age and older against influenza disease caused by influenza virus subtypes A and type B contained in the vaccine</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Fluvirin</td>
<td>For active immunization of persons 4 years of age and older against influenza disease caused by influenza virus subtypes A and type B contained in the vaccine</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Fluzone</td>
<td>For active immunization of persons 6 months of age and older against influenza disease caused by influenza virus subtypes A and type B contained in the vaccine</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Fluzone High Dose</td>
<td>For active immunization of persons 65 years of age and older against influenza disease caused by influenza virus subtypes A and type B contained in the vaccine</td>
<td></td>
</tr>
<tr>
<td></td>
<td>FluMist</td>
<td>For the active immunization of individuals 2-49 years of age against influenza disease caused by influenza virus subtypes A and type B contained in the vaccine</td>
<td></td>
</tr>
<tr>
<td>VACCINE</td>
<td>BRAND NAME</td>
<td>ACIP RECOMMENDATION</td>
<td>FDA LICENSE</td>
</tr>
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<td>-------------------------------------</td>
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<td>-----------------------------------------------------------------------------</td>
</tr>
</tbody>
</table>
| Pneumococcal Polysaccharide Vaccine (PPSV 23) | Pneumovax 23    | For vaccination of the following:  
  • All adults 65 years of age and older.  
  • Anyone 2 through 64 years of age with specific chronic conditions or in special environments or settings | For the routine vaccination for persons 50 years of age or older and persons ages ≥ 2 years with certain chronic conditions or in special environments or social settings |
| Tdap                               | Adacel/Boostrix | For vaccination of adults ages 11 through 64 and adults age 65 years and older who have or who anticipate having close contact with an infant less than 12 months of age and who previously have not received Tdap | For booster immunization against tetanus, diphtheria and pertussis as a single dose in individuals 11 through 64 years of age |
| HPV                                 | Gardasil         | For the routine vaccination of females ages 11 or 12 years with 3 doses of either HPV2 or HPV4. The vaccination series can be started beginning at age 9 years.  
  For the vaccination of females ages 13 through 26 years who have not been vaccinated previously or who have not completed the 3-dose series. If a female reaches age 26 years before the vaccination series is complete, remaining doses can be administered after age 26 years.  
  HPV4 may be given to males ages 9 through 26 years to reduce their likelihood of acquiring genital warts; ACIP does not recommend HPV4 for routine use among males.  
  ACIP recommends vaccination with HPV2 or HPV4 for prevention of cervical cancers and precancers. | For vaccination in females 9 to 26 years of age for prevention of the diseases caused by HPV types 6, 11, 16, and 18  
For vaccination in boys and men 9 through 26 years of age for the prevention of genital warts caused by HPV types 6 and 11  
For vaccination in people ages 9 through 26 years for the prevention of anal cancer and associated precancerous lesions due to HPV types 6, 11, 16, and 18  
For prevention of cervical, vulvar, and vaginal cancer |
<table>
<thead>
<tr>
<th>VACCINE</th>
<th>BRAND NAME</th>
<th>ACIP RECOMMENDATION</th>
<th>FDA LICENSE</th>
</tr>
</thead>
<tbody>
<tr>
<td>HPV</td>
<td>Cevarix</td>
<td>For the routine vaccination of females aged 11 or 12 years with 3 doses of either HPV2 or HPV4. The vaccination series can be started beginning at age 9 years. For the vaccination of females aged 13 through 26 years who have not been vaccinated previously or who have not completed the 3-dose series. If a female reaches age 26 years before the vaccination series is complete, remaining doses can be administered after age 26 years. HPV4 may be given to males aged 9 through 26 years to reduce their likelihood of acquiring genital warts; ACIP does not recommend HPV4 for routine use among males. ACIP recommends vaccination with HPV2 or HPV4 for prevention of cervical cancers and precancers.</td>
<td>For vaccination of females 10 through 25 years of age for the prevention of cervical cancer, cervical intraepithelial neoplasia (CIN) grade 2 or worse and adenocarcinoma in situ, and cervical intraepithelial neoplasia (CIN) grade 1, caused by oncogenic human papillomavirus (HPV) types 16 and 18</td>
</tr>
<tr>
<td>Herpes Zoster</td>
<td>Zostavax</td>
<td>Vaccination of all persons aged &gt;60 years who have no contraindications, including persons who report a previous episode of zoster or who have chronic medical conditions.</td>
<td>For vaccination of individuals 50 years of age and older for prevention of herpes zoster (shingles)</td>
</tr>
<tr>
<td>Meningococcal</td>
<td>Menomune</td>
<td>For the vaccination of adolescents at age 11 or 12 years, or at ages 13 through 18 years if not previously vaccinated, and also to administer the vaccine to previously unvaccinated college freshmen living in a dormitory. A booster dose should be routinely administered to adolescents 5 years after the first dose is given at ages 11 through 13 years.</td>
<td>Active immunization against invasive meningococcal disease caused by Neisseria meningitidis serogroups A, C, Y, and W-135 in persons 2 years of age and older</td>
</tr>
<tr>
<td>Meningococcal</td>
<td>Menactra</td>
<td></td>
<td>For active immunization against invasive meningococcal disease caused by Neisseria meningitidis serogroups A, C, Y and W-135</td>
</tr>
<tr>
<td>Meningococcal</td>
<td>Menveo</td>
<td></td>
<td>For active immunization to prevent invasive meningococcal disease caused by Neisseria meningitidis serogroups A, C, Y and W-135 when administered to individuals 11 through 55 years of age</td>
</tr>
</tbody>
</table>
SECTION 3: Vaccines and Their Indications
WEIGHING VACCINE BENEFIT VS. RISK
Influenza

*Five main types of influenza vaccine are available: trivalent inactivated vaccine (TIV), thimerisol-free TIV, high-dose inactivated, intradermal, and live attenuated vaccine (LAIV).*

**GENERIC NAMES:**
trivalent inactivated vaccine, thimerisol-free TIV, high-dose inactivated influenza vaccine, intradermal influenza vaccine

**BRAND NAMES:**
Afluria, Agriflu, Fluarix, FluLaval, Fluvirin, Fluzone, Fluzone High Dose, Fluzone Intradermal

**DRUG COMPANIES:**
CSL Limited, Novartis Vaccines and Diagnostics, GlaxoSmithKline Biologicals, ID Biomedical Corporation of Quebec, Novartis Vaccines and Diagnostics Limited, Sanofi Pasteur, Inc.

**TRIVALENT AND HIGH-DOSE INACTIVATED VACCINES**

**INDICATIONS**
The ACIP recommends that all adults receive the influenza vaccine on an annual basis. There are many options of standard dose inactivated influenza vaccine for healthy adults, as well as those with underlying medical conditions, including thimerisol-free TIV and a new intradermal option for adults age 18 to 64. (See p. 42.)

Inactivated influenza vaccine, either through injection or intradermally, is the recommended choice for patients with immune system problems including HIV. Pregnant women should only receive inactivated vaccine. Although influenza vaccine containing thimerisol preservative is safe for pregnant women, thimerosal-free single dose prefilled syringes and vials are available from some manufacturers.

Inactivated influenza vaccines are made from vaccine virus that has been “inactivated” or “killed.” As part of this inactivation process, only subviron and purified surface antigen are used. That is why TIV is sometimes referred to as “split” (for subviron) or subunit (for purified surface antigen) vaccines. Standard dose TIV for adults means the vaccine contains 15 mcg hemagglutinin (HA) antigen per vaccine strain, or a total of 45 mcg HA antigen.

A high-dose formulation of inactivated vaccine option for seniors age 65 and older was introduced during the 2010-2011 influenza vaccine season. Designed to improve immune response, it contains four times more hemagglutinin per dose (60 mcg per vaccine strain or a total of 180 mcg total HA antigen) as compared to the standard flu vaccine. Side effects include increases in injection site reactions. The cost is almost double the price of the standard inactivated influenza vaccine.

**CONTRAINDICATIONS**

- History of life-threatening reaction to previous flu vaccination.
- History of anaphylactic hypersensitivity to eggs or egg proteins. Current methodology for making vaccines involves
growing vaccine virus in embryonated chicken eggs. This leads to concerns that residual ovalbumin could trigger an allergic reaction.

The American Academy of Allergy and Immunology recommends administering TIV to “egg allergic” individuals in either a two-step graded challenge process along with an observation period of at least 30 minutes, or as a single dose along with a 30 minute observation period, both without prior skin testing. For patients with history of “egg anaphylaxis,” there is no clear consensus. A multi-center trial looking at this issue is underway. Look for more guidance about this topic from ACIP in the future.

- Anaphylactic hypersensitivity to other vaccine components. During the manufacturing process, additional substances are used to inactivate the influenza virus and to prevent bacterial growth. Trace amount of substances like kanamycin, neomycin, gentamicin, gelatin, and arginine are sometimes added. Because specific vaccine components can differ from brand to brand, be sure to check product labels carefully. For example, Fluarix is formulated without preservatives and does not contain thimerosal but does contain octoxynol-10, a-tocopheryl hydrogen succinate, polysorbate, residual amounts of hydrocortisone, gentamicin sulfate, ovalbumin, formaldehyde, and sodium deoxycholate. Agriflu contains trace amounts of kanamycin and neomycin.

- Latex allergy. The tip caps of the prefilled syringes for Agriflu, Fluarix, and Fluvirin may contain natural rubber latex. However, the package insert says the syringe plunger does not contain natural latex. For patients with latex allergy, be sure to check package inserts carefully and choose a product that is latex free.

- History of Guillain-Barre Syndrome (GBS). However, for individuals at high risk for severe influenza complications with past history of GBS within six weeks of receiving the influenza vaccine, weigh benefits and risks of vaccinating. Consider using antiviral chemoprophylaxis for these individuals.

- Moderate or severe acute illness with or without fever. Wait to vaccinate until symptoms improve.

**ADMINISTRATION**

Administer single dose of 0.5 ml intramuscularly in the deltoid muscle. Do not mix with any other vaccine in the same syringe or vial. Shake the syringe or multi-dose vial thoroughly. Administer the dose immediately. Once the stopper has been pierced, the multi-dose vial must be discarded within 28 days.

Needle length should be adjusted for body habitus. The needle used should be long enough to reach the muscle mass to avoid seepage of vaccine product into subcutaneous tissue, yet not so long that it involves nerves, blood vessels, or bone. Aspirating before injecting is not necessary. In general, for adults weighing less than 130 pounds, a 1/2-inch needle is sufficient to ensure intramuscular injection in the deltoid muscle. Intramuscular deltoid injections for men and women weighing 130 to 152 pounds will require a 1-inch needle. Women weighing 153 to 200 pounds and men weighing 153 to 260 pounds generally need a 1-inch or 1 1/2-inch needle. Women weighing over 200 pounds and men weighing more than 260 pounds will need a 1 1/2-inch needle.

**POSSIBLE SIDE EFFECTS**

Most common local side effects include pain, redness, and swelling at the injection site. Most common systemic side effects are headache, fatigue, myalgias, low grade fever, and malaise.

**STORAGE/HANDLING**

Keep refrigerated at 35°F to 46°F (2°C-8°C). Do not freeze.
PREGNANCY/NURSING
All pregnant women should be vaccinated against influenza. Pregnant women who contract influenza have complication rates comparable to those of seniors.

Pregnant women should be vaccinated each year with inactivated vaccine—not LAIV, which is a live virus vaccine.

TIV influenza is Category B and Category C. FDA has classified several brands of TIV as Category B because animal studies conducted with those products have not shown any fetal risk. However, some TIV products are categorized as Category C because animal studies have not been conducted on these products.

All inactivated influenza vaccines are safe for pregnant women in any trimester including influenza vaccines containing thimerisol.

A recent study found that a mother’s influenza vaccination decreased the odds of a baby acquiring influenza during the first six months of life (when he or she is too young to receive an influenza vaccine) by 63%.

It also reduced the risk of fever and respiratory infection in both baby and mom by one-third. According to the ACIP, breast-feeding is not a contraindication.

FLUZONE INTRADERMAL APPROVED BY FDA

**GENERIC NAME:**
inactivated trivalent influenza vaccine

**BRAND NAME:**
Fluzone Intradermal

**DRUG COMPANY:**
Sanofi Pasteur

**INDICATIONS**
Fluzone Intradermal is indicated for adults between the ages of 18 and 64.

**CONTRAINDICATIONS**
See Contraindications for TIV and High-Dose Inactivated.

**ADMINISTRATION**
This intradermal vaccine uses a micro injector with an ultrafine needle that is 0.06 inches in length.

**POSSIBLE SIDE EFFECTS**
Injection site reactions, including redness, swelling, induration, pain and itching were more common with the intradermal as compared to the intramuscular injection but usually resolve within three to seven days.

**STORAGE/HANDLING**
The product should be stored at 2-8°C (36-46°F). Do not freeze.

**PREGNANCY/NURSING**
Fluzone Intradermal is Category B.

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INDICATIONS

LAIV is an option for healthy non-pregnant adults under age 50.

The vaccine virus used in LAIV is attenuated or weakened but it is still a live virus vaccine. LAIV virus strains replicate locally in nasopharyngeal cells after intranasal administration, stimulating production of serum and nasal and secretory antibodies. ACIP says that people with anatomic or functional asplenia and household and other close contacts of persons with altered immunocompetence, who are otherwise healthy, may receive LAIV. LAIV does not contain thimerosal.

CONTRAINDICATIONS

• Persons with immune system problems and family members and household contacts of people so immunosuppressed that they must live in a protected environment (e.g., stem cell transplant recipients).
• History of life-threatening reaction to previous flu vaccination.
• History of anaphylactic hypersensitivity to eggs or egg proteins. Current methodology for making vaccines involves growing vaccine virus in embryonated chicken eggs. This leads to concerns that residual ovalbumin could trigger an allergic reaction.
• Moderate or severe acute illness with or without fever. Wait to vaccinate until symptoms improve.
• Hypersensitivity to gentamicin, gelatin, or arginine.
• Concomitant aspirin therapy in children and adolescents. (This is due to concern about Reye’s Syndrome since this is a live virus vaccine.)
• Concomitant antiviral therapy. Do not administer LAIV until 48 hours after stopping antiviral medications. Antiviral medications should not be given until two weeks have passed after LAIV (unless medically necessary). Administering antivirals before this two-week window may decrease vaccine effectiveness and repeat vaccination should be considered.

ADMINISTRATION

LAIV is packaged in a nasal sprayer with a dose divider clip. Each sprayer contains a prefilled single dose of 0.2 ml of LAIV vaccine. Position the tip of the nasal sprayer slightly into the nostril and then spray a dose of 0.1 ml into each nostril.

Vaccine dose does NOT need to be repeated if the patient coughs or sneezes after administration.

Persons who are severely immunosuppressed should not administer LAIV. Although they
should not receive the vaccine themselves, it is safe for pregnant women, asthmatics, people age 50 and older, and people with other underlying medical conditions to administer LAIV to others.

There is no problem administering inactivated or live vaccines at the same time as LAIV.

However, if not given at the same time, after administration of a live vaccine, at least four weeks should pass before another live vaccine is administered.

**POSSIBLE SIDE EFFECTS**
Runny nose, nasal congestion, headache, fever, and sore throat as a result of local vaccine virus replication in the nasal mucosa.

**STORAGE/HANDLING**
Keep refrigerated at 35°F to 46°F (2°C–8°C). Do not freeze.

**PREGNANCY/NURSING**
LAIV is Category C. LAIV is a live attenuated virus vaccine and should NOT be given to pregnant women. However ACIP says it is not necessary for pregnant or postpartum women to avoid contact with someone who has been recently vaccinated with LAIV. ACIP says breast feeding is not a contraindication since most live vaccines are not secreted in breast milk. Vaccine labels contain language that can be confusing, stating that it is not known if the product is excreted in breast milk, to exercise caution. This is only because confirmatory studies have not been conducted.

**CPT CODES/REIMBURSEMENT ISSUES**

### ALL INFLUENZA VACCINES

Multiple vaccine manufacturers have led to greater availability of vaccine, but unfortunately this has lead to more complicated coding for reimbursement.

For Medicare (as of 1/2/11), codes now vary according to brand of vaccine administered to a particular patient. For patients with commercial insurance, look for guidance on which type of influenza vaccine codes to use.

Medicare has assigned five separate influenza vaccine Healthcare Common Procedure Coding System (HCPCS) Q Codes to distinguish between the brand names of inactivated influenza vaccines. The following table shows the most recent brand name and manufacturer codes:

- **Afluria:** Q2035
- **Agriflu and Fluarix:** Q2039 NOS (not otherwise specified)
- **Flulaval:** Q2036
- **Fluvirin:** Q2037
- **Fluzone:** Q2038
- **Fluzone High-Dose:** 90662
- **Fluzone Intradermal:** 90654
- **LAIV:** 90660

**Administration code:** G0008 Administration of influenza vaccine for Medicare patients

**Diagnosis (ICD-9) code:** V04.81 Prophylactic vaccination and inoculation against influenza

**CPT Codes by Vaccine Type:** 90656 Influenza virus vaccine, split virus, no preservative, for use in individuals 3 years of age and older, for intramuscular use

Influenza virus vaccine, split virus, for use in individuals 3 years of age and older, for intramuscular use
FAQs

**Q: How dangerous is LAIV if it inadvertently gets sprayed into the air?**
ACIP says the risk of getting vaccine viruses from the environment is unknown; however, it is unlikely to cause problems. LAIV vaccine viruses are attenuated and they are cold adapted. There have not been any reported cases of attenuated vaccine virus infections among patients or providers exposed to attenuated virus inadvertently.

**Q: Is it OK to get LAIV if someone in the household is pregnant?**
ACIP says having a pregnant household member is not a contraindication to LAIV vaccination. It is also OK for mothers who are nursing to receive LAIV. Pregnant women should receive inactivated vaccine TIV.

**Q: Can influenza vaccine be given with other vaccines?**
Yes. ACIP says TIV can be given with other inactivated or live vaccines. However, there are a few restrictions: administer at different site and use a different syringe. However, if not given at the same time, let four weeks pass after administration of a live vaccine before administering another live vaccine.

**Q: Can influenza vaccine be given to persons who are receiving antiviral medications?**
It is fine to give TIV to someone receiving antiviral medications, but not LAIV. Antiviral medications interfere with viral replication and that is how LAIV works: it replicates in the nasal mucosa.

Do not administer LAIV until 48 hours after stopping antiviral medications. Antiviral medications should not be given until after two weeks after LAIV (unless medically necessary). Administering antivirals before this two-week window may decrease vaccine effectiveness and repeat vaccination should be considered.

**Q: Can influenza vaccine be given to patients with cellular immunodeficiency?**
Yes. TIV inactivated influenza vaccine can and should be given to patients with cellular immunodeficiency. However, patients with immune system problems may not have as a robust immunologic response after vaccination.

**Q: Is it safe for a household member of an immunocompromised person to receive LAIV?**
It is important to ascertain the type of immunosuppression before deciding to vaccinate. In some cases it may be preferable for the household member to receive TIV instead.
**Pneumococcal Polysaccharide (PPSV23)**

**GENERIC NAME:**
23-valent Pneumococcal Polysaccharide Vaccine

**BRAND NAME:**
Pneumovax 23

**DRUG COMPANY:**
Merck & Co, Inc.

**INDICATIONS**
The vaccine is indicated for vaccination of persons 2 years of age and older with certain underlying medical conditions and for persons 65 years and older for the prevention of invasive pneumococcal disease due to the strains included in the vaccine.

Among adults, the ACIP recommends vaccination with PPSV23 for:

- All persons aged 65 years and over.
- Persons aged 19 through 64 years with chronic or immunosuppressing medical conditions, including asthma.
- Persons aged 19 through 64 years who currently smoke cigarettes.

Chronic medical conditions for which vaccination is recommended include chronic heart disease, chronic lung disease, diabetes mellitus, chronic liver disease, alcoholism, cerebrospinal fluid leaks, and cochlear implants.

Immunosuppressing conditions for which vaccination is recommended include Hodgkin disease, lymphoma or leukemia, chronic kidney disease, nephrotic syndrome, multiple myeloma, HIV infection or AIDS, splenic dysfunction or splenectomy, generalized malignancy, organ transplant or anyone taking a drug or treatment that lowers the body’s resistance to infection such as long-term corticosteroids, certain cancer drugs, and radiation therapy.

**CONTRAINDICATIONS**
- History of severe allergic reaction to vaccine components, including phenol (preservative).
- History of allergic reaction to previous dose of PPSV23 vaccine.

**ADMINISTRATION**
A single dose of 0.5 mL should be administered intramuscularly in the deltoid of the upper arm or subcutaneously to the skin overlying the triceps muscle. PPSV23 may be given at the same time as other vaccines but do not mix in same syringe with other vaccines.

**POSSIBLE SIDE EFFECTS**
The most common adverse effects following PPSV23 are injection site reactions (tenderness, redness, limitation of motion), which are typically mild and resolve within a few days of vaccination. Local reactions are more frequent following a second vaccination, but are typically not severe and are self-limited.
STORAGE/HANDLING
PPSV23 is a clear, colorless solution. The vaccine is used directly as supplied. No dilution or reconstitution is necessary.

Keep refrigerated at 2°C to 8°C (35°F to 46°F). Do not freeze. Unused portions of multidose vials must be refrigerated at 2°C to 8°C (35°F to 46°F) and may be used until expired, if not contaminated.

PREGNANCY/NURSING
PPSV23 is Category C. Although there is no evidence that PPSV23 is harmful to a pregnant woman or her fetus, it is not recommended during pregnancy unless there is an indication for its use. Women who have underlying conditions known to put them at risk for invasive pneumococcal disease should be vaccinated before becoming pregnant, if possible.

REIMMUNIZATION
Those who receive PPSV23 before age 65 years for any indication should receive one booster dose of the vaccine at age 65 years or later if at least five years have passed since their previous dose. Repeated booster doses following this single booster are not recommended.

Those who receive PPSV23 at or after age 65 years should receive only a single dose.

A second dose of PPSV23 is recommended five years after the first dose for persons aged 19 through 64 years with functional or anatomic asplenia and for persons with immunocompromising conditions. Repeated booster doses following this single booster are not recommended.

CPT CODES/
REIMBURSEMENT ISSUES

PPSV23 vaccine CPT codes:
90669, 90670, 90732.

Administration code: 90472
Immunization administration (includes percutaneous, intradermal, subcutaneous, or intramuscular injections); one vaccine (single or combination vaccine/toxoid)

Add-on CPT code: 90472
Each additional vaccine (single or combination vaccine/toxoid). List separately in addition to the code for primary procedure

ICD-9 code: V05.9
Needed for other prophylactic vaccination and inoculation against single disease, unspecified single disease
FAQs

Q: Is hypertension an indication for PPSV23?
No. Persons with hypertension in the absence of chronic heart disease or other chronic disease indication should not receive PPSV23.

Q: Can PPSV23 be given at the same time as influenza vaccine?
Yes. PPSV23 can be given on the same visit as influenza vaccine by separate injection and preferably in the other arm.

Q: Is a third dose of PPSV23 ever indicated?
No. At this time, ACIP does not recommend multiple revaccinations because of uncertainty regarding clinical benefit and the potential for adverse reactions.

Q: Should Alaska natives or American Indians without underlying disease indications receive PPSV23?
No. ACIP no longer recommends routine vaccination of these groups. However, in certain situations, public health authorities may recommend PPSV23 for Alaska Natives and American Indians ages 50 through 64 years who are living in areas where the risk for invasive pneumococcal disease is increased.

Q: I hear that a pneumococcal conjugate vaccine may soon be available for adults—what is the benefit of pneumococcal conjugate over pneumococcal polysaccharide?
Pneumococcal conjugate vaccine offers benefits that the current pneumococcal polysaccharide formulation cannot offer. A pneumococcal conjugate vaccine could protect patients over their lifetime, with its enhanced ability to induce functional antibody responses, especially in the elderly. The pneumococcal conjugate vaccine invokes T-dependent immune mechanisms, with the potential for more robust immunogenicity, including better functional antibody and lessened risk of hyporesponsiveness with subsequent dosing. The significantly reduced saccharide dose compared to the polysaccharide vaccine may result in more acceptable reactogenicity upon revaccination.

An adult pneumococcal conjugate vaccine could be administered early in the risk period and administered more than once to extend the age range of protection against pneumococcal disease, by being readministered at intervals, if needed.
Tetanus Toxoid/Td/Tdap

**Tetanus Toxoid**

**GENERIC NAMES:**
tetanus toxoid, tetanus toxoid adsorbed

**BRAND NAME:**
none

**DRUG COMPANY:**
Sanofi-Pasteur

**Td**

**GENERIC NAMES:**
tetanus, diphtheria toxoids, absorbed

**BRAND NAME:**
none

**DRUG COMPANIES:**
Massachusetts Public Health Biologics, Aventis-Pasteur

**Tdap**

**GENERIC NAMES:**
tetanus toxoid, diphtheria toxoid, acellular pertussis vaccine

**BRAND NAMES:**
Adacel, Boostrix

**DRUG COMPANIES:**
Sanofi-Pasteur, GlaxoSmithKline Biologicals

**INDICATIONS**

All persons who are not allergic to the vaccine or a vaccine component should receive a primary vaccine series, ideally during childhood, of tetanus/diphtheria/pertussis vaccine. Following completion of a primary series, a booster dose of tetanus-containing vaccine should be given every 10 years to maintain immunity against tetanus.

Adults less than 65 years of age should have at least one dose of tetanus vaccine replaced with a dose of Tdap vaccine, which provides additional protection against pertussis (whooping cough). Td booster administration every 10 years should be continued.

Pregnant women after 20 weeks gestation should receive Tdap if not previously vaccinated. Unvaccinated new mothers should receive Tdap booster before leaving the hospital after delivering the baby. Grandparents of any age (see below) should also receive a Tdap booster.

ACIP recommends that adults age 65 years and older (e.g., grandparents, child care providers, and health care practitioners) who have or who anticipate having close contact with an infant less than 12 months of age and who previously have not received Tdap should receive a single dose of Tdap to protect against pertussis and reduce the likelihood of transmission. For other adults age 65 years and older, a single dose of Tdap vaccine may be given instead of Td vaccine in persons who have not previously received Tdap.

Persons who work in health care, child care, and who will have contact with infants and immunocompromised patients should be vaccinated as soon as feasible with Tdap vaccine.

Td or Tdap may also be given as tetanus wound prophylaxis. ACIP recommends that pertussis vaccination, when indicated, should not be delayed and that Tdap should be administered regardless of interval since the last tetanus or diphtheria toxoid-containing vaccine. ACIP concluded that while longer intervals between Td and Tdap vaccination could decrease the occurrence of local reactions, the benefits of protection against pertussis outweigh the potential risk for adverse events. Either vaccine can be given as tetanus wound prophylaxis in patients without known adequate immunity.

**CONTRAINDICATIONS**

**Absolute**

- A severe allergy to any component of tetanus, diphtheria, and/or pertussis vaccines.
- A life-threatening allergic reaction following a dose...
of tetanus-containing vaccine (DTP, DTaP, DT, Tdap, or Td). These patients should not receive another dose of tetanus-containing vaccine (Td or Tdap).

- Anyone who had a coma, prolonged seizure, or multiple seizures within seven days following a dose of DTP or DTaP vaccine should not be given Tdap unless a cause other than the vaccine was found.

**Relative**

- Persons with epilepsy or another nervous system problem. Defer the vaccine if these conditions are ill-defined or not yet stabilized. Carefully weigh the risk/benefit of repeated vaccination with these vaccines in the affected patient.

- Persons with severe swelling or severe pain after a previous dose of DTP, DTaP, DT, Td, or Tdap vaccine, since this type of reaction may recur with further doses. Carefully weigh the risk/benefit of repeated vaccination with these vaccines in the affected patient.

- Persons who have/have had GBS less than six weeks following a previous dose of tetanus-containing vaccine.

These patients may be at risk of recurrence or worsening with repeated doses of tetanus-containing vaccine. Carefully weigh the risk/benefit of repeated vaccination with these vaccines in the affected patient.

- A moderate or severe acute illness on the day the immunization is planned. These patients should usually wait until they recover before getting Tdap or Td vaccine. A person with a mild illness or low-grade fever can usually be vaccinated.

**ADMINISTRATION**

Td and Tdap vaccines are adjuvant vaccines; a 0.5 ml dose should be administered intramuscularly in the deltoid muscle of the arm. The anterolateral thigh is an alternate site. For men and women weighing less than 60 kg (130 lb), a 5/8- to 1-inch needle is sufficient to ensure intramuscular injection. For men and women weighing less than 60 kg (130-200 lb) and men 60-118 kg (130-260 lb), a 1 1/2-inch needle is required. For women weighing more than more than 90 kg (200 lb) or men weighing more than 118 kg (260 lb), a 1 1/2-inch needle is required.

Tdap and Td vaccines may be administered simultaneously with other adult vaccines. When two or more vaccines are to be administered, they can be given on the same day at different anatomic sites.

**Primary series:** Three doses of tetanus-containing vaccine over a six-month time period—a first dose followed by a booster dose at one month and a third dose at least six months after the first dose. If the primary series is administered in a previously unimmunized adult, Tdap may replace Td for any of the doses in the series.

**POSSIBLE SIDE EFFECTS**

Pain at the injection site is the most common local reaction, reported in about 65% patients within 14 days of the injection in vaccination trials.

Large injection site reactions may occur, but are uncommon. The most frequently reported systemic adverse events during the 15 days following vaccination were headache, generalized body aches, and fatigue (25-33% of patients in vaccine trials). Fever is less common, but also has been reported.

1. [Adacel FDA monograph](http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM142764.pdf)
2. [Boostrix Package insert](http://www.fda.gov/downloads/BiologicsBloodVaccines/UCM152842.pdf)
STORAGE/HANDLING
Td and Tdap vaccine should be refrigerated and stored at 2°C to 8°C (35°F to 46°F). Do not freeze. The vaccines should not be used beyond their marked expiration date.

PREGNANCY/NURSING
Tdap vaccine is Category C. Td vaccine may be administered during pregnancy if necessary. Tdap can be administered to pregnant women after 20 weeks gestation. In women who have not previously received a Tdap vaccine, Tdap vaccination in the immediate postpartum period is recommended to help reduce the potential for pertussis in the infant.

A registry of women who have inadvertently been given Tdap in pregnancy is being maintained. Pregnancy vaccine registries: Adacel: 800-822-2463; Boostrix: 888-825-5249.

REIMMUNIZATION/BOOSTER
Tetanus (Td or Tdap) booster vaccine should be administered every 10 years in adults.
After receipt of Tdap, persons should continue to receive Td for routine booster immunization against tetanus and diphtheria, according to previously published guidelines.

CPT CODES/REIMBURSEMENT ISSUES

**CPT code: 90703**
Tetanus toxoid adsorbed, for intramuscular

**CPT code: 90715**
Tetanus, diphtheria toxoids and acellular pertussis vaccine (Tdap), for use in individuals seven years or older, for intramuscular

**CPT code: 90718**
Tetanus and diphtheria toxoids (Td) adsorbed for use in individuals seven years or older, for intramuscular

Note: Administration of Td post injury requires an ICD-9 code that identifies the injury.

FAQs

**Q: Can a child or an adult who has had pertussis get the disease again? Should you vaccinate someone with a history of pertussis infection?**
Reinfection appears to be uncommon, but does occur. Reinfection may present clinically as a persistent cough rather than as typical pertussis.

Adolescents or adults who have a history of pertussis disease generally should receive Tdap according to the routine recommendation. Vaccination, regardless of history of prior pertussis infection, is recommended because the duration of protection induced by pertussis disease is unknown (waning might begin as early as seven years after infection) and because the diagnosis of pertussis can be difficult to confirm. Administering pertussis vaccine to persons with a history of pertussis presents no theoretical risk.

**Q: If an adolescent or adult who has never received their one-time dose of Tdap is either infected with or exposed to pertussis, is vaccination with Tdap still necessary? If so, when?**
Yes. If the illness was recent (less than five years) and the diagnosis was certain (i.e., confirmed by laboratory testing), it is reasonable to wait three to five years before administration of Tdap, unless tetanus and diphtheria toxoids are needed.
Q: When a patient seen in the ER needs tetanus protection, which vaccine should be given, Td or Tdap?

Adolescents and adults ages 10 to 64 years who require a tetanus toxoid-containing vaccine as part of wound management should receive a single dose of Tdap instead of Td if they have not previously received Tdap. If Tdap is not available or was previously administered, then Td should be used. If an adult 65 years old or older is in contact with an infant, he or she should receive Tdap if they have not already. Adults generally over the age of 65 may receive Tdap if they have not received it, at the discretion of the provider.

Q: At what age might most patients never have received a primary series?

Although young adults born in the United States who received standard pediatric health care should have been vaccinated appropriately, one should not assume the tetanus vaccination status for any person based on age alone. Only a written record is acceptable proof of immunization. Persons without documentation of immunization should be assumed to be unimmunized.

Q: If a dose of DTaP or Tdap is inadvertently given to a patient for whom the product is not indicated (e.g., wrong age group), how do we rectify the situation?

The first step is to inform the patient that you administered the wrong vaccine. Next, DTaP given to patients age seven or older can be counted as valid for the one-time Tdap dose.

Q: I have a patient who received single-antigen tetanus (TT) in the ER rather than Td or Tdap. Should he be revaccinated?

ACIP recommends that patients always be given Td or, if appropriate, Tdap rather than TT, as long as there is no contraindication to the other vaccine components. However, since it’s already been given, you can wait until the next scheduled booster dose is due and administer Td (or Tdap) at that time. There are exceptions (e.g., the patient plans to travel internationally, has potential contact with an infant younger than age 12 months) in which case you should administer Td (or Tdap) in order to reduce the potential for diphtheria and pertussis transmission.

Q: When should a person receive tetanus toxoid alone?

Single antigen tetanus toxoid should only be used in the rare instance of a person with a documented prior severe allergic response to diphtheria toxoid.

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Herpes Zoster

**GENERIC NAME:**
herpes zoster virus vaccine

**BRAND NAME:**
Zostavax

**DRUG COMPANY:**
Merck & Co., Inc.

**INDICATIONS**
The vaccine is FDA indicated for people age 50 and older to prevent zoster (shingles).
The Shingles Prevention Study showed that the vaccine reduced the overall risk of acquiring shingles by 51% and reduced the incidence of post herpetic neuralgia (PHN) by 66% in patients 60 and older.

In March 2011, the FDA extended indication to include people ages 50 to 59. In this age group, the vaccine reduced the risk of developing shingles by approximately 70%.

The vaccine is not indicated as treatment for zoster (shingles) or as a treatment for PHN.

The vaccine is not indicated for primary prevention of primary varicella infection (chickenpox).

**CONTRAINDICATIONS**
- History of anaphylactic/anaphylactoid reaction to vaccine components including gelatin and neomycin. However, history of contact dermatitis due to neomycin is not considered to be a contraindication.
- History of immune system diseases including leukemia, lymphomas, and other malignant bone marrow or lymphatic system cancers and individuals with AIDS.
- Patients on immunosuppressive therapy.
- Patients with active untreated tuberculosis.

**ADMINISTRATION**
Herpes zoster vaccine when reconstituted is a semi-hazy to translucent, off-white to pale yellow liquid.

Administer a single dose of 0.65 mL subcutaneously in the deltoid region of the upper arm. Do not inject intravascularly or intramuscularly.

The vaccination can be given to patients with mild acute illnesses with or without fever. However, for patients with severe acute illness, it is best to postpone vaccination until they are feeling better.

The package insert recommends that administration of herpes zoster vaccine and pneumococcal vaccine should be separated by a 4-week period.

**POSSIBLE SIDE EFFECTS**
The most frequent vaccine-related adverse events include headache and injection site reactions (redness, pain, tenderness, swelling, and bruising).

There is potential risk of transmitting the vaccine virus to varicella-susceptible individuals, including pregnant women who have not had chickenpox.
The risk for transmitting the attenuated vaccine virus to susceptible persons should be weighed against the risk for developing active varicella zoster virus infection that could be transmitted to a susceptible person.

Living with a pregnant household member is not a contraindication to zoster vaccination.

**STORAGE/HANDLING**

The vaccine must be stored frozen between -58°F and +5°F (-50°C and -15°C) in a freezer with a separate sealed freezer door. Note that the use of dry ice may subject the vaccine to temperatures colder than -58°F (-50°C).

In February 2010, the manufacturer released new handling and storage guidelines allowing storage and or transportation at refrigerator temperature (2° to 8°C, 35°-46°F) for up to 72 hours prior to constitution. Vaccine stored at refrigerator temperature that is not used within 72 hours should be discarded.

Diluent should be stored separately at room temperature (20° to 25°C, 68° to 77°F), or in the refrigerator (2° to 8°C, 35° to 46°F).

Time is of the essence after removing the vaccine from freezer. Reconstitute it immediately upon removal from freezer. The vaccine must be administered within 30 minutes after reconstitution. Discard reconstituted vaccine if not used within 30 minutes. Do not freeze reconstituted vaccine.

Take particular patient safety measures to make sure you don’t store zoster vaccine with other vaccines that have to be kept in freezer like varicella (chickenpox) vaccine. Both zoster and varicella vaccines must be kept frozen. Make sure that you have them clearly marked and delineated in your freezer to avert administration errors.

**PREGNANCY/NURSING**

Herpes zoster vaccine is Category C. The vaccine should not be given to women who are pregnant or to women of childbearing age.

Although naturally occurring varicella zoster virus (VZV) infection is known to sometimes cause fetal harm, the risk is small. The virus strain used in the vaccine is live but attenuated; its effect on the fetus is expected to be even less than naturally occurring infection.

Still, vaccine strain virus effects have not been studied so the effect of the vaccine strain on the fetus is unknown. ACIP also states that women should avoid becoming pregnant for four weeks following zoster vaccination. Report any exposure to zoster vaccine during pregnancy to the pregnancy registry at 800-986-8999.

Living with a pregnant household member is not a contraindication to zoster vaccination, according to ACIP.

The vaccine should not be given to women who are nursing. On the other hand, ACIP says that since most live vaccines, including varicella vaccine, are not secreted in breast milk, breast-feeding is not a contraindication for zoster vaccination.
REIMMUNIZATION/BOOSTER
Currently, no additional booster shot is recommended.

CPT CODES/REIMBURSEMENT ISSUES
Herpes zoster Vaccine CPT code: 90736
Administration code: 90471
Immunization administration

The vaccine and administration fee is covered under Medicare Part D. Coverage can vary depending on the Medicare Part D carrier. For reimbursement questions, contact the Merck Vaccine Reimbursement Support Center at 1-800-734-6282.

Patients with private insurance should refer to their insurance policy benefits.

The website eDispense can help reduce your reimbursement time by 45 days and show how much the specific Part D plan will pay per patient: https://enroll.edispense.com/ ws_enroll/login.jsp?profile=VM.

ICD-9 code: V05.9
Needed for other prophylactic vaccination and inoculation against single disease, unspecified single disease

FAQs
Q: Does one need to make sure the patient has had chickenpox before administering the vaccine?
It is not necessary to ask patients about their history of varicella (chickenpox) or to conduct serologic testing for varicella immunity.

Q: Is it OK to get the zoster vaccine if someone in the household is pregnant?
ACIP guidelines state that living with a pregnant household member is not a contraindication to receiving zoster vaccination.

Q: Can zoster vaccine be administered in patients taking intranasal steroids?
Patients taking 20 mg a day of prednisone (or the equivalent) for more than two weeks should not receive the zoster vaccination until after steroid therapy has been discontinued for at least one month. Short-term use of low- to moderate-dose steroid therapy (less than 20 mg a day for less than 14 days) is not considered to be immunosuppressive.

Q: Can patients on low-dose immunosuppressive therapy for treating rheumatological and certain chronic inflammatory diseases receive the zoster vaccination?
Low doses of methotrexate (<0.4 mg/kg/week), azathioprine (<3.0 mg/kg/day), or 6-mercaptopurine (<1.5 mg/kg/day) are also not considered sufficiently immunosuppressive to create vaccine safety concerns and are not contraindications for administration of the zoster vaccine.

Q: Can zoster vaccine be given to patients taking immune mediators and immune modulators?
The safety and efficacy of zoster vaccine administered concurrently with these agents is unknown. If it is not possible to administer zoster vaccine to patients before initiation of therapy, physicians should assess the immune status of the recipient on a case-by-case basis to determine the relevant risks and benefits. Otherwise, vaccination with zoster vaccine should be deferred for at least one month after discontinuation of such therapy.

FAQs continue on next page
Q: Can zoster vaccine be given to patients with cellular immunodeficiency?

ACIP says the vaccine should not be given to patients with clinical or laboratory evidence of other unspecified cellular immunodeficiency. However, persons with impaired humoral immunity including hypogammaglobulinemia or dysgamma-globulinemia can receive zoster vaccine.

Q: Can the zoster vaccine be given to patients taking intranasal steroids?

Use of intranasal steroids, inhaled steroids, or topical steroids is not a contraindication for zoster vaccination. The vaccine is also not contraindicated for those undergoing treatment with steroid joint, bursa, or tendon injections.

Q: Should the zoster vaccine be given to patients with a previous history of shingles?

ACIP guidelines state that people with previous history of shingles can be vaccinated unless they possess other contraindications. Shingles has a 3% recurrence rate. There is no documented safety concern if a dose of shingles vaccine is given to anyone who has already had the illness.

Q: What about vaccination after a zoster episode?

The proper time for vaccination after a zoster episode remains controversial. Expert recommendations vary from six months to two years. Vaccination should not be given during an acute episode. Zoster vaccination is not indicated to treat acute zoster or to treat PHN.

Q: Is there anything you should do if a patient receiving the vaccine develops a rash and then is exposed to someone at risk for varicella?

Although transmission of Oka/Merck strain VZV has been documented following varicella vaccination, this is rare. Also, rates of varicella-like rash appear to be less common following zoster vaccination than following varicella vaccination.

If a susceptible, immunocompromised person is inadvertently exposed to a person with a vaccine-related rash, varicella immunoglobulin need not be administered because disease associated with this type of transmission is expected to be mild. Acyclovir, valacyclovir, and famciclovir are active against live-attenuated Oka/Merck strain VZV and can be used in the unlikely situations in which a severe illness develops in the susceptible contact.

Q: Can the vaccine be given to patients anticipating immunosuppression?

This is a valid concern because the risk and morbidity for zoster is much greater in people who are immunosuppressed. ACIP recommends giving one dose of the zoster vaccine at the first possible encounter while immunity is intact. Administer the vaccine at least 14 days, preferably four weeks, before the initiation of immunosuppressive therapy.

FAQs continue on next page

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Q: Should the zoster vaccine be given to persons receiving antiviral medications?

Antivirals including acyclovir, famciclovir, and valacyclovir are effective against herpes family viruses including the strain found in VZV-based zoster vaccine. Administration of antiviral medications should be discontinued at least 24 hours prior to the administration of zoster vaccine, if possible, and should not be given for at least 14 days after vaccination. The June 6, 2008, MMWR on “Prevention of Herpes Zoster” (http://www.cdc.gov/mmwr/pdf/rr/rr5705.pdf) includes a section discussing vaccine administration to patients in certain groups, including those patients anticipating immunosuppression therapy (e.g., before stem cell transplant) and for HIV-positive individuals.

Q: Is it safe to give the vaccine to patients with past history of leukemia or lymphoma, but who are now in remission?

ACIP recommends that patients in remission can receive the vaccine as long as at least three months have elapsed since they have received chemotherapy or radiation therapy.
**HPV**

**GENERIC NAMES:**
quadrivalent HPV vaccine (HPV4),
bivalent HPV vaccine (HPV2)

**BRAND NAMES:**
Gardasil (HPV4), Cervarix (HPV2)

**DRUG COMPANIES:**
Merck & Co., Inc.,
GlaxoSmithKline

**Note:** HPV vaccines are not meant to be a treatment for HPV infection or HPV-related disease. Women must still get regular cervical cancer screening.

**QUADRIVALENT HPV VACCINE**

Only one quadrivalent HPV vaccine is currently available. It is sold as brand name Gardasil and is made by Merck & Co., Inc. HPV4 covers HPV types 6, 11, 16, 18.

**INDICATIONS**

HPV4 vaccine is indicated for girls and young women ages 9 through 26 years for prevention of genital cancers—cervical, vaginal, and vulvar cancers—and precancers.

The vaccine should be administered to boys and young men age 9 through 21 for prevention of genital warts and anal cancer. Men who have sex with men should receive HPV up to age 26.

The vaccine does not contain viral DNA so there is no risk of being infected with HPV virus from getting the vaccine.

**CONTRAINDICATIONS**

- History of severe allergic reaction to vaccine components including baker’s yeast (*Saccharomyces cerevisiae*), amorphous aluminum hydroxyphosphate sulfate (the adjuvant used in quadrivalent vaccine), and polysorbate 80.
- Patients with history of immediate hypersensitivity to yeast should not be given the HPV4.
- History of allergic reaction to previous dose of HPV vaccine.
- Pregnant or planning to get pregnant soon. (Pregnant women exposed to quadrivalent HPV vaccine should enroll in the pregnancy registry by calling 1-800-986-8999.) Pregnancy testing is not needed before vaccine administration.

**ADMINISTRATION**

The vaccine is 0.5 mL per dose in three doses administered intramuscularly in the deltoid of the upper arm or the anterolateral thigh. The second and third doses should be given at one to two months and at six months after the first dose. The minimal interval between the first and second dose is four weeks. The minimum interval between the second and third dose is 12 weeks. The minimal interval between the first and third dose is 24 weeks.

If the vaccine schedule is interrupted, the series does not have to be restarted.

Try to use the same vaccine product for all doses if possible. The series can be continued with the other vaccine product.
if the initially begun vaccine is not available. The HPV4 vaccine may be given at the same time as other vaccines but do not mix in same syringe with other vaccines.

POSSIBLE SIDE EFFECTS
Fainting or syncope after vaccine administration has been reported. Make sure the patient is observed for 15 minutes after vaccine administration. Bronchospasm and venous thromboembolism have been reported in post-marketing surveillance.

The most common adverse effect is pain, swelling, redness, itching, and bruising at the injection site. Other common adverse side effects include headache, fever, nausea, and dizziness.

STORAGE/HANDLING
Quadrivalent vaccine is a white, cloudy liquid. Shake well before using.

Keep refrigerated at 2°C to 8°C (35°F to 46°F). Do not freeze. Protect from light. Administer as soon as possible after taking the vaccine out of the refrigerator. It can be out of the refrigerator as long as the temperature is below 25°C but for no more than 72 hours.

PREGNANCY/NURSING
HPV4 vaccine is Category B. ACIP says lactating women can receive the HPV vaccine, but is contraindicated for women who are pregnant or planning to become pregnant.

REIMMUNIZATION/BOOSTER
Currently, no booster dose of HPV vaccine is recommended.

BIVALENT HPV VACCINE
Only one bivalent HPV vaccine is currently available. It is sold as brand name Cervarix and is made by GlaxoSmithKline. HPV2 covers HPV types 16, 18.

INDICATIONS
HPV2 vaccine is indicated for girls and young women ages 10 through 25 years for prevention of cervical cancers and precancers.

Currently there is no FDA indication for boys and men.

ADMINISTRATION
The vaccine is 0.5 mL per dose in three doses administered intramuscularly, preferably in the deltotid of upper arm. The second and third doses should be given one to two months and six months after the first dose. The minimal interval between the first and second dose is four weeks. The minimum interval between the second and third dose is 12 weeks. The minimum interval between first and third dose is 24 weeks.

If the vaccine schedule is interrupted, the series does not have to be restarted.

Try to use the same vaccine product for all doses if possible. The HPV vaccine may be given at the same time as other vaccines but do not mix in same syringe with other vaccines.

POSSIBLE SIDE EFFECTS
Fainting or syncope after vaccine administration has been reported. Make sure the patient is observed for 15 minutes after vaccine administration. Bronchospasm and venous
thromboembolism have been reported in post-marketing surveillance.\textsuperscript{1}

The most common adverse effect is pain, redness, and swelling at the injection site. Other adverse side effects include fatigue, headache, muscle aches, gastrointestinal symptoms, and joint aches.

**STORAGE/HANDLING**

Bivalent vaccine is a homogeneous, turbid, white suspension. Shake well before using.

Keep refrigerated at 2°C to 8°C (35°F to 46°F). Do not freeze.

Bivalent vaccine is available in single dose vial or prefilled syringe. Note that the tip and plunger contain latex.

**PREGNANCY/NURSING**

HPV2 vaccine is Category B.

ACIP says lactating women can receive the HPV vaccine, but is contraindicated for women who are pregnant or planning to become pregnant.

**REIMMUNIZATION/BOOSTER**

Booster doses are not recommended at this time.

**CPT CODES/REIMBURSEMENT ISSUES**

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Immunization administration (includes percutaneous, intradermal, subcutaneous, or intramuscular injections); one vaccine (single or combination vaccine/toxoid)

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<th>ICD-9 code: V05.9</th>
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Needed for other prophylactic vaccination and inoculation against single disease, unspecified single disease

**FAQs**

**Q: Do you have to do a pregnancy test before giving either vaccine?**

No, but neither HPV2 nor HPV4 should be given to women who are known to be pregnant or are planning to get pregnant soon.

**Q: What should you do if you find out that patient is pregnant?**

Pregnant women exposed to bivalent HPV vaccine should enroll in pregnancy registry by calling 1-888-452-9622. Both vaccines are in Pregnancy category B.

**Q: Can a patient get the HPV vaccine while nursing?**

Yes. ACIP says lactating women can receive the HPV vaccine.

**Q: Does it matter which vaccine is given to boys?**

Yes. Currently, only the quadrivalent vaccine, which provides protection against genital warts and anal cancer, is licensed for males.

**Q: Can the HPV vaccines be used to treat an abnormal pap smear?**

No. They are not meant to be a treatment for HPV infection or HPV-related disease.

**Q: Do you still have to get cervical cancer screening if you get the HPV vaccine?**

Yes. HPV vaccines are not meant to be a treatment for HPV infection or HPV-related disease. Women must still get regular cervical cancer screening.

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Meningococcal

**GENERIC NAMES:**
meningococcal conjugate vaccine (MCV4), meningococcal polysaccharide vaccine (MPSV4)

**BRAND NAMES:**
Menomune, Menactra, Menveo

**DRUG COMPANIES:**
Sanofi Pasteur, Novartis

Three quadrivalent vaccines are licensed in the United States to prevent invasive meningococcal disease (IMD) caused by *N. meningitidis* serogroups A, C, Y, and W-135 serogroup. (B is not currently preventable by United States licensed vaccines.) Available vaccines are:

- **MCV4:** Meningococcal conjugate quadrivalent vaccine (Menactra, Sanofi Pasteur, licensed in 2005, conjugated to diphtheria toxoid)
- **MCV4:** Meningococcal conjugate quadrivalent vaccine (Menveo, Novartis vaccines, licensed in 2010, conjugated to cross reactive mutant protein)
- **MPSV4:** Polysaccharide meningococcal quadrivalent vaccine (Menomune, Sanofi Pasteur, licensed in 1981)

The MCV4 vaccines are the vaccines of choice where indicated because they elicit strong primary immune responses, as well as anamnestic (long-term memory) immune responses upon exposure to the antigen(s). They also reduce asymptomatic carriage of *N. meningitidis*, providing herd immunity and protecting unvaccinated persons.

**INDICATIONS**
ACIP recommends routine immunization with MCV4 of adolescents 11 through 18 years of age and immunization of persons 2 through 54 years of age who are at elevated risk for IMD including:

- College freshman living in dormitories
- Microbiologists routinely exposed to *N. meningitidis*
- Military recruits
- Persons who travel to or reside in countries where *N. meningitidis* is hyper-endemic or epidemic, particularly if contact with the local population will be prolonged
- Persons with persistent complement component deficiency
- Persons with anatomic or functional asplenia
- Persons with HIV infection

**MPSV4 is indicated for people ages 56 and older.**

**CONTRAINDICATIONS**
- Previous known severe allergic reaction to any component of the vaccine. Safety data are not available for use of MCV4 in pregnant women.
PRECAUTIONS
Vaccination should be deferred in persons with moderate or severe acute illness until the illness resolves.

ADMINISTRATION
MCV4: For persons 11 through 54 years of age, MCV4 vaccines are given as a single 0.5 mL dose intramuscularly.
MPSV4: For persons age two years and above, the MPSV4 vaccine is given as a 0.5 mL dose subcutaneously every three to five years to persons who remain at risk for meningococcal disease.

POSSIBLE SIDE EFFECTS
Meningococcal conjugate vaccines tend to be mildly more likely to cause an inflammatory response than polysaccharide vaccines. In one study, 13% of adults receiving the MCV4 vaccine reported pain limiting arm motion in the injected arm, compared to 3% of those who received MPSV4. Low-grade fever, swelling, and redness occur in 10%-14% of MCV4 and MPSV4 recipients. Systemic and local adverse events tend to be low grade, transient, and self-resolving.

STORAGE/HANDLING
All meningococcal vaccines licensed in the United States should be refrigerated. Freezing may destroy vaccine potency, and such vaccines should not be used. For single-dose reconstituted MPSV4 vaccine, the vaccine should be used within 30 minutes. For multidose vials, where vaccine has been reconstituted, the vaccine may be used for up to 35 days if kept refrigerated.

PREGNANCY/NURSING
MPSV4 vaccine is Category C. MPSV4 vaccine is safe in pregnant women at risk for meningococcal disease. Safety data are not available for the use of MCV4 vaccines in pregnant women. Vaccine recipients may breastfeed.

REIMMUNIZATION
ACIP recommends routine vaccination of persons with quadrivalent meningococcal conjugate vaccine at age 11 or 12 years, with a booster dose at age 16 years. After a booster dose of meningococcal conjugate vaccine, antibody titers are higher than after the first dose and are expected to protect adolescents through the period of increased risk through age 21 years. For adolescents who receive the first dose at age 13 through 15 years, a one-time booster dose should be administered, preferably at age 16 through 18 years, before the peak in increased risk. Persons who receive their first dose of meningococcal conjugate vaccine at or after age 16 years do not need a booster dose. Routine vaccination of healthy persons who are not at increased risk for exposure to *N. meningitidis* is not recommended after age 21 years.

Data indicate that the immune response to a single dose of meningococcal conjugate vaccine is not sufficient in
persons with certain medical conditions such as asplenia. Persons with persistent complement component deficiencies (e.g., C5–C9, properdin, factor H, or factor D) or asplenia should receive a 2-dose primary series administered 2 months apart and then receive a booster dose every 5 years. Adolescents aged 11 through 18 years with HIV infection should be routinely vaccinated with a 2-dose primary series. Other persons with HIV who are vaccinated should receive a 2-dose primary series administered 2 months apart. All other persons at increased risk for meningococcal disease (e.g., microbiologists or travelers to an epidemic or highly endemic country) should receive a single dose.

### FAQs

**Q: Should all college freshmen receive meningococcal vaccine?**

Vaccine administration remains a recommendation from the ACIP and is not a mandate. However, individual states may mandate vaccination prior to school or college entry. Studies have estimated the risk of meningococcal disease in entering college freshmen to be two- to five-fold higher than the general public. While this is an elevated rate, the absolute number of cases is small, and the cost of the vaccine is relatively high. Cost per case prevented by vaccinating all freshmen is estimated at $1.4-$2.9 million, while cost per death prevented is estimated to be $22-$48 million.

**Q: How long does immunity last after vaccination?**

Immunity to the polysaccharide vaccine wanes after three to five years, particularly in younger children. While immunity after MCV4 vaccines is expected to last somewhat longer, recent data suggest that bactericidal antibody-based immunity wanes by five years.

### CPT CODES/REIMBURSEMENT ISSUES

**Meningococcal vaccine CPT codes:** 90733 (Menomune) and 90734 (Menactra)

**ICD-9 code:** V03.89
Hepatitis A

**GENERIC NAME:**
hepatitis A vaccine, hepatitis A/hepatitis B combination

**BRAND NAMES:**
Havrix, Vaqta, Twinrix

**DRUG COMPANIES:**
GlaxoSmithKline, Merck & Co., Inc.

**INDICATIONS**
The vaccine is indicated for all persons older than 18 years of age who provide a home or day care for a child who is an international adoptee.

It is indicated for male adolescents and adults who have sex with men, as well as for all persons who are users of injection or non-injection illicit drugs.

The vaccine is indicated for all patients with chronic liver disease or who are awaiting or have received a liver transplant as well as for individuals whose occupation requires exposure to hepatitis A-infected primates or with the virus in a research laboratory.

The vaccine is recommended for travelers to countries that have an elevated prevalence of hepatitis A infection.

**CONTRAINDICATIONS**
- History of severe allergic reaction to a previous dose of hepatitis A vaccine or a vaccine component.

**ADMINISTRATION**
The vaccine is 1 mL per dose in two doses, given six months apart, administered intramuscularly into the deltoid muscle of the upper arm. Use the same vaccine product for both doses if possible.

The combination hepatitis A/hepatitis B vaccine is licensed for use in persons older than 17 years of age. The 1 mL dose is given in a three-dose schedule at 0, 1, and 6 months. After three doses of the combination vaccine, antibody responses to both components are comparable to responses after the single-antigen vaccines given separately.

Hepatitis A vaccines may be given at the same time as other vaccines, but do not mix in the same syringe with other vaccines. The vaccines should be given at different anatomic sites.

**POSSIBLE SIDE EFFECTS**
Soreness at the injection site and headache are the most common adverse effects; low-grade fever occurs in less than 10 percent of recipients.

**STORAGE/HANDLING**
Keep refrigerated at 1°C to 8°C (36°F to 46°F). Do not freeze.

**PREGNANCY/NURSING**
Hepatitis A vaccine is Category C. (Studies in animals and humans have not been done.) The vaccines are produced from inactivated hepatitis A virus, thus there is no absolute contraindication to their use in pregnancy. Pregnant women at risk for hepatitis A, such as those traveling to developing countries, might be considered for immune globulin prophylaxis.
REIMMUNIZATION/BOOSTER
There are no indications for reimmunization.

CPT CODES/REIMBURSEMENT ISSUES

Unspecified code: 90730

Hepatitis A/Hepatitis B combination codes: 90632, 90636

FAQs

Q: Should you test for antibody before vaccination?
It is not generally cost effective to screen individuals for antibody in order to determine whether they are susceptible to hepatitis A before immunization. Pre-vaccination testing might be considered in specific circumstances where the expected prevalence of immunity is high. These might include persons who were born in areas of the world with high endemicity of hepatitis A infection and adults in certain population groups such as American Indians, Alaska Natives, and Hispanics. One must determine whether the testing process will be a barrier to the initiation of vaccination.

Q: Should the person who has been vaccinated with hepatitis A vaccine be tested for antibody to ensure immunity?
There is no need for post-immunization serologic testing because the vaccine is highly immunogenic.

Q: What should be done if the second (last) dose of hepatitis A vaccine is delayed beyond 18 months?
Administer the second dose as soon as possible. The first dose does not need to be repeated.

Q: Can hepatitis A vaccine be given to immunocompromised persons (e.g., persons on hemodialysis or persons with AIDS)?
Because hepatitis A vaccine is inactive, no special precautions need to be taken when vaccinating immunocompromised persons.

Q: Is it harmful to administer an extra dose(s) of hepatitis A or hepatitis B vaccine or to repeat the entire vaccine series if documentation of vaccination history is unavailable?
If necessary, administering extra doses of hepatitis A or hepatitis B vaccine is not harmful.

FAQs continue on next page
Q: Which groups do NOT need routine vaccination against hepatitis A?

Food service workers. Food-borne hepatitis A outbreaks are relatively uncommon in the United States. Although food handlers have a critical role in common-source food borne outbreaks, they are not at increased risk of hepatitis A because of their occupation. Consideration may be given to vaccination of employees who work in areas where community-wide outbreaks are occurring and where state and local health authorities or private employers determine that such vaccination is appropriate.

Sewage workers. In the United States, no work-related outbreaks of hepatitis A have been reported among workers exposed to sewage.

Health care workers. Health care workers are not at increased risk for hepatitis A. If a patient with hepatitis A is admitted to the hospital, routine infection-control precautions should be sufficient to prevent transmission to hospital staff.

Q: Who should receive protection against hepatitis A before travel?

All susceptible persons traveling to or working in countries that have elevated rates of hepatitis A should be vaccinated. The risk for hepatitis A exists even for travelers to urban areas, those who stay in luxury hotels, and those who report that they have good hygiene and that they are careful about what they drink and eat.

Q: How soon before travel should the first dose of hepatitis A vaccine be given?

The first dose of hepatitis A vaccine should be administered as soon as travel is considered. Immune globulin and vaccine have equivalent post-exposure efficacy and one dose of hepatitis A vaccine administered at any time before departure may provide adequate protection for most healthy persons.
Hepatitis B

**GENERIC NAMES:**
hepatitis B vaccine, hepatitis A/hepatitis B combination

**BRAND NAMES:**
Engerix-B, Recombivax HB, Twinrix

**DRUG COMPANIES:**
GlaxoSmithKline, Merck & Co., Inc.

**INDICATIONS**
The vaccine is indicated for all adolescents up to age 19.

The vaccine is indicated for the following populations, in all persons 19 years of age and older:

- **Behavioral:** Sexually active persons who are not in a long-term mutually monogamous relationship, persons seeking evaluation or treatment for a sexually transmitted disease, current or recent illicit injection-drug users, and men who have sex with men.

- **Occupational:** Health care personnel and public safety workers who may be exposed to blood or other potentially infectious body fluids.

- **Medical:** Persons with diabetes (up to age 59); persons with end-stage renal disease (including those receiving hemodialysis); persons with HIV infection, and persons with chronic liver disease.

- **Other:** Household contacts and sex partners of persons with chronic hepatitis B virus infection; clients and staff of institutions for persons with developmental disabilities.

- **Travelers:** International travelers to countries with elevated prevalence of hepatitis B infection.

**CONTRAINDICATIONS**
- History of serious adverse event after receipt of a previous dose of hepatitis B vaccine or those with a history of hypersensitivity to yeast or any vaccine component.

**ADMINISTRATION**
A three-dose schedule (1mL per dose) is recommended for both monovalent vaccines. The second dose should be given one month after the first dose; the third dose should be administered at least two months after the second dose (and at least four months after the first dose). The vaccine should be administered intramuscularly into the deltoid muscle of the upper arm.

Alternative vaccination schedules (e.g., 0, 1, and 4 months or 0, 2, and 4 months) have been shown to be as effective as the standard schedule of 0, 1, and 6 months.

In 2007 the FDA approved accelerated dosing for hepatitis A and B vaccines, as well as the combination hepatitis A and hepatitis B vaccine. Following the initial dose, subsequent doses are given at seven and 21-30 days, followed by a booster dose at 12 months. This accelerated dosing schedule can provide
protection in three weeks’ time and can be used when there is not enough time for the standard six-month dosing schedule. If the vaccine schedule is interrupted, the series does not need to be restarted.

*Special formulation and administration schedules:* Adults receiving hemodialysis or with other immunocompromising conditions should receive the dialysis formulation of Recombivax HB administered on a three-dose schedule or two doses of Engerix-B administered concurrently on a four-dose schedule at 0, 1, 2, and 6 months.

The combination hepatitis A/hepatitis B vaccine is licensed for use in persons older than 17 years of age. The 1 mL dose is given in a three-dose schedule at 0, 1, and 6 months. After three doses of the combination vaccine, antibody responses to both components have been shown to be comparable to responses after the single-antigen vaccines given separately.

The hepatitis B vaccines may be given at the same time as other vaccines but do not mix in the same syringe with other vaccines. The vaccines should be given at different anatomic sites.

**POSSIBLE SIDE EFFECTS**
Soreness at the injection site is the most commonly reported adverse event; low-grade fever may occur but is uncommon.

**STORAGE/HANDLING**
Keep refrigerated at 2°C to 8°C (36-46°F). Do not freeze.

**PREGNANCY/NURSING**
Hepatitis B vaccine is Category C. Pregnancy is not a contraindication to vaccination. The vaccines contain noninfectious hepatitis B virus surface antigen and cause no risk of infection to the fetus.

**REIMMUNIZATION/BOOSTER**
For persons with normal immune status who have been vaccinated, booster doses are not recommended.

For hemodialysis patients, the need for booster doses should be assessed by annual testing for antibody to hepatitis B surface antigen (anti-HBsAg). A booster dose should be administered when anti-HBs levels decline to <10 mIU/mL. For other immunocompromised persons, the need for booster doses has not been determined.

**CPT CODES/REIMBURSEMENT ISSUES**
Hepatitis A-Hepatitis B combination codes:
90731, 90636
FAQs

Q: Can a patient receive the first dose of hepatitis B vaccine from one manufacturer and subsequent doses from another manufacturer?
Yes. No differences in immune response are observed when vaccines from different manufacturers are used to complete the series.

Q: Is it harmful to administer an extra dose(s) of hepatitis A or hepatitis B vaccine or to repeat the entire vaccine series if documentation of the vaccination history is unavailable?
If necessary, administering extra doses of hepatitis A or hepatitis B vaccine is not harmful.

Q: Who should receive post-vaccination testing?
Testing for immunity is advised for persons whose subsequent clinical management depends on knowledge of their immune status, including the following:
• Health care workers and public safety workers at high risk for continued percutaneous or mucosal exposure to blood or body fluids
• Chronic hemodialysis patients, HIV-infected persons, and other immunocompromised persons (e.g., hematopoietic stem-cell transplant recipients or persons receiving chemotherapy)
• Sex partners of persons with chronic HBV infection

Q: When should post-vaccination testing be performed?
When necessary, post-vaccination testing for antibody to hepatitis B surface antigen (anti-HBsAg) should generally be performed one to two months after completion of the vaccine series.

Q: Is there any benefit or risk in vaccinating a person who has been infected with HBV?
Persons who have already been infected with HBV will receive no benefit from vaccination. However, there is no risk to a previously infected person who receives vaccination.

Q: Should persons be tested for immunity to hepatitis B before being vaccinated?
It is currently recommended that certain populations undergo testing for HBV infection prior to vaccination, including the following:
• Hemodialysis patients
• Pregnant women
• Persons with known or suspected exposure to HBV including the following:
  - Household contacts of HBV-infected persons
  - Persons with known occupational or other exposures to infectious blood or body fluids
• Foreign-born persons from countries of high HBV endemicity
• HIV-positive persons

For these populations, serologic assays for HBsAg and anti-HBsAg should be used to determine infection or immunity prior to vaccination.

FAQs continue on next page
Q: After receiving the hepatitis B vaccine series, what level of anti HBs is considered protective?

An anti-HBs level of >10mIU/mL is considered protective.

Q: What should be done if hepatitis series is given but laboratory testing does not show seroconversion?

Hepatitis B series should be repeated and then re-test for anti-HBs in one to two months. If the test is still negative, the person can be classified as a non-responder and is most likely susceptible to Hepatitis B infection.

Q: Do people at occupational risk (like healthcare workers) need to get additional Hepatitis B boosters if they demonstrated laboratory evidence of seroconversion after receiving the initial vaccine series even if current anti-HBs titer is less than 10 mIU/mL?

People who have shown seroconversion after initial 3 dose series do not need a booster. These patients are still protected because immune memory maintains anamnestic anti-HBs response.
Measles-Mumps-Rubella

**GENERIC NAME:**
Live-attenuated measles, mumps, and rubella vaccine

**BRAND NAME:**
MMR-II (MMR)

**DRUG COMPANY:**
Merck & Co., Inc.

**INDICATIONS**
Routine for all infants, children, and adolescents (two doses separated by at least one month).

All adults born in 1957 or later should receive at least one dose (unless contraindicated). Persons born prior to 1957 generally can be assumed to be protected.

Persons at increased risk for contraction of measles, mumps, or rubella:
- International travelers
- Persons attending post-secondary schooling
- Health care workers (HCWs)
- Women of childbearing age
- HIV-infected persons who do not have evidence of severe immunosuppression (defined as persons with total CD4+ T-lymphocyte counts greater than 200 or CD4+ T-lymphocytes greater than 14% of total lymphocytes)
- Unimmunized exposed persons (if used within 72 hours of exposure)

All HCWs should receive two doses of MMR vaccine at least 28 days apart unless they have laboratory evidence of immunity or laboratory confirmation of measles, mumps, and rubella infection, or were born before 1957. Unvaccinated HCWs who lack laboratory evidence of immunity to any of these viruses should receive two doses of MMR (at least 28 days apart) during an outbreak of measles or mumps, and one dose of MMR during a rubella outbreak.

**CONTRAINDICATIONS**

**Absolute**
- Pregnancy, severe immunosuppression (due to disease, such as HIV infection, chemotherapy, radiation, corticosteroid treatment, etc.), severe allergic reactions to any vaccine component (particularly porcine gelatin), and recent administration of blood products (due to inhibition of immune responses to the vaccine).

**Relative**
- Acute moderate to severe illness (defer until recovered), and thrombocytopenia within six weeks after a previous dose of MMR vaccine.

**ADMINISTRATION**

MMR vaccine is given as a 0.5 mL dose subcutaneously.

**POSSIBLE SIDE EFFECTS**
Transient rashes, fevers, and lymphadenopathy. Due to the nature of MMR vaccine recommendations, most reported side
effect rates have been reported from studies in children and thus may not accurately reflect adverse event rates in adults. Therefore, only the more important systemic adverse events are discussed here.

According to the CDC, thrombocytopenia occurs in one case per million doses distributed—with increased risk among persons with a history of immune thrombocytopenic purpura (ITP).

Arthralgias and arthritis have been associated with live rubella virus immunization in adolescent females. Among postpubertal, susceptible females, the incidence of this adverse event has been as high as 25%, although these side effects are transient in nature. Whether more chronic, persistent arthritis can result remains debatable.

Aseptic meningitis has been reported in other countries using alternative strains of mumps; however, the use of the Jeryl Lynn strain—the only strain used in the United States—has not been associated with such side effects. There is no evidence of increased risk of subacute sclerosing panencephalitis among persons receiving MMR or measles-containing vaccines in the United States. The CDC estimates that the risk of anaphylaxis after MMR vaccine is less than one per million doses.

**STORAGE/HANDLING ISSUES**

MMR vaccine is a lyophilized vaccine, which must be reconstituted prior to administration. Lyophilized vaccine should be stored at ≤2°C to 8°C (35°F to 46°F), and protected from light (which can inactivate the viruses). Reconstituted vaccine is stored under the same conditions, must not be frozen, and must be used within eight hours after reconstitution.

**PREGNANCY/NURSING**

MMR vaccine is Category C. As these are live, attenuated vaccine viruses, administration while pregnant is contraindicated. Registries of pregnant women who have been inadvertently immunized while pregnant have not demonstrated increased risks of fetal defects or harm. Pregnancy should be deferred for 30 days after vaccination with MMR. Such women should be asked whether they believe they may be pregnant. If the answer is “no”, simply educate regarding the need to avoid MMR immunization while pregnant and record in the medical record. Pregnancy testing is encouraged if the woman is unsure.

**REIMMUNIZATION/BOOSTER**

Routine reimmunization of otherwise fully and age-appropriately immunized persons is not necessary. Reimmunization of those initially immunized with inactivated vaccines (commonly done from 1963-1967 with measles and from 1950-1978 for mumps) or vaccine of unknown origin is recommended. Additionally, reimmunization of those persons previously immunized with a live measles vaccine concomitantly administered with immune globulin preparations (commonly done from 1963-1975) should be considered.

**CPT CODES/REIMBURSEMENT ISSUES**

- **Measles vaccine CPT code:** 90705
- **MMR vaccine CPT code:** 90707
- **Measles ICD-9 code:** V04.2
- **MMR ICD-9 code:** V06.4
FAQs

Q: Can MMR vaccine be administered on the same days as a tuberculin skin test (TST)?
Yes. However, live MMR vaccine can interfere with the immune response to tuberculin skin testing, if the TST test is administered more than one day following MMR administration. This effect is thought to last for only four to six weeks.

Q: If a patient is only susceptible to one of the three viruses in the MMR vaccine, can the vaccine be given?
There are no increased risks to giving the MMR vaccine even when the recipient is immune to one or more of its components.

Q: What about antibody testing?
Antibody testing is generally more expensive than the cost of the vaccine.

Q: Can the live viruses in the MMR vaccine be transmitted to others?
There are no reports or evidence for transmission of MMR vaccine viruses. Therefore nursing mothers can safely receive MMR vaccine as can close contacts/family members of immunocompromised individuals.

Q: Why is recent blood product administration a contraindication for receipt of MMR vaccine?
While not a safety issue, it is an immunogenicity issue as the immune globulins in such products neutralize MMR vaccine viruses, preventing development of full immunity. Depending upon the blood product used, MMR vaccination should be delayed between three and 11 months.

Q: Since measles vaccine virus is grown in chicken eggs, why is egg allergy not a contraindication to MMR vaccination?
The quantities of any residual egg protein are so small that there has been no evidence of anaphylactic reaction in egg-allergic individuals directly challenged with MMR vaccine.

Q: Should rubella-containing vaccines be avoided in adults with arthritis?
Arthritis is not a contraindication for MMR vaccine. There are no published studies demonstrating any increased risk or exacerbation of pre-existing arthritis in persons receiving rubella-containing vaccines.

Q: Can MMR vaccines be given to HIV-positive individuals?
MMR vaccine is indicated for all asymptomatic and symptomatic HIV-infected persons who do not have evidence of severe immunosuppression. For adolescents and adults, the total CD4+ T lymphocytes should be greater than 200/µL, or the CD4+ T lymphocytes should be greater than 14% of total lymphocytes.
Varicella

**GENERIC NAME:**
Varicella vaccine

**BRAND NAME:**
Varivax (live, attenuated, single antigen varicella vaccine)

**DRUG COMPANY:**
Merck & Co., Inc.

**INDICATIONS**
Varivax is approved for all persons over the age of 12 months. The vaccine is indicated for all healthy nonpregnant adults who do not have immunity, as evidenced by documentation of age-appropriate vaccination, laboratory evidence of immunity, or confirmation of disease by a laboratory or health care professional.

Birth before 1980 may be considered as evidence of immunity for some adults, but should not be considered as such for health care providers, pregnant women, and immunocompromised persons.

Special consideration for vaccination should be given to adults who do not have immunity and present an increased risk of exposure or transmission of varicella, including health care workers, persons working in environments with increased likelihood of varicella-zoster virus transmission. These include teachers, day care workers, residents and staff of institutional settings, college students, military personnel, nonpregnant women of childbearing age, adolescents and adults living in households with children or immunocompromised persons, and international travelers.

Varicella vaccination is recommended for post-exposure prophylaxis of healthy persons without evidence of immunity following exposure to varicella either individually or in an outbreak setting.

**CONTRAINDICATIONS**

**Absolute**

- Previous hypersensitivity to the vaccine or to a vaccine component, including gelatin and neomycin. A history of contact dermatitis to neomycin is not a contraindication.
- Immunocompromised patients including those with any hematologic malignancy such as leukemia, lymphoma, or other blood dyscrasias that affect the bone marrow or lymphatic system are contraindicated because the vaccine contains live attenuated varicella virus.
- Persons with primary or acquired immune deficiency such as AIDS, other cellular immunodeficiency, hypogammaglobulinemia, or dysgammaglobulinemia. Persons with HIV/AIDS over the age of eight years who have an absolute CD4 count above 200 cells/mm³ may receive the varicella vaccine.
• Persons with a family history in first-degree relatives of congenital or hereditary immunodeficiency, unless they have been tested and demonstrated to have immune competence.

• Patients on immunosuppressive medications including systemic corticosteroids ≥20 mg of prednisone equivalent daily for more than two weeks who are also at risk for more extensive vaccine-associated rash or disseminated varicella disease. Vaccine should not be given until after corticosteroid therapy has been discontinued for at least one month.

• There are no published data regarding varicella vaccination in patients taking immunomodulators such as Tacrolimus (FK506), Sirolimus, Etanercept, Infliximab, or Mycophenolate.

• Pregnant women, as the affect on the fetus is unknown, although the potential risk is considered to be low. Nonpregnant women who receive the vaccine should not become pregnant for at least one month after each injection.

Relative:
• Persons with a severe acute illness including active, untreated tuberculosis, until they have recovered from their illness. Mild illnesses, with or without fever, are not a contraindication.

• Persons who have received blood (not including washed red blood cells), plasma, or immunoglobulin should not undergo varicella vaccination for three to 11 months, depending on the dose of antibody containing blood product administered due to interference with response to the vaccine. Receipt of antibody-containing blood products may interfere with vaccine efficacy if administered within two weeks following vaccination.

ADMINISTRATION
In adolescents and adults over the age of 13 years, the dose of varicella vaccine is 0.5 mL administered subcutaneously. The outer aspect of the deltoid region of the upper arm is preferred with the anterolateral thigh being an alternate site of administration. A second dose of 0.5 mL of varicella vaccine should be administered four to eight weeks after the first dose.

Varicella vaccine may be simultaneously administered with other vaccines. While data are limited for concomitant administration of some adult vaccines, in general, studies have shown seroconversion and side effect rates similar to those following administration of vaccines separately. Vaccines administered concomitantly should be given on the same day at different anatomic sites.

POSSIBLE SIDE EFFECTS
Injection site reactions (soreness, erythema, swelling, rash, pruritus, pyrexia, hematoma, induration, or numbness) were reported by 24.4% of vaccine recipients after the first dose in a prelicensure study of adolescents and adults compared to 32.5% after the second dose. Fever was reported in about 10% after either dose. About 3% developed a varicella-like rash locally at the injection site after the first dose compared to 1% after the second dose, while 5.5% developed a generalized rash after the first dose compared to 0.9% after the second dose.

Severe complications including pneumonia, hepatitis, and severe disseminated varicella are rare and have occurred when vaccine was given to immunocompromised patients or those with other severe underlying illness.

Rarely, transmission of vaccine strain varicella virus from healthy vaccine recipients to susceptible contacts has occurred; this risk increases if the vaccine recipient has a vaccine-related rash.

STORAGE/HANDLING
Varicella vaccine is provided by the manufacturer as separate vials of lyophilized vaccine and diluent. The lyophilized vaccine must be stored frozen at a temperature between -58°F and...
+5°F (-50°C and -15°C) and must be used before the expiration date. Storage in any freezer (e.g., chest, frost-free) that reliably maintains a temperature between -58°F and +5°F (-50°C and -15°C) and has a separate sealed freezer door is acceptable. Store the diluent separately in a refrigerator or at room temperature. Prior to reconstitution, the vaccine may be stored in a refrigerator at 2°C to 8°C (35° to 46°F) for 72 hours. If not used within 72 hours, discard the vaccine—do not refreeze. Once reconstituted, administer the vaccine within 30 minutes. Reconstitute the vaccine by withdrawing 0.7mL of diluent into a syringe. Then inject the withdrawn diluent into the vial of lyophilized vaccine and agitate gently. The reconstituted vaccine is a clear, colorless to pale yellow liquid that should not have any visible particles or discoloration. Withdraw the reconstituted vaccine (the total contents of the vaccine vial after reconstitution) which should be a minimum of 0.5 ml for subcutaneous administration.

**PREGNANCY/NURSING**
Varicella vaccine is contraindicated in pregnancy as it is a live virus vaccine. The potential affect on the fetus is unknown. Women who receive the vaccine should not become pregnant for at least one month following vaccination. The manufacturer, in collaboration with the CDC, maintains a pregnancy registry to evaluate maternal-fetal outcomes in patients who received varicella vaccination within the three months preceding or during pregnancy. Reports can be made to the Varivax Pregnancy Registry at 1-800-986-8999.

### FAQs

**Q: Can a household contact of a pregnant woman receive the varicella vaccine?**
Yes, a household contact should receive the varicella vaccine if susceptible. By vaccinating the household contact this will prevent active varicella zoster virus infection in the contact and thereby prevent transmission to the pregnant woman.

**Q: Can a nursing mother receive the varicella vaccine?**
Yes, varicella virus has not been observed to transmit through breast milk and passive transmission of antibodies through breast milk is not thought to occur.

**Q: Can a patient with HIV/AIDS be given the varicella vaccine?**
It depends on the CD4 counts. Adult patients with absolute CD4 counts below 200 cells/mm³ should not be given the vaccine. Patients whose CD4 cell count is above 200 cells/mm³ may receive the vaccine.

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The Organization of Teratology Information Specialists (OTIS) coordinates the Vaccines and Medications in Pregnancy Surveillance System (VAMPSS). Whenever a pregnant woman has been inadvertently administered a vaccine, referrals can be made by calling 877-311-8972.
Women who are Pregnant or Breastfeeding

The decision to vaccinate a patient who is pregnant or breastfeeding focuses on balancing benefits of protection of the pregnant woman versus risk to the fetus. In general, inactivated vaccines and toxoids are safe during pregnancy, while live vaccines pose a theoretical risk to a developing fetus. Therefore, live virus vaccines are generally contraindicated during pregnancy and pregnancy should be avoided for at least four weeks after receiving those vaccines. There is no known risk to the fetus from passive immunization of pregnant women using immune globulin preparations.

PRENATAL SCREENING FOR VACCINE-PREVENTABLE DISEASES

ACIP recommends prenatal screening for rubella and hepatitis B and prenatal assessment for varicella.

Rubella: Women who do not have serologic evidence of rubella immunity or documentation of rubella vaccination should be vaccinated with MMR upon completion or termination of their pregnancy. Women should avoid becoming pregnant for 28 days after vaccination.

Hepatitis B (HBV): Pregnant women should be routinely tested for HBsAg during an early prenatal visit (e.g., first trimester) in each pregnancy, even if they have been previously vaccinated or tested. Infants of HBsAg-positive women must receive timely post-exposure prophylaxis and follow up. When HBsAg testing of a pregnant woman is not feasible, her infant should receive first dose of hepatitis B vaccine <12 hours of birth and should complete the hepatitis B vaccine series according to a schedule recommended for infants born to HBsAg-positive mothers.

Varicella: Varicella infection during pregnancy can have severe consequences. ACIP recommends prenatal assessment of women for varicella immunity. For pregnant women, birth before 1980 is not considered evidence of immunity. The criteria for proof of immunity includes any of the following: documentation of age-appropriate vaccination; laboratory evidence of immunity; laboratory confirmation of disease; healthcare provider diagnosis of varicella or health care provider verification of history of varicella disease; or history of herpes zoster based on healthcare provider diagnosis. Women who do not have evidence of varicella immunity should receive the first dose of vaccine as soon as possible upon completion or termination of their pregnancies, with a second dose four to eight weeks later. Women should be counseled to avoid conception for one month after each dose of varicella vaccine.

VACCINATIONS FOR BREASTFEEDING WOMEN

ACIP states that neither inactivated nor live vaccines administered to a lactating woman affects the safety of breastfeeding for mothers or infants. Breastfeeding does not adversely affect immunization and is not a contraindication for any vaccine, with the exception of smallpox vaccine. However, breastfeeding is a precaution for yellow fever vaccine. Providers need to weigh the risks and benefits of administering yellow fever vaccine to a breastfeeding woman.
VACCINES RECOMMENDED DURING PREGNANCY

• **Hepatitis B (HBV)**
  Non-immune high-risk women identified as being at risk for HBV should be vaccinated. Factors increasing risk of HBV infection include previous treatment for a sexually transmitted disease, having more than one sex partner during the previous six months, and having a sexual partner that is HbSAg positive.

• **Influenza, Inactivated**
  Women who are pregnant or who become pregnant during influenza season are at increased risk for influenza complications comparable to that of the elderly. These women should be vaccinated using inactivated influenza vaccine. Live attenuated influenza vaccine should not be administered to pregnant women.

• **Meningococcal (MPSV4-Polysaccharide)**
  This vaccine is inactivated and should be administered to a pregnant woman when indicated.

• **Rabies**
  Because of the deadly consequences of rabies exposure, pregnancy is not considered a contraindication to post-exposure prophylaxis or for pre-exposure prophylaxis if the rabies exposure risk is substantial (e.g., bite exposures, human-to-human organ transplant).

• **Tetanus-Diphtheria (Td)**
  Although there is no evidence that tetanus and diphtheria toxoids are teratogenic, waiting until the second trimester of pregnancy to administer Td is a reasonable precaution unless there is a need for immediate protection. If a booster is indicated, either give Td during pregnancy or wait to give Tdap immediately postpartum. A foreign-born pregnant woman whose tetanus vaccination status is not known should have her primary Td series started during pregnancy.

VACCINES NOT RECOMMENDED DURING PREGNANCY

All live virus vaccines are contraindicated during pregnancy:

• **Influenza (LAIV)**
  Pregnant women should be vaccinated against influenza but not with the LAIV. Instead, pregnant women should receive inactivated influenza vaccine.

• **Measles-Mumps-Rubella (MMR)**
  MMR and its component vaccines should not be administered to women known to be pregnant. Women should avoid becoming pregnant for 28 days after vaccination with measles or mumps vaccines, MMR, or other rubella-containing vaccines.

  Women who are unknowingly pregnant at time of MMR vaccination and women who become pregnant within four weeks after MMR vaccination should be counseled about the theoretical concerns for the fetus; however, MMR vaccination during pregnancy should not be regarded as a reason to terminate pregnancy. A registry of susceptible women vaccinated with rubella vaccine between three months before or after conception, called the Vaccine in Pregnancy (VIP) Registry, was kept between 1971 and 1989. Fortunately, no evidence of congenital rubella syndrome occurred in the offspring of the 226 women who received the current RA 27/3 rubella vaccine and continued their pregnancy to term.

  Rubella-susceptible women who are not vaccinated because they state they are or may be pregnant should be counseled about the potential risk for congenital rubella syndrome and the importance of being vaccinated as soon as they are no longer pregnant.
• **Varicella**
  Women who are vaccinated with varicella should avoid becoming pregnant for one month following each injection. However, for susceptible persons, living with a pregnant household member is not a contraindication to vaccination.

  If vaccination of an unknowingly pregnant woman occurs or if she becomes pregnant within four weeks of varicella vaccination, she should be counseled about the theoretical basis of concern for the fetus. However, varicella vaccination during pregnancy should not be regarded as a reason to terminate pregnancy. The manufacturer and CDC have established a Varivax Pregnancy Registry to monitor outcomes of women who received the vaccine three months before or any time during pregnancy. Call 800-986-8999.

  Varicella zoster immune globulin (VZIG) should be strongly considered for susceptible, pregnant women who have been exposed to varicella vaccine.

• **Zoster (Shingles)**
  Varicella zoster vaccine should not be administered to individuals who are or may be pregnant. It is not known if varicella zoster vaccine can cause fetal harm when administered during pregnancy. However, since naturally occurring VZV infection is known to sometimes cause fetal harm, varicella zoster vaccine should not be administered to pregnant women. Pregnancy should be avoided for three months following vaccination.

  VZIG should be strongly considered for susceptible, pregnant women who have been exposed to herpes zoster vaccine.

The following vaccines are not recommended during pregnancy but **not contraindicated:**

• **Hepatitis A**
  Hepatitis A vaccine is produced from inactivated hepatitis A virus, so the theoretical risk to the developing fetus is expected to be low. Weigh risk associated with vaccination against the risk for hepatitis A in pregnant women who may be at high risk for exposure to hepatitis A virus. This is an inactivated vaccine that is neither contraindicated nor a precaution, so if it is indicated it should be administered.

• **Human Papillomavirus (HPV)**
  HPV vaccines are not recommended for use in pregnant women. However, pregnancy testing is not needed before vaccination. Exposure to vaccine during pregnancy should be reported to the appropriate vaccine pregnancy registry:
    - For quadrivalent HPV vaccine, contact Merck at 1-800-986-8999.
    - For bivalent HPV vaccine, contact GlaxoSmithKline at 1-888-452-9622.

• **Meningococcal (MCV4-conjugate)**
  There is no data on the safety of MCV4 during pregnancy. Women of childbearing age who become aware that they were pregnant at the time of MCV4 vaccination should contact their health care provider or the vaccine manufacturer. If the vaccine is indicated it should be administered.

• **Pneumococcal (PPV23)**
  Although the safety of pneumococcal polysaccharide vaccine during the first trimester of pregnancy has not been evaluated, no adverse consequences have been reported among newborns whose mothers were inadvertently vaccinated during pregnancy. If the vaccine is indicated it should be administered.
• Polio (IPV)
Even though no adverse effects of IPV vaccination have been documented among pregnant women or their fetuses, ACIP recommends that vaccination of pregnant women should be avoided on theoretical grounds. However, if a pregnant woman is at increased risk for infection and requires immediate protection against polio, IPV can be administered.

• Tetanus, Diphtheria, and Pertussis (Tdap)
Pregnancy is not a contraindication for use of Tdap. However, if Tdap is administered during pregnancy, transplacental maternal antibodies might protect the infant against pertussis in early life but they also might interfere with the infant’s immune response to infant doses of DTaP and leave the infant less well protected against pertussis. When Tdap is given during pregnancy, the second or third trimester is preferred timing for administration.

Report Tdap administrations regardless of the trimester, to the manufacturer’s pregnancy registry.
- For Boostrix, contact GlaxoSmithKline Biologicals at 1-888-825-5249.
- For Adacel, call Sanofi Pasteur at 1-800-822-2463.

There can be situations in which potential of increased risk for pertussis might prompt health care providers to administer Tdap instead of Td to ensure pertussis protection. Individuals who may be considered for pertussis vaccination during pregnancy include:
- pregnant health care workers and child care providers to prevent transmission to infants younger than 12 months of age and to other vulnerable persons and
- pregnant women employed in an institution or living in a community with increased pertussis activity

TRAVEL VACCINES
• Japanese Encephalitis (JE)
No specific information is available on the safety of JE vaccine in pregnancy. Vaccination poses an unknown but theoretical risk to the developing fetus, and the vaccine should not be routinely administered during pregnancy.

Pregnant women who must travel to an area where risk of JE is high should be vaccinated when the theoretical risks of immunization are outweighed by the risk of infection to the mother and developing fetus.

• Typhoid
No data have been reported on the use of any of the three typhoid vaccines among pregnant women.

• Yellow Fever (YF17D)
YF17D is a live, viral vaccine. The safety of yellow fever vaccination during pregnancy has not been established. The vaccine should be administered only if travel to an endemic area is unavoidable and if an increased risk for exposure exists.

Infection of the fetus with YF17D apparently occurs at a low rate and has not been associated with congenital anomalies.

If international travel requirements are the only reasons to vaccinate a pregnant woman rather than an increased risk of infection, efforts should be made to obtain a waiver letter from the traveler’s physician.

Pregnant women who must travel to areas where the risk of yellow fever is high should be vaccinated. Despite the apparent safety of this vaccine, infants born to these women should be monitored closely for evidence of congenital infection and other possible adverse effects resulting from yellow fever vaccination.

If vaccination of a pregnant woman is deemed necessary, serologic testing to document an immune response to the vaccine can be
considered. The seroconversion rate for pregnant women in a developing nation has been reported to be substantially lower than that observed for other healthy adults and children. To discuss the need for serologic testing, contact:

- The appropriate state health department, or
- The Division of Vector-Borne Infectious Diseases at 1-970-221-6400, or
- The CDC’s Division of Global Migration and Quarantine at 1-404-498-1600.

VACCINES NOT ROUTINELY RECOMMENDED IN THE UNITED STATES

Anthrax
No studies have been published regarding use of anthrax vaccine among pregnant women. Pregnant women should be vaccinated against anthrax only if the potential benefits of vaccination outweigh the potential risks to the fetus.

Bacillus Calmette-Guerin (BCG)
Although no harmful effects to the fetus have been associated with BCG vaccine, its use is not recommended during pregnancy.

Vaccinia (Smallpox)
Live-viral vaccines are contraindicated during pregnancy; therefore, vaccinia vaccine should not be administered to pregnant women for routine non-emergency indications.

However, vaccinia vaccine has not been shown to cause congenital malformations. Although fewer than 50 cases of fetal vaccinia infection have been reported, vaccinia virus has been reported to cause fetal infection on rare occasions, almost always after primary vaccination of the mother.

Pregnant women who have had a definite exposure to smallpox virus (i.e., face-to-face, household, or close-proximity contact with a smallpox patient) and are, therefore, at high risk for contracting the disease, should be vaccinated.

Smallpox infection among pregnant women has been reported to result in a more severe infection than among nonpregnant women. Therefore, the risks to the mother and fetus from experiencing clinical smallpox substantially outweigh any potential risks regarding vaccination. In addition, vaccinia virus has not been documented to be teratogenic, and the incidence of fetal vaccinia is low.

When the level of exposure risk is undetermined, the decision to vaccinate should be made after assessment by the clinician and the patient of the potential risks versus the benefits of smallpox vaccination.

For more information, refer to www.cdc.gov/vaccines/pubs/preg-guide.htm.
<table>
<thead>
<tr>
<th>VACCINE</th>
<th>SHOULD BE CONSIDERED IF OTHERWISE INDICATED</th>
<th>CONTRAINDED DURING PREGNANCY</th>
<th>SPECIAL/CONDITIONAL RECOMMENDATION (see text)</th>
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<tbody>
<tr>
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<tr>
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<td>See Hepatitis A, page 64</td>
</tr>
<tr>
<td>Hepatitis B</td>
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<td>Human Papillomavirus (HPV)</td>
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<td>Influenza (Inact.)</td>
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<tr>
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<td>Rubella*</td>
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<tr>
<td>BCG*</td>
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<tr>
<td>Japanese Encephalitis</td>
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<td>See page 81</td>
</tr>
<tr>
<td>Meningococcal (MPSV4)</td>
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<td>See page 81</td>
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<tr>
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</tr>
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</tr>
<tr>
<td>Zoster*</td>
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</table>

* Live virus vaccine
Immunocompromised Persons

Increasing numbers of Americans are considered immunocompromised to various degrees for different reasons—conditions that are disease-based (e.g., chronic kidney disease), infection-based (e.g., HIV infection), treatment-based (e.g., radiation, chemotherapy, disease-modifying agents and biologicals), asplenia (surgical or disease-induced), or because of solid organ or bone marrow transplantation. Regardless of cause, immunocompromised persons can have significantly elevated risks for both incidence and severity of multiple invasive infections, many of which are vaccine preventable. However, those persons most severely immunocompromised and most in need of vaccines may not have an effective and protective immunologic response to a vaccine. Nonetheless, administration of vaccine, in the absence of known harm, is generally worthwhile, given that some protection to some recipients may result.

Because each condition that may cause immunosuppression is unique, it’s important to consider the specific immunocompromising condition and the context of the particular patient. In addition, it may be necessary to consult with a vaccinologist or infectious disease specialist for patients with more complex clinical issues. Finally, it is highly advised that physicians consult the ACIP guidelines for the use of vaccines in immunocompromised persons due to the increasing pace of research in this area, expansion in the number of new vaccines available, and the difficulty in making specific recommendations for the myriad of immunocompromising conditions in specific clinical situations.

Clinicians are advised to consult the ACIP General Recommendations on Immunization monograph with particular attention to the section of “Altered Immunocompetence” at www.cdc.gov/mmwr/preview/mmwrhtml/rr5515a1.htm.

The increasing availability of immunosuppressant medications (e.g., tumor necrosis factor-alpha inhibitors) adds further complexity to vaccine decisions because vaccine immunogenicity and safety have not usually been studied with concomitant use of one or more of these medications. Further, there is an insufficient knowledge base regarding the differential utility of vaccine-induced humoral and cellular immunity for many vaccines. Nonetheless, for some vaccines, such as hepatitis A and B, serologic correlates of protection exist. Because of this uncertainty, it is recommended that clinicians measure antibody levels to ascertain post-immunization immune status.

For certain vaccines (e.g., oral polio vaccine, which is not currently used in the United States, and LAIV influenza), it is important to ascertain whether anyone in the household or close contacts of the patient receiving the vaccine are immunocompromised or have altered immunocompetence before deciding to vaccinate.
INDICATIONS
The indications for the use of vaccines in immunocompromised persons depends upon the following considerations:

• Specific infectious disease risks that reflect the underlying condition or cause for immunosuppression
• Degree of immunosuppression
• Duration of immunosuppression
• Other usual considerations (age, occupation, lifestyle, etc.) for any vaccine

CONTRAINDICATIONS

• Absolute: Previous or known severe allergic reaction to any component of the vaccine, as is the case for all vaccines. For vaccine-specific contraindications based on degree of immunosuppression, please consult individual vaccine recommendations. In general (there are exceptions), the use of live viral and live bacterial (Ty21a) vaccines is contraindicated for immunosuppressed individuals.

• Relative: A moderate or severe acute illness on the day the immunization is planned. Wait until the illness resolves, if feasible.

ADMINISTRATION
See specifics for each individual vaccine being considered. In many cases, knowledge of CD4+ counts may be necessary in order to make a judgment regarding the safety of vaccine administration. Clinicians are advised to consult the ACIP’s General Recommendations on Immunization monograph with particular attention to the section of “Altered Immunocompetence” at www.cdc.gov/mmwr/preview/mmwrhtml/rr5515a1.htm.

POSSIBLE SIDE EFFECTS
Side effects are the same as for non-immunocompromised persons, with the exception of live viral vaccines.

Increased risks for live viral vaccines primarily relate to the dissemination of live virus and the inability of the individual’s immune system to control the vaccine-induced infection. For example, the administration of live measles virus vaccine to an HIV-infected person could potentially result in measles pneumonitis and death.

Note and communicate to patients that vaccine immunogenicity and conferred protection may be lower than for an immunocompetent person depending upon the degree and duration of immunosuppression. This consideration applies to all vaccines.

STORAGE/HANDLING
See specifics for each vaccine. Vaccine storage policies and specifics are identical for normal and immunocompromised host vaccine recipients.

PREGNANCY/NURSING
See specifics for each vaccine.

REIMMUNIZATION/BOOSTER
Recommendations for reimmunization of immunocompromised persons are specific to each vaccine. See individual vaccine recommendations.

CPT CODES/REIMBURSEMENT ISSUES
See specifics for each vaccine.
FAQs

Q: Can HIV-infected persons receive live viral vaccines?
Recommendations for HIV-infected hosts depend upon the specific vaccine and often the degree to which the individual is immunocompromised using proxy measures such as total CD4+ count. Therefore, the recommendations for each specific vaccine should be consulted in the case of immunocompromised hosts.

Q: What live viral vaccines are currently licensed and used in the United States?
Measles, mumps, rubella, varicella, herpes zoster, live attenuated influenza, smallpox, and yellow fever vaccines are live viral vaccines. Additionally, rotavirus vaccine is a live vaccine but is recommended for infants only.

Q: What live bacterial vaccines are licensed and used in the United States?
Oral typhoid vaccine (Ty21a) and Bacillus Calmette-Guerin (BCG) vaccine are live bacterial vaccines.

Q: What dose of corticosteroid is considered immunosuppressive?
In general, the use of a steroid dose equivalent of either >2 mg/kg of body weight or 20 mg/day of prednisone or equivalent for persons who weigh >10 kg when administered for >2 weeks is thought to induce immunosuppression. ACIP states that “vaccination providers should wait at least one month after discontinuation of high-dose systemically-absorbed corticosteroid therapy administered for more than two weeks before administering a live virus vaccine.”

Q: Where can more detailed information be found on the use of vaccines in persons with altered immunocompetence?
The recommendations for each individual vaccine contains indications for the use of the vaccine in such cases. In addition, the ACIP monograph on General Recommendations on Immunization contains a comprehensive section on the use of vaccines in such circumstances.
Patients with Anatomical or Functional Asplenia

Adults with asplenia from any cause are at increased risk of infection with encapsulated bacteria (*S. pneumonia, N. meningitidis, H. influenza type b*) bacterial infections.

INDICATIONS

Persons with anatomic or functional asplenia should receive the following vaccines:

- Pneumococcal vaccine
- Quadrivalent meningococcal vaccine
- Inactivated seasonal influenza vaccine
- Possibly Haemophilus influenzae type b (Hib) vaccine. The current ACIP recommendations note that "no efficacy data are available on which to base a recommendation about use of Hib vaccine for older children and adults with the chronic conditions associated with an increased risk for Hib disease. However, studies suggest good immunogenicity in patients who have sickle cell disease or have had splenectomies; administering Hib vaccine to these patients is not contraindicated." (*General Recommendations on Immunizations: Recommendations of the ACIP*, MMWR, December 1, 2006, www.cdc.gov/mmwr/pdf/rr/rr5515.pdf)
- Any other vaccines, such as Tdap or HPV, for which particular persons with asplenia might be indicated, for reasons unrelated to their asplenia.

CONTRAINDICATIONS

Asplenia does not increase the risks of vaccination for any vaccine; the only contraindications are those unique to a specific vaccine itself.

ADMINISTRATION

Each vaccine should be administered according to recommendations specific to that vaccine—there are no special rules or changes unique to vaccinating people with asplenia.

If a vaccine requires more than one dose and the schedule is interrupted, the series does not have to be restarted.

Pneumococcal, meningococcal, and Hib vaccines should ideally be given at least two weeks before elective splenectomy, whenever possible. If this is not feasible, it is generally advisable to administer such vaccines after medical stabilization and recovery.

POSSIBLE SIDE EFFECTS

There are no special side effects unique to patients with asplenia. The side effect profile is particular to each specific vaccine as noted in the package insert for each vaccine.

STORAGE/HANDLING

Each unique vaccine should be handled, stored, and administered according to the manufacturer’s instructions.

PREGNANCY/NURSING

Consult the package insert for each specific vaccine.
REIMMUNIZATION/BOOSTER
Inactivated influenza vaccine should be administered every year. Polysaccharide pneumococcal vaccine should be re-administered one time, five years after the original immunization. Polysaccharide quadrivalent meningococcal vaccine (MPSV4) needs to be re-administered every three to five years, while the conjugate meningococcal vaccine (MCV4) is only administered once in persons age 16 or older, with a one-time booster for patients with asplenia. MCV4 can be used in persons age 55 years and younger, while MPSV4 is preferred for those 56 years and older. Hib vaccines in the U.S. are all conjugated and only one lifetime dose is needed.

FAQs

Q: Are patients with asplenia at increased risk of a vaccine side effect?
No. The vaccine side effect profile for each vaccine is the same as that of non-asplenic.

Q: Would a patient with sickle cell anemia be considered to have functional splenia?
Yes. Because of the possibility of symptomatic and asymptomatic splenic infarcts, splenic function can be diminished, and hence such patients should be immunized appropriately.

Q: Are any vaccines contraindicated for patients with asplenia?
No. The only contraindications would be those otherwise true of any potential vaccine recipient.
Childhood Catch-up

Many adults do not have a record or knowledge of the vaccines they received in childhood. Whenever there is a question about a patient’s vaccination status, in the absence of contraindication/allergy to a vaccine (or vaccine component) and immunization data (which should indicate, at a minimum, the date and vaccine product administered), the vaccine in question should be administered.

International vaccines are most often well tested and reliable. Their documented administration—a standard similar to childhood vaccination requirements is recommended—should be accepted as proof of immunization. However, if there are concerns such as the accuracy of immunization documentation, lack of vaccine potency, disease history, or serologic testing, re-immunization with age- and disease-appropriate vaccines is recommended.

The underlying principle is that immunization is recommended in the presence of uncertain data. There is no evidence of harm associated with duplicate immunization and there is significant risk to the individual and to the community associated with under-immunization.

The CDC offers a downloadable adult immunization scheduler tool at: http://www.cdc.gov/vaccines/recs/Scheduler/AdultScheduler.htm.
# ADULT CATCH-UP VACCINES AT A GLANCE

<table>
<thead>
<tr>
<th>VACCINE</th>
<th>CATCH-UP</th>
<th>ADULT BOOSTER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tetanus, Diphtheria, Pertussis</td>
<td>2 Td doses + 1 Tdap over 6 months (0, 1 mo, 6 mo)</td>
<td>Td every 10 years</td>
</tr>
<tr>
<td>MMR</td>
<td>2 doses (or 1 dose if one in childhood)*</td>
<td>None</td>
</tr>
<tr>
<td>Varicella</td>
<td>2 doses (or 1 dose if one in childhood)*</td>
<td>None</td>
</tr>
<tr>
<td>Polio</td>
<td>Selected at-risk adults</td>
<td>Selected at-risk adults, including international travelers to places such as India, parts of Africa, and eastern Europe</td>
</tr>
<tr>
<td>Influenza</td>
<td>None</td>
<td>Annual vaccination</td>
</tr>
<tr>
<td>HPV</td>
<td>For women up to age 26, 3 doses (bivalent or quadrivalent) over 6 months; consider quadrivalent in men to age 26</td>
<td>None</td>
</tr>
<tr>
<td>Pneumococcal (PPSV23)</td>
<td>1 dose in at-risk patients</td>
<td>1 booster at 5 years only for specific indications</td>
</tr>
<tr>
<td>Meningococcal</td>
<td>MCV 1 dose if certain medical conditions or freshman college dorm resident</td>
<td>Booster only if vaccinated &gt; 5 years prior and remain at increased risk for meningococcal disease</td>
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<tr>
<td>Hepatitis A</td>
<td>Selected at-risk adults</td>
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</tr>
<tr>
<td>Hepatitis B</td>
<td>Selected at-risk adults</td>
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</tr>
</tbody>
</table>

* See Adult Schedule for details at www.cdc.gov/vaccines/recs/schedules/adult-schedule.htm
Specific vaccine recommendations:

**TD/Tdap**
- Childhood Recommendation:
  - 4 DTaP by age 18 months, booster 5th dose at 4 through 6 years
  - 1 Tdap at 11-12 years (if not given, should be given at 13-18 years)
- Catch Up Required:
  - < 3 tetanus-containing vaccines before age 18 years
- Catch-Up Schedule:
  - 3 doses: initial visit, then 1 month and 6 months following initial dose
  - Tdap suggested for first dose followed by Td for the subsequent 2 doses; although any order is acceptable
- Booster:
  - Td booster every 10 years (see Td/Tdap Section, p. 49)
  - Tdap booster for all adults (regardless of age) who have not previously received pertussis-containing vaccine in their adult lives

**MMR**
- Childhood Recommendation:
  - 2 doses MMR (or MMRV vaccine) usually at 1 year and 4 through 6 years
- Catch Up Required:
  - < 2 doses MMR before age 18 years
- Catch-Up Schedule:
  - A total of 2 doses separated by at least 28 days in non-pregnant adult (this includes doses received in childhood)
  - None

**Varicella**
- Childhood Recommendation:
  - 2 doses varicella vaccine usually administered at 1 year and 4 through 6 years
  - clinician-diagnosed varicella
  - seropositive (IgG) for varicella
- Catch Up Required:
  - < 2 doses varicella before age 18 years and no evidence of prior varicella
- Catch-Up Schedule:
  - 2 doses separated by at least 28 days in non-pregnant adult (this includes doses received in childhood)
  - None

**Polio**
- Childhood Recommendation:
  - 3 doses IPV (or combination vaccine containing polio) before age 12 months followed by booster dose at 4+ years
- Catch Up Required:
  - As there is no native poliomyelitis in the United States, only U.S. adults at increased risk of polio exposure (e.g., travelers to areas where polio is endemic or epidemic, in an outbreak setting, and laboratory and health care workers potentially exposed to poliovirus) warrant catch-up polio vaccination
- Catch-Up Schedule:
  - 3 doses IPV given at initial visit, 1 to 2 months later and then 4 through 6 months; accelerated schedule with doses given at 4-week intervals is acceptable
• Booster:
  - No routine booster
  - IPV booster is recommended one time only in adults who received a childhood series and who may be at risk due to travel or laboratory exposure

HPV
• Childhood Recommendation:
  - 3-dose series for girls and women between ages 9 and 26 years (either bivalent or quadrivalent vaccine) ideally prior to any sexual activity
  - 3-dose series may be considered for boys and men between ages 9 and 26 years (quadrivalent vaccine only), ideally administered prior to any sexual activity.

• Catch Up Required:
  - Less than a 3-dose series for women up to age 26 who have not previously been vaccinated

• Catch-Up Schedule:
  - 3 doses at initial visit, 2 months, and 6 months
  - No need to reinitiate series for delayed completion

• Booster:
  - None

Other: See HPV Section, p. 58

MENINGOCOCCAL VACCINE
• Childhood Recommendation:
  - 1 dose of meningococcal conjugate vaccine in children at 11 to 12 years, or at 13 to 18 years if not previously vaccinated

• Catch Up Required:
  - 1 dose recommended for previously unvaccinated adults prior to travel to areas with endemic meningococcal disease. (For more information see the CDC’s Health Information for International Travel [“The Yellow Book”] at www.cdc.gov/travel/content/yellowbook/home-2010.aspx)

• Catch-Up Schedule:
  - 1 dose of meningococcal conjugate in adults with indications

• Booster:
  - 1 dose of meningococcal conjugate vaccine is recommended in persons who received meningococcal polysaccharide or conjugate vaccine 5 years or more previously and who remain at increased risk of meningococcal disease

Other: See Meningococcal Section, p. 61

HEPATITIS A
• Childhood Recommendation:
  - 2 doses of hepatitis A vaccine separated by a minimum of 6 months

• Catch Up Required:
  - No routine recommendation for hepatitis A vaccination in adults
  - Recommended in unvaccinated adults with specific medical and behavioral risks
  - Recommended for travelers to endemic regions.

• Catch-Up Schedule:
  - 2 doses at least 6 months apart
  - No need to restart series if completion is delayed

• Booster:
  - None

Other: See Hepatitis A Section, p. 64
FAQs

Q: Can multiple vaccines be administered on the same day?
Multiple routine vaccines may be administered on the same day, but should be given using separate needles and at separate sites. If two vaccines are to be given in the same extremity, the injections should be given at sites separated by at least one inch to help the clinician determine the cause if there is a local reaction.

Q: Are there additional considerations required regarding live-virus vaccines?
Live virus vaccines (injectable or intranasal) that are not given on the same day should be given at least 28 days apart if possible, due to data indicating a possible reduction in efficacy for the vaccinations administered.

Q: Why are combination vaccines preferred to single vaccine products?
Combination vaccines (when available) may increase patient acceptance and increase immunization rates. If one component of the vaccine is not needed, the combination vaccine may still be used if it will decrease the number of injections and there is no contraindication to the additional component.

Q: If a series of vaccines is initiated but not completed, does the series need to be started again?
If a vaccine series has not been completed, it does not have to be completely restarted. The sole current exception to this is oral typhoid vaccine.

Q: Does the administration of blood products affect vaccines and vaccination timing?
Immune globulin and blood products can diminish immunogenicity of MMR and varicella vaccine when the immune globulin is given within 14 days after the vaccine or during a certain time period before. The length of time that antibody-containing products can interfere with immunogenicity varies from three to 11 months depending on the particular product and the dose. (See Figure 1, p. 95.) If immune globulin or blood products were given when it may have interfered with the immunogenicity of the vaccine, consider re-immunizing or checking serologies after the appropriate period. This does not apply to washed red blood cells. If giving a vaccine and immunoglobulin at the same time (as with rabies), use different needles/syringes and different sites.

FAQs continue on next page
Q: Are there any interactions between TST and vaccines?
TST may be placed at the same time that live-virus vaccines are given without affecting reactivity. Measles vaccine may suppress tuberculin reactivity for four weeks, so delaying the TST for at least four weeks after MMR is recommended when possible. The effects of live viruses on interferon-release assays for Mycobacterium tuberculosis are unknown. The effects of other live-virus vaccines are also unknown; therefore, the same spacing is recommended for these entities.

Q: Are there specific medical illnesses which would require delay in or avoidance of specific vaccines?

**Tuberculosis:** Delay MMR in patients with untreated, active TB until they have started treatment due to theoretical concerns for the measles vaccine affecting cell-mediated immunity which could, in theory, worsen the tuberculosis illness. A similar concern exists for other live-virus vaccines including varicella and zoster vaccines; although this has not been specifically studied.

HIV: HIV patients with CD4 counts of less than 200 cells/mm\(^3\) may not have an appropriate immune response to vaccines; therefore vaccination should, in most cases, be delayed until the CD4 count has been improved to greater than this level. There is also a concern about administration of live-virus vaccines to HIV patients with low CD4 counts.

**Immunosuppression due to malignancy or immunosuppressive medications:** Live virus vaccines should not be administered in most circumstances.

Q: What vaccines are specifically recommended prior to college entry?
All vaccines should be up-to-date in concordance with the patient’s age. Most important for disease prevention in college settings would be vaccination to prevent influenza, Tdap, MMR, varicella, and meningococcal disease. Many colleges have specific pre-matriculation vaccine requirements, and require institution-specific documentation. The American College Health Association’s recommendations for universities are available at [www.acha.org](http://www.acha.org).
**FIGURE 1. SUGGESTED INTERVALS BETWEEN ADMINISTRATION OF ANTIBODY-CONTAINING PRODUCTS FOR DIFFERENT INDICATIONS AND MEASLES-CONTAINING VACCINE AND VARICELLA-CONTAINING VACCINE**

<table>
<thead>
<tr>
<th>PRODUCT/INDICATION</th>
<th>DOSE, INCLUDING mg IMMUNOGLOBULIN G (lgG)/kg BODY WEIGHT</th>
<th>RECOMMENDED INTERVAL BEFORE MEASLES OR VARICELLA-CONTAINING VACCINE ADMINISTRATION (months)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respiratory syncytial virus immune globulin (IG) monoclonal antibody (Synagis™)*</td>
<td>15 mg/kg intramuscularly (IM)</td>
<td>None</td>
</tr>
<tr>
<td>Tetanus IG</td>
<td>250 units (10 mg lgG/kg) IM</td>
<td>3</td>
</tr>
<tr>
<td>Hepatitis A IG</td>
<td>- Contact prophylaxis: 0.02 mL/kg (3.3 mg lgG/kg) IM</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>- International travel: 0.06 mL/kg (10 mg lgG/kg) IM</td>
<td>3</td>
</tr>
<tr>
<td>Hepatitis B IG</td>
<td>0.06 mL/kg (10 mg lgG/kg) IM</td>
<td>3</td>
</tr>
<tr>
<td>Rabies IG</td>
<td>20 IU/kg (22 mg lgG/kg) IM</td>
<td>4</td>
</tr>
<tr>
<td>Measles prophylaxis IG</td>
<td>- Standard contact: 0.25 mL/kg (40 mg lgG/kg) IM</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>- Immunocompromised contact: 0.50 mL/kg (90 mg lgG/kg) IM</td>
<td>6</td>
</tr>
<tr>
<td>Blood transfusion</td>
<td>- Red blood cells (RBCs), washed: 10 mL/kg negligible lgG/kg intravenously (IV)</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td>- RBCs, adenine-saline added: 10 mL/kg (10 mg lgG/kg) IV</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>- Packed RBCs (hematocrit 65%): 10 mL/kg (60 mg lgG/kg) IV</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>- Whole blood (hematocrit 35%-50%): 10 mL/kg (80-100 mg lgG/kg) IV</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>- Plasma/platelet products: 10 mL/kg (160 mg lgG/kg) IV</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td>- Cytomegalovirus intravenous immune globulin (IGIV): 150 mg/kg maximum</td>
<td>6</td>
</tr>
<tr>
<td>IGIV</td>
<td>- Replacement therapy for immune deficiencies¶</td>
<td>300-400 mg/kg IV¶</td>
</tr>
<tr>
<td></td>
<td>- Immune thrombocytopenic purpura: 400 mg/kg IV</td>
<td>8</td>
</tr>
<tr>
<td></td>
<td>- Postexposure varicella prophylaxis†</td>
<td>400 mg/kg IV</td>
</tr>
<tr>
<td></td>
<td>- Immune thrombocytopenic purpura: 1000 mg/kg IV</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>- Kawasaki disease: 2 g/kg IV</td>
<td>11</td>
</tr>
</tbody>
</table>

*This table is not intended for determining the correct indications and dosages for using antibody-containing products. Unvaccinated persons might not be fully protected against measles during the entire recommended interval, and additional doses of immune globulin or measles vaccine might be indicated after measles exposure. Concentrations of measles antibody in an immune globulin preparation can vary by manufacturer's lot. Rates of antibody clearance after receipt of an immune globulin preparation also might vary. Recommended intervals are extrapolated from an estimated half-life of 30 days for passively acquired antibody and an observed interference with the immune response to measles vaccine for 5 months after a dose of 80 mg lgG/kg.

†Contains antibody only to respiratory syncytial virus

§Assumes a serum IgG concentration of 16 mg/mL

¶Measles and varicella vaccinations are recommended for children with asymptomatic or mildly symptomatic human immunodeficiency virus (HIV) infection but are contraindicated for persons with severe immunosuppression from HIV or any other immunosuppressive disorder.

†The investigational product VarizIG, similar to licensed VZIG, is a purified human immune globulin preparation made from plasma containing high levels of anti-varicella antibodies (immunoglobulin class G [lgG]). When indicated, health care providers should make every effort to obtain and administer VarizIG. In situations in which administration of VarizIG does not appear possible within 96 hours of exposure, administration of immune globulin intravenous (IGIV) should be considered as an alternative. IGIV also should be administered within 96 hours of exposure. Although licensed IGIV preparations are known to contain anti-varicella antibody titters, the titer of any specific lot of IGIV that might be available is uncertain because IGIV is not routinely tested for antivaricella antibodies. The recommended IGIV dose for postexposure prophylaxis of varicella is 400 mg/kg administered once. For pregnant women who cannot receive VarizIG within 96 hours of exposure, clinicians can choose either to administer IGIV or closely monitor the woman for signs and symptoms of varicella and institute treatment with acyclovir if illness occurs. (Source: CDC. A new product for postexposure prophylaxis available under an investigational new drug application expanded access protocol. MMWR 2006;55:209-10).
Health Care Workers (HCWs)

INDICATIONS
By virtue of direct or indirect patient contact, HCWs can be both at risk for acquiring vaccine-preventable diseases, and/or for transmitting such diseases to the patients with whom they interact. Recent U.S. outbreaks of pandemic influenza, annual seasonal influenza, pertussis, and measles remind all HCWs of the seriousness of protecting both our patients and ourselves against vaccine-preventable diseases.

In particular, over the last decade, there has been increasing awareness of the role HCWs play in protecting the patients under their care by ensuring that all HCWs receive the annual influenza immunization. The scientific, legal, and ethical foundations for such requirements have been well documented and published. Currently four randomized clinical trials have demonstrated decreased patient morbidity and mortality when the HCWs caring for them received influenza immunization. Notably, all U.S.-based infectious disease professional organizations (the Infectious Disease Society of America and the National Foundation for Infectious Diseases), all U.S.-based infection control professional organizations (the Association for Professionals in Infection Control and the Society for Healthcare Epidemiology of America), all major U.S. primary care professional organizations (ACP, AAP, AMA), and the National Patient Safety Foundation endorse mandatory annual influenza immunization of HCWs. Many additionally note that immunization is a condition of initial employment and of continuing employment and professional privileges.

All HCWs should consider it an ethical and moral obligation to protect the patients they care for from transmissible infectious diseases by receiving such vaccines themselves, and by following all recommended infection control measures.

Absent an individual contraindication, all HCWs should routinely receive the following vaccines:

- Acellular pertussis booster (one time dose)
- Hepatitis B (3-dose series) and laboratory confirmation of seroconversion
- MMR vaccine (2-dose series) unless laboratory evidence of immunity
- Monovalent pandemic influenza vaccine (when appropriate and recommended)
- Influenza vaccine (annually)
- Varicella (2 doses) unless laboratory evidence of immunity

Some HCWs may have job responsibilities that place them at risk for other diseases for which vaccines exist. These may include:

- Vaccinia vaccine for laboratory workers who work with orthopox viruses, and first response clinical teams
- Hepatitis A vaccine for HCWs who travel to disaster areas in endemic areas to provide clinical care or who work with this virus in laboratory settings
- Meningococcal vaccine for those who work with this bacteria in laboratory settings or provide clinical care in highly endemic areas of the world
- Rabies vaccine for veterinary workers and animal research and for those HCWs who provide care in rabies endemic settings
- Anthrax vaccine for specific civilian and Department of Defense HCWs who either work in a laboratory setting with this bacteria or who are deployed to specific geographic regions where such vaccine is required by the authorities
- Polio vaccine for those who work in polio-active geographic regions or who receive patients from these locations
- Typhoid vaccine for laboratory workers and those clinical staff who work in typhoid-risk areas
CONTRAINDICATIONS
Other than individual potential medical contraindications to a specific vaccine, HCWs as a group have no specific contraindications to any of the vaccines routinely recommended for them. However, it is preferred that HCWs taking care of patients sufficiently immunocompromised who are in reverse isolation thus take inactivated, rather than live, influenza vaccines. If, on the other hand, live influenza vaccines are the only vaccine available, such HCWs may use live influenza vaccine but take the precaution of wearing a mask for seven days afterwards when in contact with such patients. (See p. 43 for LAIV vaccine recommendations.)

ADMINISTRATION
Each vaccine should be administered according to recommendations specific to that vaccine. There are no special rules or changes unique to vaccinating HCWs.

If a vaccine requires more than one dose and the schedule is interrupted, the series does not have to be restarted.

POSSIBLE SIDE EFFECTS
There are no special side effects unique to HCWs. The side effect profile is particular to each specific vaccine as noted in the package insert for each vaccine.

STORAGE/HANDLING
Each unique vaccine should be handled, stored, and administered according to the manufacturer’s instructions.

PREGNANCY/NURSING
See the package insert for each specific vaccine. This can be a particularly important issue given that the age structure of HCWs is heavily weighted toward younger females where such concerns are important to acknowledge and understand. No pregnancy contraindications exist for receiving hepatitis B vaccines, inactivated influenza vaccines, or acellular pertussis vaccines. It is recommended that live attenuated influenza vaccines be avoided in pregnant women. MMR and varicella vaccines should be administered at least 30 days before pregnancy or after pregnancy has ended.

REIMMUNIZATION/BOOSTER
Hepatitis B: After the recommended 3-dose series, no further doses or boosters are needed for hepatitis B vaccine. However, given the importance of HBV immunity and implications for further vaccination and/or post-exposure prophylaxis, all HCWs should have an anti-HBs antibody performed four to eight weeks after dose 3 to ensure immunity. If immunity is not achieved, additional doses of hepatitis B should be given according to a published algorithm.

• Influenza: Annual influenza immunization is needed.

• MMR: Two doses of MMR vaccine are required for HCWs (see p. 71 for MMR vaccine recommendations). A past history of disease is no longer considered adequate evidence of immunity.

• Pertussis: Acellular pertussis vaccine may be given at any interval after a previous Td booster, and is only recommended one time according to current recommendations. Two doses of varicella vaccine are required. Whether further doses of varicella vaccine will be required is currently unknown.

• Varicella: There are no current recommendations for booster doses at this time.
FAQs

Q: Are HCWs at increased risk of pertussis?
Yes. Pertussis is a moderately transmissible disease. Without booster immunization, HCWs no longer have immunity from the DTP series they received as children. The ACIP recommends that all HCWs should receive a single dose of Tdap as soon as feasible if they have not previously received Tdap.

Q: Should a pregnant HCW receive influenza vaccine?
Yes. Both because of the likelihood of self-exposure and the risk of transmitting influenza to compromised and elderly patients all HCWs should receive annual influenza immunization as well as adhere to other infection control measures. In particular, pregnant HCWs may safely receive TIV at any stage of pregnancy. LAIV is contraindicated during pregnancy.

Q: Are HCWs at increased risk for hepatitis A or meningococcal disease?
No. As long as the recommended infection control measures are followed, HCWs are not at increased risk for these diseases despite taking care of patients with these diseases. HCWs who provide mouth-to-mouth resuscitation to a patient with active meningococcal infection are at increased risk and should be treated with appropriate antibiotics.
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