

**For pediatricians, physicians, nurses,
medical assistants, and office managers**



DEDICATED TO THE HEALTH OF ALL CHILDREN®



Immunization Training Guide & Practice Procedure Manual

**For pediatricians, physicians, nurses,
medical assistants, and office managers**

This training guide is designed to assist pediatric office staff in all aspects of immunizing a practice's patients. Use this guide to educate and properly train physicians, nurse practitioners, physician assistants, nurses, medical assistants, office managers, and other office staff. Consider having staff responsible for various activities read through the most relevant portions of this guide. While reading through the guide, use the text box fields to fill in personal notes, policies, and state-specific contact information.

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American Academy of Pediatrics








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Index of Abbreviations, Vaccines, and Terms

Abbreviations

AAP: American Academy of Pediatrics
 ACIP: Advisory Committee on Immunization Practices
 AIRA: American Immunization Registry Association
 ASP: average sales price
 AWP: average wholesale price
 CDC: Centers for Disease Control and Prevention
 CHOP: Children's Hospital of Philadelphia
 CMS: Centers for Medicare & Medicaid Services
 CPT®: *Current Procedural Terminology*
 EHR: electronic health record
 FDA: Food and Drug Administration
 GPO: group purchasing organization
 HIPAA: Health Insurance Portability and Accountability Act of 1996
 HRSA: Health Resources and Services Administration
 IAC: Immunization Action Coalition
 ICD-10-CM: *International Classification of Diseases, Tenth Revision, Clinical Modification*
 IIS: immunization information system
 IM: intramuscular; intramuscularly
 MI: motivational interviewing
 NVAC: National Vaccine Advisory Committee
 NVICP: National Vaccine Injury Compensation Program
 OIG: Office of Inspector General
 PBG: physician buying group
 SQ: subcutaneous; subcutaneously
 VAERS: Vaccine Adverse Event Reporting System
 VFC: Vaccines for Children
 VIS: Vaccine Information Statement
 VSD: Vaccine Safety Datalink
 VTrckS: Vaccine Tracking System

Vaccines

- DT, Td: diphtheria and tetanus toxoids, pediatric, or tetanus and diphtheria toxoids, adult
- DTaP, Tdap: diphtheria, tetanus, acellular pertussis combinations
- HepA, HepB, HepA-HepB: hepatitis
- Hib: *Haemophilus influenzae* type b
- HPV: human papillomavirus
- IPV: inactivated poliovirus vaccine
- LAIV: live attenuated influenza vaccine (nasal spray)
- MCV: meningococcal conjugate vaccine
- MMR: measles-mumps-rubella
- MPSV: meningococcal polysaccharide vaccine
- PCV: pneumococcal conjugate vaccine
- PPSV: pneumococcal polysaccharide vaccine
- Rotavirus
- Varicella: chickenpox
- Zoster: shingles

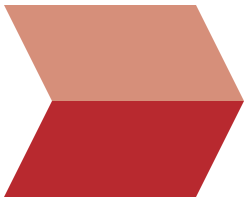
Terms

Diluent: An agent causing dilution or serving to dilute.
 Excise tax. Determined by the federal government and set at \$0.75 per vaccine component.
 Intramuscular: Injection of a substance directly into a muscle.
 Nasal: Referring to the nose.
 Opportunity cost: Refers to the fact that vaccines must be purchased before administration and receiving payment for them. During this time, money is tied up and unavailable for other purchases or investment.
 Oral: Referring to the mouth.
 Subcutaneous: Needle inserted just under the skin. Vaccine can then be delivered into subcutaneous tissues.
 Thimerosal. Mercury-based preservative that has been used to prevent contamination of vaccines with bacteria and fungi.

Strategies That Work

Please use this text box to add additional strategies implemented by this office that have led to increased immunization rates.

- Make a strong recommendation for vaccines. Studies show most parents trust the recommendation of their pediatrician and want to hear their pediatrician's strong recommendation for all vaccines on the immunization schedule, especially human papillomavirus.
- Use reminder and recall systems. Immunization reminder and recall systems are cost-effective methods to identify and notify families whose children are due soon for immunizations (reminder) or already behind (recall). Reminder and recall systems are powerful ways to ensure optimal immunization rates.
- Check for vaccines that are due at every visit. Administer them, barring any contraindications.
- Create a Quality Improvement Team with staff to evaluate immunization rates in your practice and assess opportunities to implement changes.



1 Financing, Ordering, and Maintaining Supply

Introduction

Administering vaccines in pediatric practices is a critical service provided to patients. It is a service that shouldn't create a financial burden for practices. With a basic understanding of the financial aspects of immunizations, including ordering, storage and handling, and administering vaccines, practices can continue their mission of helping children stay healthy, while sustaining appropriate profits.

Learning Objectives

On completion of this unit, the health care professional will be able to

- Manage common contributions to vaccine overhead for their pediatric practice.
- Summarize the differences among conventional pricing models for vaccines.
- Properly use appropriate *Current Procedural Terminology (CPT®)* codes for vaccine products and vaccine administration, and *International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM)* codes for vaccine refusal.
- Begin to determine the immunization supply needs of their practice and order according to those needs.

Professional Policies

The American Academy of Pediatrics (AAP) policy statement "Principles of Health Care Financing" (<http://pediatrics.aappublications.org/content/126/5/1018>) calls for vaccine payments to exceed the acquisition costs to account for the product expense and related overhead for ordering and storage. *The Business Case for Pricing Vaccines* (https://www.aap.org/en-us/Documents/immunizations_thebusinesscase.pdf) outlines the specific costs and the need for appropriate payment

Please feel free to use this text box to add your practice's specific policies on this topic or other notes you wish to include in your final document.

Purchasing Vaccines

There are multiple ways to order vaccines for your practice. It is vital to understand the pros and cons of each to ensure your practice remains financially viable.

1. **Standard programs:** Direct purchasing access is offered by all major vaccine manufacturers.
Pros: Easy access, prompt pay discounts, online order discounts, and promotional sales.
Cons: Large fluctuations in pricing depending on market competitiveness, lack of discounted pricing due to lower volume being purchased by individual practices.
2. **Physician buying groups:** These offer access to 1 or 2 major vaccine manufacturers. Competing vaccine companies will not be in a physician buying group (PBG) together. (Sanofi and GlaxoSmithKline will not be part of the same group, because they offer similar vaccines).
Pros: Lower cost than purchasing as an individual, due to group pricing discounts; all the “pros” listed for standard programs; potential rebates (depending on the manufacturer with whom the PBG is contracted).
Cons: The limited ability to purchase vaccines from manufacturers that are not part of the PBG contract, the potential for being dismissed from the PBG if terms of membership aren't met or honored.
3. **Group purchasing organizations:** These are typically operated by hospital-affiliated purchasing groups.
Pros: Purchases are not limited to certain vaccine manufacturers or products.
Cons: Pricing models are not as favorable as in PBGs.

For more information on group purchasing organizations, please visit the AAP Immunizations: Managing Costs Web page (<https://www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/immunization/Pages/managing-costs.aspx>).

No matter what model a practice uses to order vaccines, it is vital that appropriate questions be directed to the purchasing group. Those questions should include

- Which manufacturers are included in the program? Under what circumstances can we purchase outside the plan (eg, if one manufacturer has a recall or shortage)? What are the purchasing compliance requirements?
- On the basis of this contract, how will our usual vaccine routine be affected? Will we need to administer different vaccines (eg, Pediarix vs Pentacel)? How will this affect office education or nurses' time?
- If we have to change our routine, will the change be worth it? Will another option with similar pricing allow us to continue ordering what we currently use?

- Is there a cost to participate? What is the length of the contract commitment? Does this plan provide rebates to its participants?
- Is pricing tied to volume? Do all participants in the purchasing group have the same terms?
 - How do these discounts compare with our current pricing?
 - Does placing large- or small-volume orders allow us to receive the optimal discount?
 - How frequently are we permitted to order? What is the process to order vaccines (online, calling)? Is a code needed to order online? Is there an administrator to call for the purchasing group? Is pricing tied to volume?
- Do all participants in the purchasing group have the same terms?
- Will additional manufacturer discounts apply through this program (eg, promotions, prompt pay discounts)?
- Will we reduce our practice's time and resources, spent on ordering vaccines, so maximum discounts will still be achieved? Will the program eliminate the need to order strategically to achieve best pricing?
- What customer service resources are in place to answer our questions and provide assistance? How long has the purchasing group been in business? How many physicians does the purchasing group represent? (You can also ask your manufacturer representative, if you have one, for their views of the purchasing group.)
- Are there geographic limitations to participation?
- What value-added services (eg, payment support) does the purchasing group provide?

Adapted with permission from American Academy of Pediatrics. *Immunizations: Best Business Practices* [PediaLink course-retired]. Elk Grove Village, IL: American Academy of Pediatrics; 2009.

The AAP offers guidance on managing immunization-related costs at <https://www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/immunizations/Practice-Management/Pages/managing-costs.aspx>.

Vaccine Pricing

CDC Vaccine Price List for the Private Sector

Vaccine pricing must “be free of any discounts and based on a transparent and verifiable data source, such as the [Centers for Disease Control and Prevention (CDC)] vaccine price list for the private sector,” which is available at <https://www.cdc.gov/vaccines/programs/vfc/awardees/vaccine-management/price-list/index.html>.

Please note: The CDC does its best to keep this list updated with private sector costs; however, manufacturers are not obligated to provide private sector costs, so they may not be up-to-date.

Average Sales Price and Average Wholesale Price

Two other models exist: average sale price (ASP) and average wholesale price (AWP).

The AWP is the average manufacturer's price for a vaccine that is developed by various vendors that is based on the vaccine price plus a 20% to 25% markup. Because of multiple AWP sources, pediatricians need to carefully review any payer's fee schedule using AWP. The ASP is based on vaccine manufacturers' quarterly sales reports. A concern with ASP is that it reflects discounts, many of which are not available to pediatric practices, thereby deflating the cost of the vaccine. These prices can lack transparency, and practices may want to insist that insurance contract language refers to the CDC vaccine price list as a basis for payment, with an additional clause that the vaccine fee schedules will be updated as soon as there is a price increase or at least quarterly.

Overhead Costs When Providing Immunizations

Calculating the total cost of providing a vaccine to a patient involves more than the cost of the vaccine itself. Additional costs arise from the processes of purchasing, storing, and administering the vaccine.

An excise tax of \$0.75 per vaccine component, in addition to the vaccine price, is applied by the federal government. This tax is used to fund the National Vaccine Injury Compensation Program.

Sales tax is determined by local governments.

Staff time for

- **Ordering vaccines and managing inventory**
The major component of this portion of additional cost is personnel. Choose the employee most qualified to perform these tasks, as vaccines represent approximately 30% to 35% of an office's overhead. Train personnel to correctly manage inventory volumes. Too much inventory can increase opportunity cost, create cash flow problems, and increase inventory insurance. With too little inventory, a practice may run out of vaccine, which creates the administrative hassle of maintaining a list of patients to recall once the vaccine product arrives.
- **Negotiating prices**
Minimal time is needed for this cost component. Staff time will be used when researching physician buying groups or group purchasing organizations, and while periodically reviewing the market for better deals.
- **Billing and collections activity**
Personnel choice is very important. Having an effective billing department (whether done in-house or through a third party) is critical for the survival of a pediatric practice. Claims should be filled promptly, payments reconciled quickly, and the appeals process, streamlined and rigorous. Ideally, every payment should be compared with what is expected from the insurance company, and any deviation from the expectation should be dealt with immediately. Choosing a practice management system that can have these data loaded into its system will provide a tremendous benefit over time, as initially, a practice will spend time on reviewing payment amounts. Taking time to ensure proper payment through a thorough review will translate into increased revenue.

An in-depth discussion of this topic is beyond the scope of this guide, but it is important to note that costs associated with staff time remain one of the biggest contributors to vaccine administration overhead.

Storage (purchase of refrigerator, freezer, generator, data loggers, monitoring systems)

Quality and reliability are vital when it comes to storing vaccines. Invest in quality equipment, designed specifically for vaccine storage. Equipment costs will be allocated among thousands of vaccine doses and will minimally affect per-dose overhead

Insurance

Purchasing insurance for your vaccine inventory is critical and prudent. If an office refrigerator malfunctions, your practice could lose money without insurance coverage. The insurance does not contribute significantly to overhead. Like the cost of storage, it is spread out over many vaccine doses.

Opportunity Cost

Opportunity cost refers to the fact that vaccines must be ordered before one administers and receives payment for them. There are many ways to mitigate opportunity cost.

There are 3 periods over which one has some control: the time between ordering vaccines and administering them; the time between ordering vaccines and paying for them; and the time between administering vaccines and receiving payment. Ideally, payment will be received from the insurance company before payment is due to the manufacturer.

- **Period 1:** Control inventory by minimizing the time between ordering/receiving the vaccines and administering them. Time spent assessing inventory needs will help optimize the finances of this period. Balance the risk of supply shortfall with quantity pricing.
- **Period 2:** Defer paying for vaccines when ordering. All manufacturers offer this option on their Web site, which varies in length, depending on the manufacturer. In addition, by choosing to pay by credit card, there is an additional 20- to 30-day deferral period, based on the credit card's payment cycle.
- **Period 3:** The time between administering vaccine and receiving payment is the most difficult to control, and the most important. A practice management system should provide a practice with the average number of days elapsed before receiving payment on a claim.

If it is >45 days, payments are not being received in a timely manner. The goal should be to receive payment within 30-45 days (or sooner). A detailed discussion of decreasing accounts receivable days is beyond the scope of this guide. Prompt electronic submittal of claims that have been carefully reviewed for error will expedite the process. If your office receives many claim rejections because of improper submission, immediately analyze and correct the problem.

Wasted Doses and Unpaid Claims

This component of overhead includes

- Errors by physicians or nurses in the administration of vaccines
- Patients who agree to a vaccine and then refuse administration
- Billing errors (eg, forgetting to bill for a given vaccine)
- Incorrectly denied claims
- Claims you are unable to collect that end up as a personal balance on an account

The goal of your office should be to keep costs for this component under 5% and preferably closer to 1%. If your office records more than this amount, determine which one of the previously mentioned causes is the major contributor and do your best to fix the problem.

Adapted with permission from American Academy of Pediatrics. *Immunizations: Best Business Practices* [PediaLink course—retired]. Elk Grove Village, IL: American Academy of Pediatrics; 2009.

The AAP offers guidance on managing immunization-related costs at <https://www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/immunizations/Practice-Management/Pages/managing-costs.aspx>.

Furthermore, some insurers will recognize code **99211** for immunization-only visits. However, there are specific rules on the appropriate use of this code. The AAP has a helpful resource at https://www.aap.org/en-us/Documents/coding_aap_position_paper_99211_ia_2016.pdf. You may also want to contact insurance companies to inquire about circumstances under which they will pay for code **99211**.

Determining the Needs of Your Practice

Before you can order vaccines for your practice, you will want to know what your needs are. Having too many of any type of vaccine can lead to spoilage and wastage. With vaccines being rather expensive, this should always be avoided. However, if you have too few vaccines available, some patients might miss out on receiving an on-time immunization. The following steps can help you determine how much vaccine to order:

- Decide how much inventory you want to keep on hand by reviewing past records and determining how often you want to order. Your vaccine representatives can be good resources.
- Determine what vaccines you are going to use and when they will be used. Each practice should develop its own immunization schedule within CDC recommendations (www.cdc.gov/vaccines).
- Conduct frequent inventories to ensure limited lost or wasted vaccines.

Practices must pay special attention to *wastage*, which is an important factor that can cause a loss of thousands of dollars a year. Let's look at a fictional example to further understand this.

Vaccine X costs the practice \$200 per dose (\$180 to purchase the vaccine and \$20 to administer it). It is lifesaving, so, of course, the practice decides to purchase and administer it. To be sure your practice receives appropriate payment, you charge \$300 for vaccine X. The average insurance payment, however, is \$220. That's not horrible—your practice makes \$20 on each dose. But one day, a nurse draws up the vaccine before you have a chance to discuss it with the patient. The patient refuses. The vaccine is now bad and you must throw it away—\$200 wasted. But the practice lost much more. Because your average payment is only \$20 over the cost, you must now give 10 doses of the vaccines before you make any profit because of one lost dose ($\$20 \times 10 = \200).

Payment for Vaccine Administration

It is reasonable to expect that a practice will be appropriately paid for the immunization services in which it partakes. No practice should lose money administering vaccines to patients.

Proper coding is the key to correct payment. Each vaccine has an individual *ICD-10-CM* code to use. That code should be paired with an administration code to cover some of the previously mentioned overhead costs. Please see the Commonly Administered Pediatric Vaccines coding table (https://www.aap.org/en-us/Documents/coding_vaccine_coding_table.pdf) for a list of all *ICD-10-CM* and *CPT*® codes required for administering vaccines.

Insert your practice's specific immunization schedule, your state's Vaccines for Children (VFC) contact information, and any other notes you wish to add.

Insert your state's VFC contact information, your order information, and any other notes you wish to add.

Supply (Vaccines for Children Program)

- Check with your state to see what vaccines are available.
- Find out how often the state prefers you to order to determine supply.

Ordering (Private)

- Purchasing groups can be a good resource for getting the best bang for your buck. Be sure to get all the details; some are product specific and limit what vaccines you can order or use.
- Using a credit card with cash back or rewards can be a good way to purchase vaccines. You may also get a discount from some vaccines companies for prompt payment.
- Compare cost and payment. This may determine which vaccines you use.
- Determine the best way to order (eg, by calling the representative, through purchasing groups).
- Which vaccines are available?

Key Facts

- Understand all components of vaccine financing.
- Have helpful Web sites handy for assistance to understand billing and ordering and order according to your needs.

Tools and Resources

- Links for additional learning
 - Centers for Disease Control and Prevention Current Vaccine Shortages & Delay (<https://www.cdc.gov/vaccines/hcp/clinical-resources/shortages.html>)
 - Pediatric/VFC vaccine price list (www.cdc.gov/vaccines/programs/vfc/awardees/vaccine-management/price-list/index.html)
 - American Academy of Pediatrics vaccine purchasing groups (<https://www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/immunizations/Practice-Management/Pages/managing-costs.aspx>)
- Documents you may include in your personalized manual
 - American Academy of Pediatrics
 - AAP Position Paper 99211 (www.aap.org/en-us/Documents/coding_aap_position_paper_99211_ia_2016.pdf)
 - Red Book® Online Vaccine Status Table (<http://redbook.solutions.aap.org/DocumentLibrary/vaccstatus.pdf>)
 - Commonly Administered Pediatric Vaccines table (https://www.aap.org/en-us/Documents/coding_vaccine_coding_table.pdf)

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When is it Appropriate to Report 99211 During Immunization Administration?

American Academy of Pediatrics Committee on Coding and Nomenclature

~~~~~  
**Abstract:** Code **99211** should not be reported for every nurse-only vaccine administration patient encounter. Rather, careful consideration needs to be given regarding the significance and medical necessity for such a visit.  
 ~~~~~

When vaccines are given in the pediatric office, questions often arise concerning the reporting of evaluation and management (E/M) services performed during the same visit where vaccines are administered. The answer always depends on whether the provider performs a *medically necessary and significant, separately identifiable E/M visit, in addition to the immunization administration*. If such a service is performed, an E/M code is reported, most likely from the **99201-99215** code family (office or other outpatient service), in addition to the appropriate code for immunization administration (**90460-90461** or **90471-90474**) plus the code for the vaccine product(s). In such cases, payers may require that modifier **25** (*significant, separately identifiable evaluation and management service by the same physician on the same day of the procedure or other service*) be appended to the E/M code to distinguish it from the actual administration of the vaccine.

The identification of a significant, separately identifiable service for E/M codes usually involves the performance and documentation of the “key components” (ie, history, physical examination, and medical decision making) or time. However, the reporting of code **99211** is unique among E/M codes in having no key component requirements. The *Current Procedural Terminology (CPT®)* descriptor for code **99211** states, “Office or other outpatient visit for the evaluation and management of an established patient, that may not require the presence of a physician. Usually, the presenting problem(s) are minimal. Typically, 5 minutes are spent performing or supervising these services.” Therefore, how this concept is defined when the E/M code in question is **99211** needs further clarification.

To address this issue, it becomes important to determine the following:

- What services are included in the immunization administration codes?
- What additional services are required to appropriately report a **99211**?
- What are the documentation requirements for a **99211**?

What Services Are Included in the Immunization Administration Codes?

Updated January 2016

The following services are included in the immunization administration *CPT* codes:

- Administrative staff services, such as making the appointment, preparing the patient chart, billing for the service, and filing the chart
- Clinical staff services, such as greeting the patient, taking routine vital signs, obtaining a vaccine history on past reactions and contraindications, presenting a Vaccine Information Sheet (VIS) and answering routine vaccine questions, preparing and administering the vaccine with chart documentation, and observing for any immediate reaction

The relative value units (RVUs) for the immunization administration codes were significantly increased in 2005 and 2006. These increases can be attributed to the fact that CMS views many of the services that are included under code **99211** as part of the immunization administration codes. Accordingly, the RVUs for code **99211** have essentially been “built” into the RVUs for the immunization administration codes.

The immunization administration codes are valued on the Medicare physician fee schedule (Resource-Based Relative Value Scale [RBRVS]) as follows:

CPT Code	Work RVUs	Non-Facility Practice Expense RVUs	Malpractice RVUs	Total Non-Facility RVUs	2016 Medicare Non-Facility Payment
90460†	0.17	0.53	0.01	0.71	\$25.44*
90461†	0.15	0.19	0.01	0.35	\$12.54
90471	0.17	0.53	0.01	0.71	\$25.44
90472	0.15	0.19	0.01	0.35	\$12.54
90473	0.17	0.53	0.01	0.71	\$25.44
90474	0.15	0.19	0.01	0.35	\$12.54

RVUs = Relative Value Units

†Codes 90460 and 90461 require vaccine counseling to be performed by the physician or other qualified health care professional

*Sample conversion for 90460

Medicare 2016 conversion factor = \$35.8279

0.71 RVUs x \$35.8279 = \$25.44

What Additional Services Are Required to Appropriately Report a 99211?

The E/M service must exceed those services included in the immunization administration codes. In addition, there are 2 principles to keep in mind. They are as follows:

1. The service must be medically necessary.
2. The service must be separate and significant from the immunization administration.

When the provider (usually the nurse) evaluates, manages, and documents the significant and separate complaint(s) or problem(s), the additional reporting of **99211** is justified. In such circumstances, the nurse typically conducts a brief history and record review along with a physical assessment (eg, indicated vital signs and observations) and provides patient education in helping the family or patient

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manage the problem encountered. These nursing activities are all directly related to the significant, separate complaint, and unrelated to the actual vaccine administration.

What Are the Documentation Requirements for a 99211?

All reported E/M codes must meet documentation requirements as outlined in *CPT* guidelines or in the Centers for Medicare & Medicaid Services (CMS) Documentation Guidelines. For most of the E/M services that physicians perform, this means that some designated combination of the key components of history, physical examination, and medical decision making must be met and clearly documented. Alternatively, if more than 50% of the time spent during the E/M service is spent in counseling or coordinating care, time becomes the “key” or controlling factor in selecting a code.

Code 99211 is the one E/M service typically provided by the nurse and not the physician. As such, its documentation requirements differ. There are no required key components typical of the physician services noted above. Further, the typical time published in *CPT* for **99211** is 5 minutes. The American Academy of Pediatrics encourages documenting the date of service and reason for the visit, a brief history of any significant problems evaluated or managed, any examination elements (eg, vital signs or appearance of a rash), a brief assessment and/or plan along with any counseling or patient education done, and signatures of the nurse and supervising physician.

While not required, it may help payers to better understand the medical necessity of the nurse E/M service if it is linked to a different *International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM)* code than the one used for the vaccine given when appropriate. Further, encounter documentation should be a separate entry from the charting of the vaccine itself (product, lot number, site and method, VIS date, etc, which usually are all recorded on the immunization history sheet). Each practice should consider developing protocols and progress note templates for vaccine services.

Finally, if the nurse provides the **99211** visit, it is reported under the physician’s name/tax ID number, making it inherently an “incident to” service. In such situations, it is a service restricted to established patients and requires the supervising physician’s “direct supervision,” which is defined by the CMS as the physician being physically present in the office suite (not in the patient’s room) and immediately available to provide assistance. Most “nurse” E/M services are carried out under a protocol of orders developed by the physician for the particular service and should be fully documented in the record. As always, the physician supervising the care should sign the chart entry.

Coding Information From *Current Procedural Terminology* and CMS

The American Medical Association provides some instruction on the correct reporting of **99211** at the time of immunization administration via *Current Procedural Terminology* guidelines. Within the Immunization Administration for Vaccines/Toxoids section of the CPT nomenclature, it states, “If a significant separately identifiable Evaluation and Management service (eg, office of other outpatient services, preventive medicine services) is performed, the appropriate E/M service code should be reported in addition to the vaccine and toxoid administration codes.”

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CMS also provides direction for reporting **99211** during visits where only the nurse sees the patient and gives an injection. Under CMS Medicare payment policy, it is not correct to report an E/M service if the nurse services are only related directly to the injection itself. In that vein, CMS significantly increased its Medicare fee for immunization administration in 2005, providing reimbursement for the typical activities of the nurse as listed above under the immunization administration codes.

Coding Examples

Vignette #1

A 7-month-old girl visits your office to be immunized against influenza and is seen only by your nurse. The nurse takes a brief history and learns the infant has a cough without change in appetite, sleep, or activity level. He takes vital signs and assesses that the infant has no contraindications to getting the vaccine, and discusses the office practice protocol for the management of the respiratory problem with the mother. Additionally, the nurse documents that the patient meets the current guidelines for vaccination and has no contraindications to the immunization per the Centers for Disease Control and Prevention (CDC) guidelines. Next, he reviews the VIS with the mother and obtains consent for the immunization. The nurse then administers the influenza vaccine.

The encounter would be reported as follows:

CPT

99211-25 (E/M service)

90657 (influenza vaccine)

90471 (immunization administration)

ICD-10-CM

R05 (*cough*)

Z23 (encounter for immunization) [link to both the vaccine product and administration]

An example of written documentation for this **99211** encounter follows (the actual vaccine data with lot number and site/route and VIS date are recorded on a separate immunization record):

The patient is here for the influenza vaccine. Mother reports a cough for several days without any fever. She is eating well and there has been no wheezing or rapid breathing. Her temperature is 98.7°F and respiratory rate is 38/minute – she appears well. The symptomatic treatment of the cough per protocol was discussed and the mother was instructed to call or return if the problem worsened. She has no allergies to foods or history of reactions to past vaccines. The risks and potential side effects of the hepatitis B vaccine were discussed after the VIS was given, and the mother was informed of the correct dosage of an antipyretic should fever or fussiness occur afterwards. An influenza vaccine was given.

K. Brooks, LPN/R. Dunn, MD (signatures/date)

Vignette #2

A five-year-old is brought in by the mother for a catch-up measles-mumps-rubella (MMR) vaccine. She says the child is fine and has already been counseled on the vaccine and has no concerns. The nurse proceeds to review the vaccine history, presents the VIS, and receives an order for the vaccine from the

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physician. She then administers and documents the vaccine. In this situation, the service is only vaccine related and no significant or separate E/M service is provided. Therefore, the only services reported are the immunization administration and the vaccine product code.

The encounter would be reported as follows:

CPT

90707 (MMR vaccine)

90471 (immunization administration)

ICD-10-CM

Z23 [link to both vaccine product and administration]

Vignette #3

A 4-month-old patient had an illness with high fever at her preventive medicine visit 2 weeks ago, and now returns to see your nurse for her second hepatitis B vaccine. The nurse performs an interval history, finding the symptoms from the earlier illness had resolved. She then confirms that the infant is afebrile by taking the infant's temperature, and makes the observation that the infant is playful. After assessing that the patient is currently in good health, she confirms that there are no contraindications to the immunization per the CDC guidelines. Next, the nurse reviews the VIS with the father, antipyretic dosage for weight, and gets the father's consent for the immunization. The nurse then administers the hepatitis B vaccine, observes for immediate reactions, and schedules the third hepatitis B immunization visit for 2 months later.

This encounter would be reported as follows:

CPT

99211-25 (E/M service)

90744 (hepatitis B vaccine)

90471 (immunization administration)

ICD-10-CM

Z09 (encounter for follow-up examination after completed treatment)

Z23 [link to both vaccine product and administration]

An example of written documentation for this **99211** encounter follows (the actual vaccine data with lot number and site/route and VIS date are recorded on a separate immunization record):

The patient is here for a missed hepatitis vaccine and has had no fever for 7 days, is eating again, and seems to be well per father. Past vaccines have been well tolerated. Her temperature now is 98.7°F and she appears well. The risk and potential side effects of the hepatitis vaccine were discussed after the VIS was given and the parent was informed of the correct dosage of an antipyretic should fever or fussiness occur afterwards. The night call system was explained and the access number given.

K. Brooks, LPN/R. Dunn, MD (signatures/date)

NOTE: Some payers may inappropriately deny claims that link code **99211** to a "Z" ICD-10-CM code. Neither CPT nor ICD-10-CM guidelines** prohibit such reporting when the ICD-10-CM code reported is the most specific one available to describe the patient encounter. Furthermore, CPT guidelines clearly outline the requirements for reporting a given level E/M code. If the key components of history, physical examination, and medical decision making or time requirements (when greater than 50% of the visit is spent counseling/coordinating care) are met for a given code, the physician is correct in the reporting of that code. *Current*

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Procedural Terminology guidelines do not make the reporting of a certain level E/M code contingent upon the patient exhibiting certain symptoms or falling under a particular diagnosis. *Current Procedural Terminology* guidelines correctly recognize that there can be considerable variation in the treatment of a patient with a particular diagnosis and that it is inappropriate to validate the legitimacy of a reported E/M code by the presence of a certain diagnosis(es). Claims adjudication processes that prohibit the reporting of “Z” ICD-10-CM codes with anything other than Preventive Medicine Services CPT codes are inconsistent with CPT and ICD-10-CM guidelines and are counterintuitive to the continuum of care that can be provided for a patient with a given diagnosis. Further, it should be noted that the Office or Other Outpatient Services CPT codes (99201-99215) are *not* limited to “sick” visits only. Therefore, it is appropriate to report “Z” codes or any other ICD-10-CM codes that most appropriately reflect the reason for the encounter with the Office or Other Outpatient Services codes.

***International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) Official Guidelines For Coding and Reporting*

a. Use of Z codes in any healthcare setting

Z codes are for use in any healthcare setting. Z codes may be used as either a first-listed (principal diagnosis code in the inpatient setting) or secondary code, depending on the circumstances of the encounter. Certain Z codes may only be used as first-listed or principal diagnosis.

b. Z Codes indicate a reason for an encounter

Z codes are not procedure codes. A corresponding procedure code must accompany a Z code to describe any procedure performed.

c. Categories of Z Codes

2) Inoculations and vaccinations

Code Z23 is for encounters for inoculations and vaccinations. It indicates that a patient is being seen to receive a prophylactic inoculation against a disease. Procedure codes are required to identify the actual administration of the injection and the type(s) of immunizations given. Code Z23 may be used as a secondary code if the inoculation is given as a routine part of preventive health care, such as a well-baby visit.

For questions, please contact the AAP Coding Hotline at aapcodinghotline@aap.org

Red Book® Online: Vaccine Status Table*

Table 1: Status of Recently Submitted, Licensed, and Recommended Vaccines & Biologics

Click on disease names for current *Red Book*® recommendations. General Recommendations on Immunization from ACIP - cdc.gov/mmwr/preview/mmwrhtml/r6002a1.htm
Vaccine supply shortages may result in changes to recommendations. Please consult cdc.gov/vaccines/vac-gen/shortages/default.htm

Vaccines and Biologics	Manufacturer	BLA submitted	BLA age indications**	FDA licensure	Status of AAP/CDC recommendations***
Cholera vaccine	Pax Vax Bermuda Ltd.	Oct 2015	18 through 64 years of age	June 2016	Pending
DTaP-IPV (Quadracel)	Sanofi Pasteur	Mar 2014	4 through 6 years of age. May be used to complete the DtaP and IPV series	Mar 2015	CDC: cdc.gov/mmwr/preview/mmwrhtml/mm6434a5.htm
Hib-conjugate (Hibertix®)	Wyeth	Mar 2015	Age extended to include infants 6 weeks of age and older	Apr 2016	CDC: cdc.gov/mmwr/volumes/65/wr/mm6516a3.htm
Hib-MenCY (MenHibrix®)	GSK	Aug 2009	High risk for meningococcal disease: 2 through 23 months of age. May be used for Hib series	Jun 2012	CDC: cdc.gov/mmwr/preview/mmwrhtml/r6202a1.htm
HPV9 (Gardasil 9)	Merck	Feb 2014	Females and Males 9 years through 14 years of age (2-dose regimen) Females 9 years through 26 years of age; Males 9 years through 26 years of age	Dec 2014	CDC: cdc.gov/mmwr/preview/mmwrhtml/mm6411a3.htm CDC: https://www.cdc.gov/mmwr/volumes/65/wr/mm6549a5.htm AAP: aap.org/en-us/Documents/Immunizations_hpv_implementation_guidance.pdf
Influenza vaccines	several	Varies	See Influenza Vaccine Table	varies	AAP: pediatrics.org/content/early/2016/09/01/peds.2016-2527 CDC 2016-2017: cdc.gov/mmwr/volumes/65/wr/mm6505a1.htm CDC Seasonal: cdc.gov/flu Red Book Online Influenza Resource Page: aapredbook.org/ss/influenza-resources.aspx
Japanese Encephalitis (IXIARO®)	Novartis	Dec 2007	Greater than or equal to 17 years of age	Mar 2009	CDC: cdc.gov/mmwr/preview/mmwrhtml/r65901a1.htm May 2011 Update: cdc.gov/mmwr/preview/mmwrhtml/mm6020a6.htm
MCV4 (Menactra®)	Novartis	Jul 2012	Booster dose	Sep 2011	CDC: cdc.gov/mmwr/preview/mmwrhtml/mm6020a5.htm
			Greater than or equal to 2 months of age	May 2013	CDC: cdc.gov/mmwr/preview/mmwrhtml/mm6245a3.htm
			Routine: 11 through 21 years of age	Jan 2005	
	Sanofi Pasteur	Dec 2003	High Risk: 9 months through 55 years of age	Apr 2011	AAP: pediatrics.aappublications.org/content/128/6/1213.full
			Routine: 11 years through 21 years of age	Feb 2010	CDC: cdc.gov/mmwr/preview/mmwrhtml/r6202a1.htm
	Novartis	Apr 2010	High Risk: 2 years through 10 years of age	Jan 2011	CDC: https://www.cdc.gov/mmwr/volumes/65/wr/mm6543a3.htm
			High Risk: 2 months through 23 months of age	Aug 2013	CDC: cdc.gov/mmwr/preview/mmwrhtml/mm6324a2.htm CDC: https://www.cdc.gov/mmwr/volumes/65/wr/mm6543a3.htm
Meningococcal Group B (Trumenba®)	Pfizer/Wyeth	Jun 2014	10 years through 25 years of age	Oct 2014	CDC: cdc.gov/mmwr/preview/mmwrhtml/mm6441a3.htm
Meningococcal Group B (Bexsero®)	Novartis	Jun 2014	10 years through 25 years of age	Jan 2015	CDC 2 through 23 months: cdc.gov/mmwr/preview/mmwrhtml/mm6324a2.htm CDC Greater than or equal to 10 years: cdc.gov/mmwr/preview/mmwrhtml/mm6422a3.htm
PCPV13 (Prevnar 13®)	Pfizer	Mar 2009	Routine: 2 months through 71 months of age	Feb 2010	CDC: cdc.gov/mmwr/preview/mmwrhtml/r65911a1.htm
			6 years through 18 years of age with high risk conditions	Jan 2013	CDC: cdc.gov/mmwr/preview/mmwrhtml/mm6225a3.htm
			19 years of age and older with immunocompromising conditions	Feb 2010	CDC: cdc.gov/mmwr/preview/mmwrhtml/mm6140a4.htm CDC: cdc.gov/mmwr/preview/mmwrhtml/mm6434a4.htm
			50 through 64 years of age	Dec 2011	Pending review
			Greater than or equal to 65 years of age	Dec 2011	CDC: cdc.gov/mmwr/preview/mmwrhtml/mm6337a4.htm
PPSV23 (Pneumovax 23®)	Merck		All adults aged 65 years and older and those children and adults 2 through 64 years with underlying medical conditions that put them at greater risk for serious pneumococcal infection	Sep 2010	CDC: cdc.gov/mmwr/preview/mmwrhtml/mm6337a4.htm CDC: cdc.gov/mmwr/preview/mmwrhtml/mm6434a4.htm

(continued on next page)

BLA = biologics license application; VRBPAC = Vaccines and Related Biological Products Advisory Committee; FDA = Food and Drug Administration; AAP = American Academy of Pediatrics; ACIP = Advisory Committee on Immunization Practices, Diphtheria, Tetanus and Pertussis; Haemophilus influenzae b vaccine, HIBv = Inactivated influenza vaccine; LANI = Live attenuated influenza vaccine-inflant; PCV13 = Pneumococcal conjugate vaccine, 13-valent conjugate; PPS23 = 23-Valent Pneumococcal Polysaccharide Vaccine; Toxap = Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine, adsorbed

*Age licensure can change following FDA review, until final package insert approved
**ACIP recommendations do not become official until adopted by the CDC Director and Department of HHS and publication in MMWR

Vaccines and Biologics	Manufacturer	BLA submitted	BLA age indications**	FDA licensure	Status of AAP/CDC recommendations***
Tdap (ADACEL®)	Sanofi Pasteur	Aug 2004	Pregnancy Repeat dose in pregnancy	Off Label Off Label Licensed (1/1/2011)	AAP: pediatrics.aappublications.org/cgi/content/full/117/2/284/809 CDC Pregnancy: cdc.gov/mmwr/preview/mmwrhtml/mm6041a4.htm ; 2012 Update: cdc.gov/mmwr/preview/mmwrhtml/mm6207a4.htm
Tdap (BOOSTRIX®)	GSK	Jul 2004			

Table Updated: 1/25/17

Table available on Red Book Online: aapredbook.org/vaccine-status.aspx?qbosid=167073Current Recommended Immunization Schedules: [0-18 Years](#) | [Catch-up Schedule](#) | [Adult](#)

BLA = biologics license application, VRBPAC = Vaccines and Related Biological Products Advisory Committee, FDA = Food and Drug Administration, AAP = American Academy of Pediatrics, ACIP = Advisory Committee on Immunization Practices, DTaP = Diphtheria, Tetanus and Pertussis, Hib = Haemophilus influenzae b, IPV = inactivated Poliovirus vaccine, IPV = inactivated Poliovirus vaccine, LAV-T = Live attenuated influenza vaccine-trivalent, MCV4 = Meningococcal conjugate vaccine, MMV = measles, mumps, rubella, varicella, PCV13 = Pneumococcal 13-valent conjugate, PPSV23 = 23-Valent Pneumococcal Polysaccharide Vaccine, Tdap = Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine, adsorbed

*Information from vaccine manufacturers, from ACIP meetings and from AAP

**Age licensure can change following FDA review; not final until package insert approved

***ACIP recommendations do not become official until adopted by the CDC Director and Department of HHS and publication in MMWR

Commonly Administered Pediatric Vaccines

Effective 6/1/2017

CPT ® Product Code	Separately report the administration with Current Procedural Terminology (CPT®) codes 90460-90461 or 90471-90474 [Please see table below]	Manufacturer	Brand	# of Vaccine Components
90702	Diphtheria and tetanus toxoids (DT), adsorbed when administered to younger than seven years, for IM use	SP	Diphtheria and Tetanus Toxoids Adsorbed	2
90700	Diphtheria, tetanus toxoids, and acellular pertussis vaccine (DTaP), when administered to <7 years, for IM use	SP GSK	DAPTACEL INFANRIX	3
90696	Diphtheria, tetanus toxoids, and acellular pertussis vaccine and inactivated poliovirus vaccine (DTaP-IPV), when administered to children 4-6 years of age, for IM use	GSK SP	KINRIX Quadracel	4
90697	Diphtheria, tetanus toxoids, acellular pertussis vaccine, inactivated poliovirus vaccine, Haemophilus influenza type b PRP-OMP conjugate vaccine, and hepatitis B vaccine (DTaP-IPV-Hib-HepB), for IM use	↗	↗	6
90698	Diphtheria, tetanus toxoids, acellular pertussis vaccine, haemophilus influenza Type B, and inactivated poliovirus vaccine (DTaP-IPV/Hib), for IM use	SP	Pentacel	5
90723	Diphtheria, tetanus toxoids, acellular pertussis vaccine, Hepatitis B, and inactivated poliovirus vaccine (DTaP-Hep B-IPV), for IM use	GSK	PEDIARIX	5
90647	Haemophilus influenza B vaccine (Hib), PRP-OMP conjugate, 3 dose, for IM use	Merck	PedvaxHIB	1
90648	Haemophilus influenza B vaccine (Hib), PRP-T conjugate, 4 dose, for IM use	SP GSK	ActHIB HIBERIX	1
90633	Hepatitis A vaccine (Hep A), pediatric/adolescent dosage, 2 dose, for IM use	GSK Merck	HAVRIX VAQTA	1
90740	Hepatitis B vaccine (Hep B), dialysis or immunosuppressed patient dosage, 3 dose, for IM use	Merck	RECOMBIVAX HB	1
90743	Hepatitis B vaccine (Hep B), adolescent, 2 dose, for IM use	Merck	RECOMBIVAX HB	1
90744	Hepatitis B vaccine (Hep B), pediatric/adolescent dosage, 3 dose, for IM use	Merck GSK	RECOMBIVAX HB ENERGIX-B	1
90746	Hepatitis B vaccine (Hep B), adult dosage, for IM use	Merck GSK	RECOMBIVAX HB ENERGIX-B	1
90747	Hepatitis B vaccine (Hep B), dialysis or immunosuppressed patient dosage, 4 dose, for IM use	GSK	ENERGIX-B	1
90748	Hepatitis B and Hib (Hep B-Hib), for IM use	Merck	COMVAX	2
90651	Human Papillomavirus vaccine types 6, 11, 16, 18, 31, 33, 45, 52, 58, nonavalent (HPV), 3 dose schedule, for IM use (*Use also for 2-dose schedule*)	Merck	GARDASIL 9	1
90630	Influenza virus vaccine, quad (IIV4), split virus, preservative free, for intradermal use	SP	Fluzone Intradermal Quad	1
90656	Influenza virus vaccine, trivalent (IIV3), split virus, preservative free, 0.5ml dosage, for IM use	Merck Novartis	AFLURIA Fluvirin	1
90658	Influenza virus vaccine, trivalent (IIV3), split virus, 0.5ml dosage, for IM use	Merck Novartis	AFLURIA Fluvirin	1
90672	Influenza virus vaccine, quad (LAIV), live, intranasal use	MedImmune	Flumist Quad	1
90673	Influenza virus vaccine, trivalent (RIV3), derived from recombinant DNA, hemagglutinin (HA) protein only, preservative and antibiotic free, IM	Protein Sciences	Flublok	1
90674	Influenza virus vaccine, quad (ccIIV4), derived from cell cultures, subunit, preservative and antibiotic free, 0.5 mL dosage, IM (Do not use for multi-dose – report 90749)	Seqirus	Flucelvax	1
90685	Influenza virus vaccine, quad (IIV4), split virus, preservative free, 0.25ml dose, for IM use	SP	Fluzone Quad	1
90686	Influenza virus vaccine, quad (IIV4), split virus, preservative free, 0.5ml dosage, for IM use	Seqirus SP GSK GSK	Afluria Fluzone Quad FLUARIX Quad FLULAVAL	1
90687	Influenza virus vaccine, quad (IIV4), split virus, 0.25ml dosage, for IM use	SP	Fluzone Quad	1
90688	Influenza virus vaccine, quad (IIV4), split virus, 0.5ml dosage, for IM use	SP GSK	Fluzone Quad FLULAVAL	1
90707	Measles, mumps, and rubella virus vaccine (MMR), live, for subcutaneous use	Merck	M-M-R II	3

CPT® Product Code	Separately report the administration with Current Procedural Terminology (CPT®) codes 90460-90461 or 90471-90474 [Please see table below]	Manufacturer	Brand	# of Vaccine Components
90710	Measles, mumps, rubella, and varicella vaccine (MMRV), live, for subcutaneous use	Merck	ProQuad	4
90620	Meningococcal recombinant protein and outer membrane vesicle vaccine, serogroup B, 2 dose schedule, for IM use	Novartis	Bexsero	1
90621	Meningococcal recombinant lipoprotein vaccine, serogroup B, 3 dose schedule, for IM use	Pfizer	Trumenba	1
90644	Meningococcal conjugate vaccine, serogroups C & Y and Hemophilus influenza B vaccine (MenCY-Hib), 4-dose schedule, (children 6 weeks-18 months of age), for IM use	GSK	MenHibrix	2
90733	Meningococcal polysaccharide vaccine, serogroups A, C, Y, W-135, quad (MenACWY or MPSV4), for subcutaneous use	SP	Menomune	1
90734	Meningococcal conjugate vaccine, serogroups A, C, Y and W-135 quad (MenACWY or MCV4), for IM use	SP Novartis	Menactra Menveo	1
90670	Pneumococcal conjugate vaccine, 13 valent (PCV13), for IM use	Pfizer	PREVNAR 13	
90732	Pneumococcal polysaccharide vaccine, 23-valent (PPSV23), adult or immunosuppressed patient dosage, when administered to 2 years or older, for subcutaneous or IM use	Merck	PNEUMOVAX 23	1
90713	Poliovirus vaccine (IPV), inactivated, for subcutaneous or IM use	SP	I POL	1
90680	Rotavirus vaccine, pentavalent (RV5), 3 dose schedule, live, for oral use	Merck	RotaTeq	1
90681	Rotavirus vaccine, human, attenuated (RV1), 2 dose schedule, live, for oral use	GSK	ROTARIX	1
90714	Tetanus and diphtheria toxoids (Td) adsorbed, preservative free, when administered to seven years or older, for IM use	SP	TENIVAC	2
90715	Tetanus, diphtheria toxoids and acellular pertussis vaccine (Tdap), when administered to 7 years or older, for IM use	SP GSK	ADACEL BOOSTRIX	3
90716	Varicella virus vaccine (VAR), live, for subcutaneous use	Merck	VARIVAX	1
90749	Unlisted vaccine or toxoid	Please	See CPT	Manual
Immunization Administration (IA) Codes				
IA Through Age 18 With Counseling[^]				
90460	IA through 18 years of age via any route of administration, with counseling by physician or other qualified health care professional; first or only component of each vaccine or toxoid component administered (Do not report with 90471 or 90473)			
+90461	IA through 18 years of age via any route of administration, with counseling by physician or other qualified health care professional; each additional vaccine or toxoid component administered			
Immunization Administration				
90471	IA, one injected vaccine (Do not report with 90460 or 90473)			
+90472	IA, each additional injected vaccine			
90473	IA by intranasal/oral route; one vaccine (Do not report with 90460 or 90471)			
+90474	IA by intranasal/oral route; each additional vaccine			

ICD-10-CM code **Z23** is reported for all vaccine related encounters for all vaccines given. Link both the CPT vaccine product code and the CPT immunization administration code to **Z23**. Remember that the **Z23** is reported in addition to any health exam ICD-10-CM codes.

✈ Vaccine pending FDA approval [<https://www.ama-assn.org/practice-management/cpt-category-i-vaccine-codes>]

+ Denotes add-on code. Report code only with appropriate primary procedure. Report 90461 with 90460 only. Report 90472 and 90473 in addition to 90460 or 90471 or 90473.

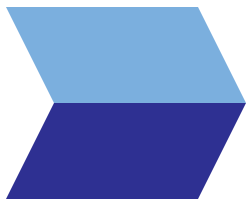
[^] Counseling must be done by a qualified healthcare professional such as a physician, nurse practitioner, or physician assistant. Clinical staff is not included.

For information on pricing and National Drug Codes visit <https://www.cdc.gov/vaccines/programs/vfc/awardees/vaccine-management/price-list/index.html>

Abbreviations: GSK: GlaxoSmithKline; Quad: Quadrivalent; SP: Sanofi Pasteur

Developed and maintained by the American Academy of Pediatrics. For reporting purposes only. The AAP puts forth every effort to ensure this is updated; however, vaccine changes may occur more frequently than this is updated.

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2 Storage and Handling of Vaccines

Introduction

It is important that vaccines be stored at proper temperatures to protect quality and potency. Health care professionals need to know which vaccines should be refrigerated and which should be frozen. In addition, it is important to know which vaccines must be reconstituted and how diluents should be stored.

In June 2012, the Office of the Inspector General (OIG) published a report on vaccine storage and handling practices, which uncovered improper vaccine practices that could lead to loss of potency. The report found that 76% of sampled Vaccines for Children (VFC) providers had vaccines that were exposed to temperatures outside the recommended ranges for more than 5 hours over a 2-week period. In response to this report, the Centers for Disease Control and Prevention (CDC) developed guidance, which includes many new recommendations for safe storage and handling practices. The guidance is available in the CDC “Vaccine Storage and Handling Toolkit.”

Learning Objectives

On completion of this unit, the health care professional will be able to

- Describe general steps to safeguard a vaccine supply.
- Identify steps to take if temperature goes out of range.
- Develop an action plan for emergency preparedness.
- Locate resources such as manufacturers and state and local health departments.
- List vaccines that need to remain frozen.
- List vaccines that need to remain refrigerated.

Professional Policies

Nurses and medical assistants are the health care professionals most commonly in charge of storing and handling vaccines. A minimum of 2 designated health care professionals in an office should be assigned responsibility for maintaining and documenting vaccine storage and handling. A physician should always oversee vaccine activities led by other office staff.

Please use this text box to add your practice's specific policies on this topic, the individuals who are responsible for maintaining and documenting vaccine storage and handling, and any other notes you wish to include in your final document.

About Storage and Handling

It is important to verify that vaccines were shipped properly in an insulated container and kept at manufacturer-required temperatures. If there are concerns about the condition of a vaccine on arrival, immediately place the vaccine in the recommended storage unit and isolate it from other vaccines; then contact the manufacturer's quality control office or state VFC coordinator for guidance.

Most pediatric vaccines used in the United States should be stored in an appropriate refrigeration unit at 2°C to 8°C, with their diluent (if applicable). There are some exceptions.*

- Hibrix vaccine diluent can be stored in the refrigeration unit with vaccine or alone at room temperature.
- MMR II can be stored in the refrigerator or freezer. The diluent should be stored in the refrigerator or at room temperature. Do not freeze.
- Rotarix vaccine diluent should be stored at room temperature, separate from vaccine.
- Varicella-containing vaccine (Varivax and Zostavax) and measles-mumps-rubella and varicella virus vaccine (Proquad) should be stored in the freezer at -50°C to -15°C. Diluents for varicella-containing vaccine should be stored separately, in the refrigerator or at room temperature.

In most cases, the vaccine should be administered shortly after withdrawal from the vial. Multidose vials should be immediately returned to the refrigerator once the dosage has been withdrawn from the vial. Multidose vials can then be used until the expiration date but, because of US Food and Drug Administration rules, only in the location where the first dose was extracted.

Special Instructions for Shelf Life After Opening

1. Measles-mumps-rubella multidose vials must be reconstituted just before use. Vials may be refrigerated, but discard if additional doses are not used within 8 hours after reconstitution.
2. RotaTeq (rotavirus) single-dose pouches should be used shortly after withdrawal from the refrigerator. The dosing tube should not be returned to the refrigerator once the cap has been removed.
3. Rotarix (rotavirus) oral applicator should be administered within 24 hours of reconstitution.
4. Varicella vaccine must be discarded if reconstituted vaccine is not used within 30 minutes. Do not freeze reconstituted vaccine.

Temperatures of refrigerators and freezers should be checked at least twice each day and documented on a temperature log, which should be posted on refrigerator and freezer doors. Refrigerators should measure between 2°C and 8°C. **It is unacceptable for refrigerator temperatures to reach below 2°C, because vaccines could freeze and be rendered ineffective.** Freezers should measure -15°C or lower. Temperature logs should be maintained a minimum of 3 years, unless state regulations require a longer period. If temperature falls outside the requirements, label the vaccines “Do Not Use” and store under proper conditions immediately; then call the manufacturer, for private vaccine, or state immunization program, for VFC vaccine, to determine whether potency has been affected. A plan should be in place on how to maintain safe storage during power outages.

Inventory should be rotated so that oldest vaccines are routinely used first. Electronic systems and state VFC tracking systems, some of which are integrated with the registries, can be used to monitor inventory.

*International vaccines and storage requirements vary. Consult the package insert from the manufacturer(s) of the vaccines you use.

Please use this text box to add your practice's specific plan on how to maintain safe storage of vaccines during a power outage and any other notes you wish to include in your final document.

Additional Instructions and Notes

- Rotate stock so oldest vaccines are used first.
- No food or drinks can be stored in the vaccine freezer or refrigerator.
- Use a stand-alone refrigerator and stand-alone freezer suitable for vaccine storage rather than a combination (refrigerator plus freezer) or other units not designed for storing vaccines.
- Dormitory-type refrigerators are no longer allowed, even for short-term or daily storage.
- A minimum of 2 employees need to be designated in charge of storage and handling.
- Vaccines should be stored
 - In the middle of the freezer and refrigerator
 - In clear, breathable plastic containers
 - Two to 3 in from the sides and back of refrigerator and other plastic containers
 - Not in the door of the vaccine storage unit

- Post a sign on the door to indicate which vaccines are to be stored in the refrigerator and which should be stored in the freezer.
- A certified calibrated buffered thermometer probe should always be kept in the refrigerator and freezer.
- Use digital data loggers with detachable probes that record and store temperature data at frequent programmable intervals. They should be capable of storing several months or years of temperature data in addition to displaying the maximum and minimum reading since last reset.
- Water bottles should line the back, top, bottom, and doors of the refrigerator to help maintain consistent temperatures, but should not crowd the vaccine.
- If domestic refrigerators are used, vaccines should be stored away from refrigerator vents.
- Ice packs or subzero phase change material should be stored in the freezer to help maintain cold temperatures.
- A “Do Not Unplug” sign must be posted by the outlet to the freezer and refrigerator.
- The state immunization program should be contacted for instructions on how to dispose of expired VFC vaccines. If a private-purchase vaccine inadvertently expires, always contact the manufacturer, who may offer a vial-for-vial replacement of non-flu vaccine.
- Varicella and zoster vaccines will lose potency if stored in a temperature warmer than -15°C or colder than -80°C (although such low temperatures are not generally achievable without specialized equipment).
- Vaccines meant to be stored in the refrigerator can undetectably freeze if the temperature ever falls below 0°C . It is recommended that temperatures stay above 2°C to avoid any such exposure. Freezing destroys the usefulness of refrigerated vaccine.
- A backup plan should be developed in case of power outages or equipment failure. Phone-enabled monitors that can notify personnel promptly are readily available for purchase.

Key Facts

- Refrigerator should always be between 2°C and 8°C .
- Freezer should always measure below -15°C .
- Vaccines meant to be stored in the refrigerator should never be—even briefly—exposed to freezing temperatures.
- Current temperatures, including maximums and minimums, of both the refrigerator and freezer thermometers should be manually recorded at least twice each day in a temperature log.
- Vaccines are best stored in refrigerators designed to store vaccines. These units have electronic thermostats, interior fans, and wire shelves, and are purposefully designed for safe vaccine storage.

Tools and Resources

- Links for additional learning
 - Immunization Action Coalition (www.immunize.org)
 - National Institute of Standards and Technology Physical Measurement Laboratory (www.nist.gov/pml/div685/grp01/vaccines.cfm)
 - Centers for Disease Control and Prevention (www.cdc.gov/vaccines) “Vaccine Storage and Handling Toolkit” (www.cdc.gov/vaccines/recs/storage/toolkit/default.htm)
 - California Department of Public Health
 - Setting up your refrigerator and freezer for vaccine storage
 - Refrigerator: (<http://eziz.org/assets/docs/IMM-962.pdf>)
 - Freezer: (<http://eziz.org/assets/docs/IMM-965.pdf>)
 - Storing vaccines in your refrigerator and freezer
 - Refrigerator: (<http://eziz.org/assets/docs/IMM-963.pdf>)
 - Freezer: (<http://eziz.org/assets/docs/IMM-966.pdf>)
- Documents you may include in your personalized manual (included below)
 - American Academy of Pediatrics
 - *Refrigerators, Freezers, and Vaccine Storage* (www.aap.org/en-us/Documents/immunization_vaccinestoragerf.pdf)
 - *Data Loggers and Vaccine Monitoring* (www.aap.org/en-us/Documents/immunization_dataloggers.pdf)
 - *Checklist for Proper Storage and Handling Practices* (www.aap.org/en-us/Documents/immunizations_sh_checklist.pdf)
 - *Disaster Planning* (www.aap.org/en-us/Documents/immunization_disasterplanning.pdf)
 - Centers for Disease Control and Prevention
 - *Packing Vaccines for Transport during Emergencies* (<http://www.cdc.gov/vaccines/recs/storage/downloads/emergency-transport.pdf>)
 - Immunization Action Coalition (Acquired with permission from www.immunize.org on June 15, 2016. We thank the Immunization Action Coalition.)
 - Temperature logs for vaccines
 - Fahrenheit: (www.immunize.org/catg.d/p3039f.pdf)
 - Celsius: (www.immunize.org/catg.d/p3039c.pdf)
 - *Don't Be Guilty of These Preventable Errors in Vaccine Storage and Handling* (www.immunize.org/catg.d/p3036.pdf)
 - *Emergency Response Worksheet* (www.immunize.org/catg.d/p3051.pdf)
 - *Checklist for Safe Vaccine Storage and Handling* (www.immunize.org/catg.d/p3035.pdf)



AAP Immunization Resources

Storage and Handling Series

Refrigerators, Freezers, and Vaccine Storage

The Centers for Disease Control and Prevention (CDC) offers [guidance on proper storage and handling of vaccines](#), including recommendations on storage units for vaccines, in the [Vaccine Storage and Handling Toolkit](#).

The American Academy of Pediatrics (AAP) has assembled some tips to help you choose the best equipment to meet the needs of your practice and keep your vaccine stock safe.

NEVER FREEZE REFRIGERATED-VACCINE

Silently freezing vaccine is the biggest threat to the potency and efficacy of your refrigerated-vaccine. It is impossible to visually detect whether a vaccine has been frozen. If such a vaccine is given to children, it may not prevent disease. Take precautions against freezing your vaccine by using the recommended equipment and properly setting up your refrigerator. For visuals of how to do this see the [CDC Vaccine Storage and Handling Toolkit](#) and the [EZIZ Preparing Refrigerators for Vaccine Storage](#).

Key Points:

- Stand-alone refrigerator and freezer units are safest for storing vaccines.
- Medical- or pharmacy- grade refrigerators have electronic thermostats, audible door-ajar alarms, wire shelves, interior fans and ports to pass through sensor wires.
- Freezers are much smaller and can be manual or auto-defrost. They can have simpler analog thermostats, but should have a port for sensor wires. If picking a manual defrost unit, there should be a spare or second unit in the same office capable of holding the frozen vaccine while the defrost is completed.

CDC recommendations for stand-alone refrigerators and freezers

CDC strongly recommends replacing old, combination (domestic) units with stand-alone refrigerator and freezer units. Dual pharmacy-grade units with independent refrigerator and freezer compressors (not combo domestic units sharing a single compressor) are also excellent in offices where space is limited. Refrigerator/Freezer units can vary in size, from a compact, under-the-counter style to large, double-door units. The use of standard domestic combination refrigerator/freezer units is no longer appropriate, and many VFC programs may require their immediate replacement. The use of dormitory or bar-style refrigerator/freezers (small refrigerator units with interior freezer sections) has been banned for several years due to freezing vaccine risks.

CDC recommendations for stand-alone refrigerators and freezers (continued)

The characteristics of an appropriate **refrigerator storage system** include:

- ability to maintain within $\pm 2^{\circ}\text{C}$ of 5°C despite fluctuating ambient temperatures
- vaccine storage areas do not exceed the $+2^{\circ}\text{C}$ to $+8^{\circ}\text{C}$ $+35^{\circ}\text{F}$ to 46°F temperature range
- electronic / digital thermostat preset to 5°C (or possibly 4°C)
- wire shelves with good interior circulation to minimize internal temperature variance to $\pm 2^{\circ}\text{C}$
- door ajar audible alarm and temperature excursion alarm
- enough extra room to hold the practice's vaccine stock, including flu vaccine at least 4 inches from the unit's walls
- certified continuous data logger with max/min displaying thermometer accurate to $\pm 0.5^{\circ}\text{C}$ $\pm 1^{\circ}\text{F}$



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Refrigerators, Freezers, and Vaccine Storage

The characteristics of an appropriate **freezer storage system** includes:

- ability to store frozen vaccine not warmer than -15°C $+5^{\circ}\text{F}$
- nor colder than -50°C -58°F
- room to store the year's largest inventory of Varivax, ProQuad and MMR II
- certified data logging max/min displaying thermometer accurate to $\pm 0.5^{\circ}\text{C}$
- automatic defrost or ability to defrost manually (practices using a freezer that needs to be defrosted manually will need a second freezer in which to store vaccine during the defrost process)

Half-liter drinking water bottles can be added to vaccine refrigerators to increase cold mass and thus stabilize temperature swings. Always cool water bottles in an alternate refrigeration unit before placing in a vaccine refrigerator. Chilled water bottles may be placed in empty shelves or the floor, but do not allow them to obstruct the air flow by touching the rear wall, nor should vaccines block the cover of the unit motor compartment. Typically, the air flow is down the rear walls from the circulating fan in the top and then back up the front.

Frozen water bottles may be placed in freezers to add cold mass. To help freezers retain their temperature longer in power outages, a [phase change material](#) -23°C -9°F capable of passively maintaining temperatures below 15°C $+5^{\circ}\text{F}$ is needed.

Types of refrigerator & freezers

Biologic-grade Full-sized Refrigerators

Biologic-grade (“medical”; “purpose-built”; “vaccine”; “blood-bank”; “laboratory”) refrigerators are considered the best, most secure option for vaccine storage. These are the “gold-standard” in vaccine units and have electronic thermostats, wire shelving to improve circulation, small ports for the entry of a temperature probe wire and interior fans to equalize the temperature throughout. Manufacturers in this category offer a range of sizes and options to fit any clinic’s needs. Size options include one-door and two-door bulk storage units, under-counter units and small point of service units to replace the disallowed dorm units. Units with glass doors help with inventory management. Keep in mind, biologic-grade units often require over a month to deliver. Some manufacturers will sell refrigerators classified as “biologic grade” with a mechanical or analog thermostat – avoid these. If purchasing a vaccine grade refrigerator, it should always have a “microprocessor controlled” or “electronic / digital” thermostat. These units are designed to run at approximately 5°C 41°F and rarely need any adjustment by the end-user. They are much safer than refrigerator units with analog dials.

Biologic-grade Freezers and Domestic Freezers

Freezers are easier to construct since they do not need a precise range – they just need to be always colder than -15°C $+5^{\circ}\text{F}$. Freezers can be much smaller than what is normally used in a home. Although frost-free freezers are recommended, that feature is often found only in freezers much larger than what is generally needed. (Large

practices with <5 providers might consider a large 5+ cu ft freezer.) If not specially designed, freezers advertised as “frost-free” may warm up considerably above -15°C $+5^{\circ}\text{F}$ during defrost when the evaporator coils are heated to melt any frost or ice. Often it is less expensive to purchase two small manual defrost units and keep one as a “cold spare”, than to purchase an appropriate auto-defrost unit. (The cold spare unit could hold the vaccine while the primary unit is being manually defrosted.) Be careful not to purchase more freezer than you need – vaccines containing Varivax are the only pediatric vaccines that require frozen storage, although MMR can be optionally stored frozen. Adequate freezers for 3 or 4 pediatricians can be as small as 1.5 cubic feet and cost as little as

\$250. If ordering a unit for under the counter, check the height of your countertop before ordering. Standard countertops are 36” high and may not be able to accommodate all freezers.



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Remember, small refrigerators and freezers can be sold as “counter top” or “built-in”. That refers to the air circulation needed for cooling. “Built-ins” are able to exhaust waste heat out of the front of the unit.

Standard Refrigerators and Freezers and “Commercial Grade”

Standard domestic refrigerators and freezers are found in homes and appliance stores. Higher-end models are sometimes referred to as “commercial-grade,” are most often used in the food service industry. They are not “biologic-grade”. Currently, use of domestic refrigerator-only and freezer-only units is not prohibited, but future guidance may disallow them, as many VFC programs have done. Commercial food service refrigerators look very much like vaccine refrigerators, but there can be differences. Food service units are designed to rapidly cool large quantities of warm/hot food – and thus could get too cold (below **0°C** **32°F**) when the compressor turns on. In an emergency, it is possible for a domestic refrigerator-only unit to be used safely for vaccine storage with proper precautions. If used for VFC vaccine, you should consult with your local VFC.

Other Features and Alarms

Glass doors may help the practice with inventory control, but they lose heat much faster in a power outage. While a solid door unit may maintain an acceptable temperature for 2 hours without power, glass door units rarely go longer than 30 minutes. Having generator power is prudent if looking for a glass door unit.

Certified, continuous data-logging thermometers with a maximum and minimum display are required. [Read more about these](#). It is also important to purchase a temperature monitor that can call, text, or otherwise notify several people if the unit has a temperature excursion. Best are those that will keep calling/notifying a list of staff until one acknowledges the notification with a response. Active notification could prevent nearly 80% of vaccine wastage due to temperature excursions.

The refrigerator may come with an electronic digital display of temperature, but the VFC program will require a separate certified data logger in a glycol buffer.

Manufacturers and Distributors of Biologic-grade Units

The manufacturers and distributors below are a sample of some that you may wish to consider for safe vaccine storage in your practice. Please note that the American Academy of Pediatrics cannot endorse or recommend specific products or brands. If you are a manufacturer of equipment and wish to add or edit information below, please contact immunize@aap.org.

Aegis	http://www.aegisfridge.com
American Biotech Supply	http://americanbiotechsupply.com/find-a-dealer
Compact Appliance	http://www.compactappliance.com/on/demandware.store/Sites-Appliance-Site/default/Search-Show?q=american+biotech
Fisher Scientific	https://www.thermofisher.com/us/en/home/life-science/lab-equipment/cold-storage/vaccine-cold-storage-solutions.html
Follett	http://www.follettice.com
Helmer	http://www.helmerinc.com/
Lab Research Products	http://www.labresprod.com/
Migali Scientific Refrigeration	http://migaliscientific.com/
Panasonic Healthcare	http://www.panasonic-healthcare.com/us/biomedical
Powers Scientific	www.powersscientific.com
ThermoFisher Scientific	www.thermofisher.com/us/en/home.html



AAP Immunization Resources

Storage and Handling Series

Refrigerators, Freezers, and Vaccine Storage

Use the following to determine the appropriate equipment size for your practice

Refrigerator:

Offices generally have either one large central storage unit, or a bulk storage unit with smaller refrigerators at a nursing desk that maintains a few days-worth of supply. The advantage of the central-storage style is that there is just one unit to be inventoried, set up, and monitored. Disadvantages include crowding by staff when multiple vaccine administrators need to retrieve vaccines, and inefficiency of the vaccine administrator needing to leave the area to retrieve the vaccine. In a bulk-storage style, a very large unit could be placed out of the high-flow area and infrequently accessed. The vaccine administrator would pull mainly from a smaller unit near their vaccine preparation area and not need to walk to the central unit. The disadvantage is that there are more units to monitor and larger initial cost.

Sizing a unit is difficult. Consider getting something larger than what exists currently. If just starting out, consider visiting a practice of the size you hope to be and look at their vaccine storage units. Vaccines come in many varied and oddly shaped boxes, so just counting expected dosages is rarely helpful. Remember to factor in the space needed for FluMist and injectable Flu vaccine.

Freezer:

Freezers can be much smaller. Since only Varivax containing vaccine must be stored in it, a 1.5 cu ft unit can hold enough vaccine for 3 or 4 pediatricians. Generally it works best to have a second cold spare unit so units can be manually defrosted. If you have a cold spare and you get tight for room, the second unit, if set up with its own certified thermometer, can serve as an overflow unit as well. MMR can be stored frozen and most pediatricians store it in the freezer. Since only two visits (12m and 4y) require Varivax and MMR, the freezer can be placed in a less busy area of the office. Again, in selecting a size, base your needs on your current storage ability or visit another practice to see what works for them.

Special thanks to the Oregon Immunization Program for sharing material from their 2012 Refrigerator Guide and to the California Department of Public Health for sharing material from their Refrigerator Buying Guide!

One final suggestion: When ordering large refrigerators, measure all doors and entry ways and check unit dimensions to verify that the unit(s) you ordered can fit into your building and into the appropriate room. Have two different people measure at least twice. These units are often used in university labs and hospitals and are quite large and tall. When ordering, ask for and pay extra for “inside delivery”. Otherwise, the shipping company (which is not who sold you the unit) may leave your new 500 pound refrigerator crated in a box in the parking lot.



AAP Immunization Resources Storage and Handling Series Data Loggers and Vaccine Monitoring

The Centers for Disease Control and Prevention (CDC) has developed guidance for storage and handling of vaccines. To see the current guidance issued by the CDC, view the [Vaccine Storage and Handling Toolkit](#).

Key Points:

- CDC recommends that practices maintain a calibrated, temperature monitoring device (data logger) and manually record temperatures in each unit containing Vaccines For Children (VFC) vaccines. This should be done twice daily.
- Data loggers have many different features. CDC recommendations are below, but call your VFC coordinator to learn what is required in your state.
- Consider a phone-enabled or internet-aware alarm to alert you by phone/internet anytime temperature excursions occur. Multiple people should be on the notification list to ensure the best chance that appropriate action is taken to correct the problem.

It is recommended that your data logger have the following functionality:

- Hi/Lo auditory alarm for out-of-range temperatures;
- Displays current temperature, as well as the minimum and maximum temperatures recorded since last manual recording of temperature (values must be visible from outside of the vaccine storage unit);
- Low battery indicator;
- Accuracy of ± 0.5 degrees C (± 1 degrees F) as certified by a current Certificate of Traceability and Calibration.
 - Certificates may last 1-2 years.
 - Speak to your VFC coordinator for your options. It may be cheaper to purchase a new device, or they can discuss acceptable testing laboratories.);
- Records continuously with memory storage of at least one month of data* (no less than 4,000 readings);
- Data recording loops when memory is full.* (Remember to download and transfer data to more permanent storage. Reset device after each data download.);
- Detachable, buffered temperature probe, that can remain in the unit while the temperature is displayed on the outside of the unit (near vaccines); and
- User programmable logging interval (or sampling rate) of 10 minutes or less.* While the CDC recommends 15 minutes or less, a more frequent sampling rate is allowed and may be preferable to capture more data points and to better estimate the duration of temperature excursions.

What do I do with the data stored on my data logger?

Even though the data logger is recording, the temperature will need to be checked and manually recorded by office staff twice daily, along with the maximum and minimum temperatures since the last data reset. This recommendation can prevent inadvertent loss of vaccine and the potential need for revaccination by allowing temperature excursions to be identified quickly so that immediate corrective action can be taken. This also provides an opportunity to visually inspect the storage unit, reorganize vaccines by date, and remove any expired vaccines.

*Please note this adds to CDC guidance.



AAP Immunization Resources

Storage and Handling Series

Data Loggers and Vaccine Monitoring

Data logger temperature data should be downloaded, reviewed weekly, and stored for at least 3 years. Documentation of known excursions or thermometer malfunctions should be recorded along with the temperature data and should include corrective actions taken to address the excursions. Software will likely be needed in order to view the stored data. Many data loggers are sold with software included, but some are sold separately. You must be able to review historical data.

What else do I need to consider?

- **Contact your VFC Program to determine their requirements**

The CDC has published recommendations for the local VFC Awardees who administer the VFC program to pediatricians. Being familiar with the CDC published recommendations will help pediatricians anticipate new requirements – but it is the requirements of the pediatrician's individual VFC program that must be followed per VFC contracts.

- **Alerts/Alarm phone-dialer** (alerts through landline, text, e-mail and/or mobile phone)

A phone-dialer is able to alert you to a temperature excursion during which no one is in the office to hear the local alarm. This allows someone to correct the problem in time to prevent the loss of vaccine. No single notification method works best in all situations – sometimes you may need a combination of methods. Understand the likely outages (eg, local and regional power failure, local and regional internet service, local and regional phone/cellular/Voice over Internet Protocol) that you may experience and realize the notification system can fail under such adverse conditions. Your office should have a plan in place for vaccine storage and transport during emergencies. Please see the [AAP Vaccine Storage and Handling Disaster Planning](#) resource.

- Equipment failure, door left open: This is by far the most common occurrence about which to be notified. As mentioned above, your data logger should have an alarm for temperatures exceeding either the high or low threshold. These alarms can notify staff who are physically near and able to respond. You may want to look for a unit that will allow you to program or specify a short/minimal delay before the alarm rings. This will allow you to avoid notification during routine inventory maintenance.
- Off-site notification: This type of notification can be used after office hours to reach one or more staff responsible for immunizations. Each office should have at least one staff immunization champion – a nurse or medical assistant who takes responsibility for and performs regular vaccine management tasks – and one physician who oversees immunizations. These staff members can be alerted via phone call, e-mail, or text. The best devices require a response from the person notified – a return text or acknowledgement code entered via the phone – and will continue to dial staff members until the acknowledgement is received.
- Power outages: Although the phone-dialer may have its own battery, the phone service going to the dialer may fail.
 - Local power failure (circuit breaker, single building outage) can disable most phone systems unless they have battery backup or a generator. A standard “land line,” tied directly to the dialer (does not go through an office phone system) is the most reliable and does not require a power source. Cellular service is also quite reliable and has the advantage of texting and/or voice-calling. E-mail notification, cable phone service, and Voice over Internet Protocol phone systems require internet service which may also be dysfunctional in the building, as modems, routers, switches, and servers all need power to be working. Service



AAP Immunization Resources Storage and Handling Series Data Loggers and Vaccine Monitoring

can also be lost in the immediate area, thus rendering these methods less dependable. Some internet devices constantly notify send notifications to an offsite device. If these notifications stop (for example in the case of a power outages), the offsite device will begin calling staff members. This method works even if total power failure occurs.

- Regional power failure (natural disasters, floods, hurricane, snow storm, large-scale grid failure) can make notification more difficult since the infrastructure can be compromised. Usually a responsible staff can be aware of such events and should physically go to the site to inspect. Understand the likely outages (local and regional power failure, local and regional internet service, local and regional phone/cellular/VOIP) that you may experience and realize the notification system can fail under such adverse conditions.
- **A back-up thermometer**
 - Have a back-up thermometer to use if/when your primary unit is being tested for calibration. It may be more cost-effective to purchase a new thermometer than to maintain 2 with updated certifications of calibration.
- **A unit with a continuous-tracking feature**
 - Older thermometers may directly record the unit's temperature onto a circular piece of graph paper. These have been totally replaced by electronic versions and should not be used. (**Please note: use of continuous tracking with a data logger does not preclude you from manually recording the temperature twice daily!**).
- **Vaccine Insurance**
 - When private-purchase vaccine expires or is destroyed by temperature excursions, the manufacturer may take back non-influenza vaccine and exchange all for new vaccine. Replacement is not an option if the vaccine is physically destroyed (fire) or in case of theft. Returning vaccine is not currently an option for doses purchased through the CDC VFC contract and given to practices. Practice owners may be financially responsible for all VFC vaccine spoilage. Follow state VFC program guidance on returning vaccine. The degree of VFC financial risk is determined by the local VFC program, not the CDC. Contact your local VFC program to determine your financial risk when storing VFC vaccine. Practices with excellent storage programs may be excused from financial responsibility for events beyond their reasonable control.
 - Insurance is an option for both private-purchase and VFC vaccine. As with any insurance policy, be very sure you understand exactly what is and is not covered - write the insurance agent asking: "Please give me a list in writing as to what losses you **will not** cover."
- **Spare refrigerator and transport containers**
 - Consider placing a spare thermometer (with a buffered probe) in your employee or break-room refrigerator and maintain/monitor that refrigerator between **2°C and 8°C** (**35° F and 46° F**) just like you would a vaccine refrigerator. That way if you have an unexpected equipment failure, you can remove all food and have a readily available refrigerator that you know is capable of storing the vaccine at the appropriate temperature.
 - Have coolers capable of safely transporting your vaccine to an alternate refrigerator in case of power failure stored in your building. Conditioned frozen water bottles make excellent coolant for transport of refrigerated vaccine and should be on hand at all times. (See [CDC Packing Vaccines for Transport during Emergencies](#)).



AAP Immunization Resources

Storage and Handling Series

Data Loggers and Vaccine Monitoring

- **Electrical backup for refrigerators**
 - Although battery backups are appropriate for computers to help deal with minor power outages, battery backups are NEVER appropriate for refrigerators. Refrigerator compressors draw too much current for battery backup devices and will likely fail. If the power returns in a few moments, the device will remain “off” and so will the refrigerator.
 - In areas at risk for power outages, propane or natural gas emergency generators are appropriate. They must have automatic start and be professionally installed by an electrician.
 - Gasoline and diesel fuel are not appropriate fuels for emergency refrigerators because they age quickly.
 - Be aware that refrigerators can exceed **8°C (46°F)** in about 3 hours of no power at room temperature.
- **How do you determine if the refrigerator is failing or the data logger is wrong?**
 - To check the accuracy of a data logger, you can do an Ice Melting Point Test. [Watch this demonstration](#).
 - An easy method is to purchase a soup thermos, fill with more ice than water, and place the certified probe into the water + ice while in the refrigerator. If, after 10 minutes, the thermometer reads within **+/- 0.5° of 0°C (+/- 1° of 32°F)** and holds that range for another 10 minutes, then the thermometer passed and demonstrated that it is accurate. If it fails, it should be replaced.
 - Refrigerators can slowly decline in function. If you find that you are turning the thermostat colder and colder to maintain **5°C (41°F)** you should replace the refrigerator immediately.
 - View the [Immunization Action Coalition Resources](#) for documenting and correcting any unacceptable vaccine storage event.
 - If testing shows the device is reporting inaccurate temperature do not try to adjust it, replace the temperature monitoring device.
- **How do you place a data logger in a refrigerator?**
 - The data loggers with a removable temperature probe usually have a wire leading to the probe. There are some that function wirelessly, but most use a wire. Purpose-built (vaccine/medical) refrigerators often have a plug that covers a hole through the side or rear wall of the unit designed to feed the probe wire into the unit without gapping the door.
 - If the storage unit has no port, the probe should enter through the door opening on the hinge side high in the top corner. The seals are sensitive to gaps caused by the monitor wire and frost will build up in freezers due to the gap allowing moist air to enter. This can be reduced by tightly taping the wire in the door frame with thin clear packing tape for a good seal.
 - Place the probe in glycol in the center of the refrigerator with several loops of extra wire. That will allow you to move it throughout the vaccine storage area to verify that the entire refrigerator is kept at the temperature appropriate for vaccines.





AAP Immunization Resources Storage and Handling Series Data Loggers and Vaccine Monitoring

Special thanks to the Oregon Immunization Program for sharing material from their 2012 Thermometer Guide!

Please note that the American Academy of Pediatrics cannot endorse or recommend specific products or brands. This guide is only meant to aid you in your selection of vaccine storage equipment. The terms and conditions related to your purchase are between you and the vendor.

While we attempt to keep this document updated, model numbers, styles, and features change often. Before making your final decision, contact the manufacturer/vendor for up-to-date pricing and specifications, and check with your VFC coordinator to verify a product meets their requirements.

Data logger manufacturers and distributors:

Accsense	http://www.accsense.com/p_p_a102.html
Berlinger	http://www.berlinger.com/en/temperature-monitoring/products-hardware/data-loggers/
Control Solutions Inc.	www.vfcdataloggers.com
Dickson	http://www.dicksondata.com/products/find/data-logger
DeltaTrak	http://www.deltatrak.com/flashkink-vaccine-usb-pdf#specifications
Lascar Electronics	http://www.lascarelectronics.com/data-logger/
Onset (Hobo)	http://www.onsetcomp.com/
SensoScientific	http://www.sensoscientific.com/vaccine-vfc/
T&D Corporation	http://www.tandd.com/#fragment-1
Temperature Guard	http://temperatureguard.com/
Temperature@lert	http://www.temperaturealert.com/Temperature-Alarm.aspx
Tip Temperature Products	www.tiptemp.com

Alarm phone-dialer manufacturers:

Dickson	http://www.dicksondata.com/
DeltaTrak	http://www.deltatrak.com/flashtrak-wrm#specifications
Sensaphone	http://www.sensaphone.com
Temperature Guard	http://temperatureguard.com/
United Security Products	http://www.unitedsecurity.com/
Temperature@lert	http://www.temperaturealert.com/Temperature-Alarm.aspx



AAP Immunization Resources

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Data Loggers and Vaccine Monitoring

In order to be assured your data logger meets all desired specifications, you may want to discuss them with your vendor. Below is a list of questions to ask your vendor to help you understand all the functions of a data logger. You may use the chart on the next page to fill-in information and compare models.

Questions to ask about desired specifications:


- Does this data logger display the current, minimum, and maximum temperature? Is the display outside of the vaccine storage unit (refrigerator or freezer) where it can be easily accessed?
- Does the unit have an alarm that will alert the user if temperature exceeds the high/low thresholds?
- Does the unit have a reset button that clears the minimum and maximum temperatures since the last clearing?
- Does the unit have a low battery indicator?
- Does the unit have one or more detachable temperature probe(s) in glycol or suitable temperature buffer?
- Does the temperature probe and unit measure accurately, within $\pm 0.5^{\circ}\text{C}$ ($\pm 1^{\circ}\text{F}$) and come with a Certificate of Traceability and Calibration?
- Can it record at least a month worth of readings at a 10 minute sample rate?
- Does this unit loop data (record over the oldest data) when memory is full?
- Is the logging interval customizable? At what intervals can this device record?

Questions to ask about additional features:

- Can this unit connect more than one probe?
- Can this unit transmit data wirelessly?
- Is a power cord available?
 - If not, does the battery last at least 1 year?
 - How long does the battery last?
 - Is the battery replaceable?
- Is software included or available for separate purchase? (If separate, considering purchasing to access your stored data).
- What are the system requirements for the software?
- Can this unit place phone calls (landline and mobile), send text messages, and/or send e-mail messages to several numbers and addresses if it detects a temperature excursion?
 - If so, can a user query the monitor for additional readings while traveling to the office? (If it “recovers” as in a power outage, you want to be able to return home).

AAP Immunization Resources Storage and Handling Series Data Loggers and Vaccine Monitoring

You may use this chart to fill-in information and compare models. Please note that the American Academy of Pediatrics cannot endorse specific products. This guide is only meant to aid you in your selection of vaccine temperature monitoring equipment. The terms and conditions related to your purchase are between you and the vendor.

Data logger make/model	Cost	Hi/Lo alarm	Current min & max temp display	Maximum and Minimum Temperature Reset button	Low battery indicator	Accuracy	Memory storage	Programmable logging interval of 10 minutes or less? Y/N Rate?	Does data loop when memory is full?	Data displayed outside of unit and downloaded without disruption of probe?	Frequency & Cost of Re-Calibration	Other features
Monitor ABC	\$500	Yes	Yes	Yes, logger can be cleared	Yes (indicates when A/C power is removed)	±0.45°C	60,000	Y Various intervals available	Yes	Yes, remote probe	Annually \$99-\$269 Check with VFC Coordinator	Relay (function for external alarm hook-up); UBS/flash card 



AAP Immunization Resources Storage and Handling Series Checklist for Proper Storage and Handling Practices

The [CDC Vaccine Storage and Handling Toolkit](#) suggests activities at regular intervals to maintain proper vaccine storage and handling.

Use the following list to maintain good vaccine storage and handling practices. Good storage and handling practices will keep your vaccines safe and potent and prevent financial losses due to vaccine spoilage. Your office should maintain a vaccine storage log book (electronic or paper), where data and/or notes can be recorded as described below.

The following should be done **DAILY**:

- Monitor refrigerator temperatures for 24 hours using a certified digital max/min data-logging thermometer with a **glycol-encased probe** or a similar temperature-buffered probe.
- Manually read and document temperatures twice daily (the temperature should be read on the data logger outside of the refrigerator, so the door remains closed).
- Check to make sure the refrigerator and freezer are in working condition and doors are closed.

The following should be done **WEEKLY**:

- Download and review stored temperature data to allow timely review and appropriate response to issues. Appropriate responses include:
 - If temperature monitoring equipment shows a near-excursion, determine the cause and correct it. This may include closing the refrigerator door completely, doing stock manipulation/re-stocking in multiple short sessions, adjusting the thermostat if using an older, manual unit, or calling for repair if the unit is not working properly.
 - If vaccines have been exposed to temperature excursions, immediately segregate all compromised vaccine in a container or bag and place at the proper temperature **2°C to 8°C** **35°F to 46°F** for refrigerated-vaccines, **≤ -15°C** **≤ +5°F** for frozen vaccine and mark "DO NOT USE".
 - Do not discard vaccine exposed to warmth; most vaccine has a range of heat tolerance.
 - Call vaccine distributors and VFC state programs for guidance on whether vaccines can still be used.
- Always delete the data upon downloading it from the data logger. This should be done each time and is especially important if memory does not "loop". This will prevent the unit's memory from filling and resulting in loss of data. Always save downloaded data for 3 years.
- Review vaccine and diluent expiration dates; remove expired items.
- Rotate vaccine so that product with soonest expiration date are moved to the front and note vaccine stock in log book or electronic inventory system. Record how much of each product remains and when the expiration dates are. These notes will help with ordering. Weekly inventory may also help to check for appropriate billing.





AAP Immunization Resources Storage and Handling Series Checklist for Proper Storage and Handling Practices

The following should be performed **MONTHLY**:

- Clean refrigerator coils and motor. Consider contracting with a local refrigerator repair company for regular maintenance.
- For freezers, check for ice/frost buildup especially manually defrosted units.
 - If buildup is excessive or near door seal, immediately plan for defrost. To defrost, have an additional freezer nearby that is pre-chilled to $\leq -15^{\circ}\text{C}$ $\leq +5^{\circ}\text{F}$. Move frozen vaccine to a temporary storage unit with a data logger. Unplug the power to primary unit. De-ice with a hair dryer or similar. Dry thoroughly. Plug in the unit and measure temp. When the unit has reached the proper temperature, restock vaccine, and download the data logger that stayed with the vaccine. If any excursions occurred, contact appropriate agencies as above.
- Check door seals of refrigerator and freezer. Visually and tactically inspect the seals – they should not be torn or brittle and there should be no gaps between the seal and the body of the unit when the door is closed. The door should open and close properly and fit squarely against the body of the storage unit. You can also put a piece of paper at the door seam, close the door, and pull the paper. You should feel tension as you pull. Check along the entire seal.

The following should be performed **ANNUALLY**:

- Update written routine storage and handling plans and repost in a prominent and easily accessible location near the vaccine storage unit(s).
- Update written emergency storage and handling plans and repost. For help, see [AAP Disaster Planning Tip Sheet](#).
- Provide the vaccine champions of the office with continuing education on vaccine management.
- Verify thermometer certification date and replace or renew if required.
 - Generally it is less expensive to replace an expired certified thermometer, than to re-certify.
 - If re-certification is preferred, send device for verification or calibration to a laboratory with accreditation from an International Laboratory Accreditation Cooperation Mutual Recognition Arrangement signatory body.
 - The following are links for listings of accredited laboratories:
 - [The American Association for Laboratory Accreditation \(A2LA\)](#)
 - [International Accreditation Service \(IAS\)](#)
 - [Perry Johnson Laboratory Accreditation, Inc. \(PJLA\)](#)
 - Consider an [ice melting point test](#). For vaccines supplied through the Vaccines for Children program, check with your state VFC program coordinator to see if this is an acceptable option.



AAP Immunization Resources

Storage and Handling Series

Disaster Planning

The [Centers for Disease Control and Prevention Vaccine Storage and Handling Toolkit](#) suggests that all practices have a plan in place for keeping vaccine supply safe during a power failure or other disaster.

The Centers for Disease Control and Prevention (CDC) requires that Vaccine for Children (VFC) providers develop and follow a written emergency vaccine storage and handling plan. This plan should be simple and the process outlined in the plan should be clear and concise.

Key Points:

- An emergency plan is needed to keep your vaccine stored safely at all times to prevent loss.
- Post the emergency plan in a prominent place where staff can find it easily.
- Update the plan annually.
- As part of your emergency plan, include a designated place you can take vaccines for safe storage during an emergency.
- Be sure you have all the equipment necessary on hand to carry out your plan.
- Once power is restored, do not discard vaccines that have been exposed to temperature excursions. Call your VFC coordinator or the manufacturer for guidance.

Remember!

Comprehensive vaccine management protocols will help practice staff address future vaccine supply challenges (i.e., vaccine shortages or supply allocations) and help ensure appropriate vaccine handling procedures throughout the years.

Why is a written emergency vaccine storage and handling plan needed?

In order to maintain potency and efficacy of vaccine products, they must be stored at the temperatures specified by the manufacturer at all times. The following events may jeopardize your practice's ability to maintain vaccine at the appropriate temperature:

- Storage unit malfunction
- Power outages
- Natural disasters
- Other emergencies





AAP Immunization Resources

Storage and Handling Series

Disaster Planning

A written plan that specifies actions to take when faced with these situations will allow your practice to proceed most efficiently in protecting vaccine stock.

Steps to take before the emergency

- Designate primary and alternate vaccine coordinators with emergency contact information. In addition to routine vaccine storage activities, coordinators should:
 - monitor the operation of the vaccine storage equipment and systems;
 - track inclement weather conditions;
 - set up and maintain a monitoring/notification system during times of inclement weather or other conditions that might cause a power outage (a continuous-monitoring temperature alarm/notification system should be considered, especially for facilities with large inventories, see [AAP Data Loggers and Vaccine Monitoring](#);
 - post emergency contact information on circuit breaker(s) or electrical panel;
 - manage the appropriate handling of vaccine during a disaster or power outage;
 - verify 24-hour access to the building and vaccine storage unit(s).
- Secure backup energy source (generator).
 - Maintain sufficient fuel supply to continuously run the generator for at least 72 hours.
- Have your written emergency vaccine storage and handling plan posted where staff can easily find it, preferably near the vaccine storage units.
- Provide staff access to up-to-date phone numbers for vaccine distributors, vaccine manufacturers, and VFC Coordinators.
- Verify all staff have read and understand the emergency vaccine storage and handling plan.
- List the name and contact information of a local refrigeration repair shop that could potentially fix a failed unit.
 - Maintain a list of vaccine storage unit specifications (brand name, model number, and serial number) to provide to the repair technician.

Developing your emergency plan:

- Designate an alternate site with 24-hour access where vaccines and diluents can be safely stored.
 - Considerations when choosing a site include types of:
 - storage unit(s) available
 - temperature monitoring capabilities
 - back-up generator
 - Potential back-up locations include:
 - local hospitals and health departments
 - another provider's facility
 - retail or clinic pharmacies
 - long-term care facilities
 - the Red Cross.
- Develop written protocols and list of vehicles and drivers for transporting vaccines to and from the alternate vaccine storage facility.



AAP Immunization Resources

Storage and Handling Series

Disaster Planning

- Obtain and store an adequate number of appropriate packing containers and materials (e.g., polystyrene coolers, frozen water bottles, bubble wrap) in the facility from which vaccines will be packed for safe transport.
 - Safe transport tips are described in the [CDC Packing Vaccines for Transport during Emergencies](#).
 - Communicate to staff where everything is kept.
 - Include written directions for packing vaccines and diluents for transport.
 - A pre-chilled, calibrated thermometer and data logger should be placed in each packing container.

Sample activities to include in your emergency plan:

- Incorporate written procedures for managing potentially compromised vaccines.
- Include contact information for vaccine manufacturers and/or the VFC Coordinators.
- Include written instructions for entering your facility and vaccine storage spaces in an emergency if the building is closed. These instructions should include:
 - the building security/after-hours access procedure,
 - a floor diagram,
 - and the locations of the following:
 - Alarms (including instructions for use)
 - Doors
 - Flashlights
 - Spare batteries
 - Light switches
 - Keys
 - Locks
 - Circuit breakers
 - Packing materials

During a power outage:

- Do not open freezers and refrigerators, except to transport vaccine to an alternative storage location, if alternative storage with reliable power is available. Refrigerators will generally be warmer than 8°C 46°F within 3 hours of a power outage. If it is likely for the power to be off for more than 3 hours, plan on moving the vaccine to a safer location or for refrigerated vaccine, consider “Shelter In Place” in hard sided coolers or shipping containers cooled with conditioned frozen water bottles and appropriate data logger as used in emergency transportation.
- Always carefully follow proper transport protocols (see CDC [Packing Vaccines for Transport during Emergencies](#)) and include them in your plan.
- Continue to monitor temperatures. If possible, do so without opening the door.
- After the event, do not discard vaccine that has been warm. Most vaccines are relatively heat tolerant. Immediately segregate all compromised vaccine in a container or bag and place refrigerated vaccine between 2°C and 8°C 35°F and 46°F and frozen vaccine at $\leq -15^{\circ}\text{C}$ $\leq +5^{\circ}\text{F}$. Mark “DO NOT USE”.
- Call vaccine distributors and VFC Coordinators to cancel any upcoming vaccine deliveries.



AAP Immunization Resources

Storage and Handling Series

Disaster Planning

Once power is restored:

- Record the temperature in the vaccine storage unit as soon as possible, after the power has been restored. Continue to monitor and record. It can take a domestic refrigerator 4-8 hours to cool below **8°C** **46°F**. Verify the unit reaches the proper **2°C to 8°C** **35°F to 46°F** range prior moving the vaccine back to the unit. Record temperature and download the data from the logger in the vaccine storage unit after conditions stabilized.
- Record the duration of any temperate excursions observed.
- Separate any vaccine product exposed to temperature excursions from vaccine that was not exposed, but store the compromised vaccine in the proper temperature range until final dispensation. Mark "DO NOT USE".
- Do not administer or discard any vaccine that has been exposed to temperature excursions until speaking with the proper authorities.
 - Call your VFC Coordinator to report the event and ask for advice on handling the compromised vaccine. You should also report any privately purchased compromised vaccine directly to the appropriate manufacturers. It is possible that your VFC Program and the manufacturer may have differing guidance, and you may have to clarify with both parties which is the most appropriate.
 - If instructed that private vaccine should not be administered, discuss returning the vaccine for a credit with the vaccine manufacturer.
 - Document the event, the calls, and the corrective action taken in your vaccine log book. To learn more about what should be recorded in a log book and regular vaccine storage and handling tasks, please see the [AAP Storage and Handling Checklist](#).
- Notify vaccine distributors or VFC Coordinator to resume vaccine deliveries.

Resources:

- [AAP Storage and Handling Web page & resources](#)
- [CDC Vaccine Storage and Handling Recommendations and Guidelines](#)
- [CDC Vaccine Storage and Handling Toolkit](#)
- [CDC Packing Vaccines for Transport during Emergencies](#)
- [Immunization Action Coalition Emergency Response Worksheet](#)

Packing Vaccines for Transport during Emergencies

Be ready BEFORE the emergency

Equipment failures, power outages, natural disasters—these and other emergency situations can compromise vaccine storage conditions and damage your vaccine supply. **It's critical to have an up-to-date emergency plan with steps you should take to protect your vaccine.** In any emergency event, activate your emergency plan immediately, and if you can do so safely, follow the emergency packing procedures for refrigerated vaccines.

1 Gather the Supplies



Hard-sided coolers or Styrofoam™ vaccine shipping containers

- Coolers should be large enough for your location's typical supply of refrigerated vaccines.
- Can use original shipping boxes from manufacturers if available.
- Do NOT use soft-sided collapsible coolers.



Conditioned frozen water bottles

- Use 16.9 oz. bottles for medium/large coolers or 8 oz. bottles for small coolers (enough for 2 layers inside cooler).
- Do NOT reuse coolant packs from original vaccine shipping container, as they increase risk of freezing vaccines.
- Freeze water bottles (can help regulate the temperature in your freezer).
- Before use, you must condition the frozen water bottles. Put them in a sink filled with several inches of cool or lukewarm water until you see a layer of water forming near the surface of bottle. The bottle is properly conditioned if ice block inside spins freely when rotated in your hand.



Insulating material — You will need two of each layer

- **Insulating cushioning material** – Bubble wrap, packing foam, or Styrofoam™ for a layer above and below the vaccines, at least 1 in thick. Make sure it covers the cardboard completely. Do NOT use packing peanuts or other loose material that might shift during transport.
- **Corrugated cardboard** – Two pieces cut to fit interior dimensions of cooler(s) to be placed between insulating cushioning material and conditioned frozen water bottles.



Temperature monitoring device – Digital data logger (DDL) with buffered probe. Accuracy of $\pm 1^{\circ}\text{F}$ ($\pm 0.5^{\circ}\text{C}$) with a current and valid certificate of calibration testing. Pre-chill buffered probe for at least 5 hours in refrigerator. Temperature monitoring device currently stored in refrigerator can be used, as long as there is a device to measure temperatures for any remaining vaccines.

Why do you need cardboard, bubble wrap, and conditioned frozen water bottles?

Conditioned frozen water bottles and corrugated cardboard used along with one inch of insulating material such as bubble wrap keeps refrigerated vaccines at the right temperature and prevents them from freezing. **Reusing vaccine coolant packs from original vaccine shipping containers can freeze and damage refrigerated vaccines.**



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Visit www.cdc.gov/vaccines/SandH
for more information, or your state
health department.

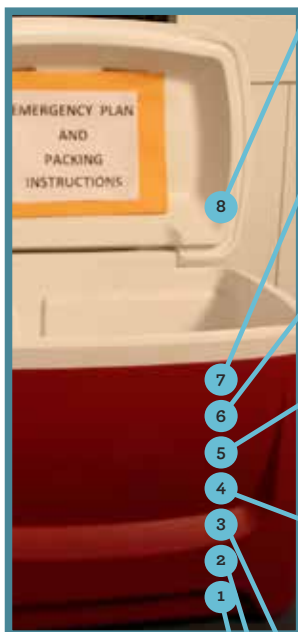
CS249275-1 August 2015

Packing Vaccines for Transport during Emergencies

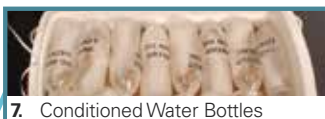
2 Pack for Transport

Conditioning frozen water bottles

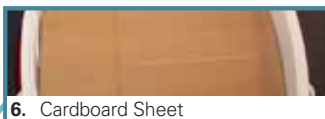
- Put frozen water bottles in sink filled with several inches of cool or lukewarm water or under running tap water until you see a layer of water forming near surface of bottle.
- The bottle is properly conditioned if ice block inside spins freely when rotated in your hand.
- If ice “sticks,” put bottle back in water for another minute.
- Dry each bottle.
- Line the bottom and top of cooler with a single layer of conditioned water bottles.
- Do NOT reuse coolant packs from original vaccine shipping container.



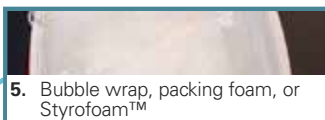
8. Temperature Monitoring Device Display (on lid)



7. Conditioned Water Bottles



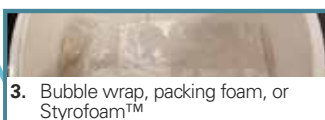
6. Cardboard Sheet



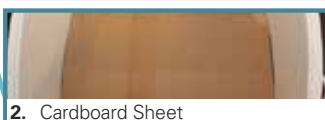
5. Bubble wrap, packing foam, or Styrofoam™



4. Vaccines, Diluents, and Temperature Monitoring Device Probe



3. Bubble wrap, packing foam, or Styrofoam™



2. Cardboard Sheet



1. Conditioned Water Bottles

Close lid – Close the lid and attach DDL display and temperature log to the top of the lid.

Conditioned frozen water bottles – Fill the remaining space in the cooler with an additional layer of conditioned frozen water bottles.

Insulating material – Another sheet of cardboard may be needed to support top layer of water bottles.

Insulating material – Cover vaccines with another 1 in. layer of bubble wrap, packing foam, or Styrofoam™

Vaccines – Add remaining vaccines and diluents to cooler, covering DDL probe.

Temperature monitoring device – When cooler is halfway full, place DDL buffered probe in center of vaccines, but keep DDL display outside cooler until finished loading.

Vaccines – Stack boxes of vaccines and diluents on top of insulating material.

Insulating material – Place a layer of bubble wrap, packing foam, or Styrofoam™ on top (layer must be at least 1 in. thick and must cover cardboard completely).

Insulating material – Place 1 sheet of corrugated cardboard over water bottles to cover them completely.

Conditioned frozen water bottles – Line bottom of the cooler with a single layer of conditioned water bottles.

NOTE:

This packout can maintain appropriate temperatures for up to 8 hours, but the container should not be opened or closed repeatedly.

3 Arrive at Destination

Before opening cooler – Record date, time, temperature, and your initials on vaccine temperature log.

Storage – Transfer boxes of vaccines quickly to storage refrigerator.

Troubleshooting – If there has been a temperature excursion, contact vaccine manufacturer(s) and/or your immunization program before using vaccines. Label vaccines “Do Not Use” and store at appropriate temperatures until a determination can be made.



Temperature Log for Refrigerator – Fahrenheit

DAYS 1–15

Month/Year _____ VFC PIN or other ID # _____
Facility Name _____

Monitor temperatures closely!

1. Write your initials below in “Staff Initials,” and note the time in “Exact Time.”
2. Record temps twice each workday.
3. Record the min/max temps once each workday—preferably in the morning.
4. Put an “X” in the row that corresponds to the refrigerator’s temperature.
5. If any out-of-range temp, see instructions to the right.
6. After each month has ended, save each month’s log for 3 years, unless state/local jurisdictions require a longer period.

Take action if temp is out of range—too warm (above 46°F) or too cold (below 35°F).

1. Label exposed vaccine “do not use,” and store it under proper conditions as quickly as possible. Do not discard vaccines unless directed to by your state/local health department and/or the manufacturer(s).
2. Record the out-of-range temps and the room temp in the “Action” area on the bottom of the log.
3. Notify your vaccine coordinator, or call the immunization program at your state or local health department for guidance.
4. Document the action taken on the “Vaccine Storage Troubleshooting Record” on page 3.

Day of Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Staff Initials															
Exact Time	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM
Min/Max Temp (since previous reading)															
Danger! Temperatures above 46°F are too warm! Write any out-of-range temps and room temp on the lines below and call your state or local health department immediately!															
TEMPERATURES	46° F														
	45° F														
	44° F														
	43° F														
	42° F														
	41° F														
Aim for 40°	40° F														
ACCEPTABLE	39° F														
	38° F														
	37° F														
	36° F														
	35° F														
Danger! Temperatures below 35°F are too cold! Write any out-of-range temps and room temp on the lines below and call your state or local health department immediately!															
ACTION	Write any out-of-range temps (above 46°F or below 35°F) here:														
	Room Temperature														

If you have a vaccine storage issue, also complete “Vaccine Storage Troubleshooting Record” found on page 3.

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Adapted with appreciation from California Department of Public Health
Technical content reviewed by the Centers for Disease Control and Prevention
www.immunize.org/catg.d/p3037f.pdf • Item #P3037F (8/13)

Vaccine Storage Troubleshooting Record (check one) ☐ Refrigerator ☐ Freezer

Page 3 of 3

Use this form to document any unacceptable vaccine storage event, such as exposure of refrigerated vaccines to temperatures that are outside the manufacturers' recommended storage ranges. A fillable troubleshooting record (i.e., editable PDF or WORD document) can also be found at www.immunize.org/clinic/storage-handling.asp.

Date & Time of Event If multiple, related events occurred, see Description of Event below.		Storage Unit Temperature at the time the problem was discovered	Room Temperature at the time the problem was discovered	Person Completing Report
Date:	Temp when discovered:	Minimum temp:	Temp when discovered:	Name:
Time:	Maximum temp:	Comment (optional):		Title:
Description of Event (If multiple, related events occurred, list each date, time, and length of time out of storage.) <ul style="list-style-type: none"> General description (i.e., what happened?) Estimated length of time between event and last documented reading of storage temperature in acceptable range (35° to 46°F [2° to 8°C] for refrigerator; -58° to 5°F [-50° to -15°C] for freezer) Inventory of affected vaccines, including (1) lot #s and (2) whether purchased with public (for example, VFC) or private funds (Use separate sheet if needed, but maintain the inventory with this troubleshooting record.) At the time of the event, what else was in the storage unit? For example, were there water bottles in the refrigerator and/or frozen coolant packs in the freezer? Prior to this event, have there been any storage problems with this unit and/or with the affected vaccine? Include any other information you feel might be relevant to understanding the event. 				
Action Taken (Document thoroughly. This information is critical to determining whether the vaccine might still be viable.) <ul style="list-style-type: none"> When were the affected vaccines placed in proper storage conditions? (Note: Do not discard the vaccine. Store exposed vaccine in proper conditions and label it "do not use" until after you can discuss with your state/local health department and/or the manufacturer[s].) Who was contacted regarding the incident? (For example, supervisor, state/local health department, manufacturer—list all.) IMPORTANT: What did you do to prevent a similar problem from occurring in the future? 				
Results <ul style="list-style-type: none"> What happened to the vaccine? Was it able to be used? If not, was it returned to the distributor? (Note: For public-purchase vaccine, follow your state/local health department instructions for vaccine disposition.) 				

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www.immunize.org/catg.d/p3041.pdf • Item #P3041 (8/13)

Vaccine Storage Troubleshooting Record (check one) ☒ Refrigerator ☐ Freezer

Use this form to document any unacceptable vaccine storage event, such as exposure of refrigerated vaccines to temperatures that are outside the manufacturers' recommended storage ranges. A fillable troubleshooting record (i.e., editable pdf or WORD document) can also be found at www.immunize.org/clinic/storage-handling.asp

Date & Time of Event If multiple, related events occurred, see Description of Event below.	Storage Unit Temperature at the time the problem was discovered	Room Temperature at the time the problem was discovered	Person Completing Report
Date: (see below)	Temp when discovered: 45°F	Temp when discovered: 77°F	Name: Nancy Nurse
Time: (see below)	Minimum temp: 38°F Maximum temp: 53°F	Comment (optional): temp is approx	Title: VFC Coordinator Date: 6/24/13
Description of Event (If multiple, related events occurred, list each date, time, and length of time out of storage.) <ul style="list-style-type: none"> General description (i.e., what happened?) Estimated length of time between event & last documented reading of storage temperature in acceptable range (33° to 46°F [2° to 8°C] for refrigerator; -58° to 5°F [-50° to -15°C] for freezer) Inventory of affected vaccines, including (1) lot #s and (2) whether purchased with public (for example, VFC) or private funds (Use separate sheet if needed, but maintain the inventory with this troubleshooting record) At the time of the event, what else was in the storage unit? For example, were there water bottles in the refrigerator and/or frozen coolant packs in the freezer? Prior to this event, have there been any storage problems with this unit and/or with the affected vaccine? Include any other information you feel might be relevant to understanding the event. <p>At 8 am on Monday (6/24/13) morning when clinic opened, identified 4 temperature excursions over the weekend in refrigerator with readings as high as 54°, 50°, 49° & 53°F in primary vaccine storage unit #1. Recordings taken every 15 min on calibrated digital data logger overnight. Data logger probe in glycol located in middle of refrigerator with vaccines.</p> <p>Total time out of range: approximately 3 hrs — maximum temp 53°F (see attached document of continuous temp readings)</p> <p>Inventory of vaccines: see attached</p> <p>Water bottles in refrigerator door. No vaccine stored in freezer. No problems with storage unit prior to Saturday night. Thunderstorms in area over weekend may have affected power.</p>			
Action Taken (Document thoroughly. This information is critical to determining whether the vaccine might still be viable!) <ul style="list-style-type: none"> When were the affected vaccines placed in proper storage conditions? (Note: Do not discard the vaccine. Store exposed vaccine in proper conditions and label it "do not use" until after you can discuss with your state/local health department and/or the manufacturer[s].) Who was contacted regarding the incident? (For example, supervisor, state/local health department, manufacturer—list all.) IMPORTANT: What did you do to prevent a similar problem from occurring in the future? <p>Vaccines currently stored appropriately at 45°F. Refrigerator and vaccines labeled "Do Not Use."</p> <p>My State Immunization Program contacted at 8:30 am. Spoke with Victor Vaccine. Provided Victor with details of event and list of vaccines. Vaccine to remain quarantined until we hear back from Victor.</p> <p>Called electric company and confirmed 2 short power outages during weekend.</p> <p>Checked refrigerator seals — called refrigerator maintenance company to replace seals.</p> <p>Checked plug on unit — placed tape over plug to prevent inadvertent dislodging. Plan to purchase plug guard.</p> <p>Plan to follow up with Immunization Program on data loggers with alarms that could be sent to coordinator and back-up phones.</p>			
Results <ul style="list-style-type: none"> What happened to the vaccine? Was it able to be used? If not, was it returned to the distributor? (Note: For public-purchase vaccine, follow your state/local health department instructions for vaccine disposition.) <p>Late on Monday, I talked with Victor regarding continued use of vaccine. Victor had checked with manufacturers which confirmed that vaccine is acceptable for use. He told me that vaccine could therefore be removed from quarantine. I discussed the entire situation with Susie Supervisor and Dr. Director (clinic medical director) who agreed that we could put vaccine back in use.</p>			

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Vaccine Storage Troubleshooting Record (check one) ☒ Refrigerator ☐ Freezer

Use this form to document any unacceptable vaccine storage event, such as exposure of refrigerated vaccines to temperatures that are outside the manufacturers' recommended storage ranges. A fillable troubleshooting record (i.e., editable pdf or WORD document) can also be found at www.immunize.org/clinic/storage-handling.asp

Date & Time of Event If multiple, related events occurred, see Description of Event below.	Storage Unit Temperature at the time the problem was discovered	Room Temperature at the time the problem was discovered	Person Completing Report
Date: 7/16/2013	Temp when discovered: 28°F	Temp when discovered: 77°F	Name: Nancy Nurse
Time: 8:00 am	Minimum temp: 28°F Maximum temp: 42°F	Comment (optional): temp is approx	Title: VFC Coordinator Date: 7/15/13
Description of Event (If multiple, related events occurred, list each date, time, and length of time out of storage.) <ul style="list-style-type: none"> General description (i.e., what happened?) Estimated length of time between event & last documented reading of storage temperature in acceptable range (35° to 46°F [2° to 8°C] for refrigerator, -58° to 5°F [-50° to -15°C] for freezer) Inventory of affected vaccines, including (1) lot #s and (2) whether purchased with public (for example, VFC) or private funds (Use separate sheet if needed, but maintain the inventory with this troubleshooting record) At the time of the event, what else was in the storage unit? For example, were there water bottles in the refrigerator and/or frozen coolant packs in the freezer? Prior to this event, have there been any storage problems with this unit and/or with the affected vaccine? Include any other information you feel might be relevant to understanding the event. <p>When checked main clinic fridge (in lab) at 8:00 am on Tuesday, 7/16/2013, digital readout on data logger read 28°F. Data logger located in center of fridge with probe in glycol. Review of computer readings (taken every 15 minutes) showed steady drop in temps from 42°F at 8:15 pm (7/15/2013) to 28°F reading discovered when arrived at clinic on Tuesday morning (7/16/2013). Readings hit 34°F at 11 pm (7/15) and 32°F at 2 am (7/16). Total time out of recommended storage temps = 9 hours, with 6 hours at freezing or below (see attached document of continuous temp readings). Inventory of vaccines attached.</p> <p>Water bottles in refrigerator door and crisper area. No vaccines stored in freezer. No recent adjustments to temp controls and no previous temp excursions noted with this refrigerator before 7/15.</p>			
Action Taken (Document thoroughly. This information is critical to determining whether the vaccine might still be viable!) <ul style="list-style-type: none"> When were the affected vaccines placed in proper storage conditions? (Note: Do not discard the vaccine. Store exposed vaccine in proper conditions and label it "do not use" until after you can discuss with your state/local health department and/or the manufacturer[s].) Who was contacted regarding the incident? (For example, supervisor, state/local health department, manufacturer—list all.) IMPORTANT: What did you do to prevent a similar problem from occurring in the future? <p>Upon discovery, vaccines marked "Do Not Use" and stored in 2nd clinic fridge (in exam room #3 at 41°F). Also placed "Do Not Use" note on main fridge in lab. Notified Susie Supervisor about the issue. Contacted Victor Vaccine at My State Immunization Program at 8:30 am. Provided Victor with details of event and list of vaccines in fridge. Victor said to maintain vaccines in 2nd fridge and that he would check with manufacturers to determine next steps.</p> <p>Called Jim's Appliance Repair to examine fridge. Repairman found and replaced faulty thermostat in unit.</p> <p>Reset data logger on center shelf in fridge with probe in glycol.</p>			
Results <ul style="list-style-type: none"> What happened to the vaccine? Was it able to be used? If not, was it returned to the distributor? (Note: For public-purchase vaccine, follow your state/local health department instructions for vaccine disposition.) <p>After fridge thermostat repaired, monitored temps in empty fridge for 1 week, per state requirements. Fridge maintained 38°-40°F temps for entire week. Submitted repair documentation and data logger readings to Victor Vaccine for approval and ordered replacement vaccines. Victor had checked with manufacturers who confirmed that all vaccines in fridge EXCEPT MMR were no longer viable and should be returned per state policy guidelines. MMR may be used because pkg insert allows storage down to -58°F. Discussed entire situation with Susie Supervisor and clinic director, Dr. Director, who agreed on continued use of MMR. Will continue to monitor fridge closely to watch for pattern of temp fluctuations indicating potential problem with thermostat. If problems, contact Victor Vaccine for advice on purchasing new fridge meeting criteria for appropriate vaccine storage.</p>			

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www.immunize.org/catg.d/p3041.pdf • Item #P3041 (8/13)



Temperature Log for Freezer – Fahrenheit

DAYS 1–15

Month/Year _____ VFC PIN or other ID # _____
 Facility Name _____

Monitor temperatures closely!

1. Write your initials below in “Staff Initials,” and note the time in “Exact Time.”
2. Record temps twice each workday.
3. Record the min/max temps once each workday—preferably in the morning.
4. Put an “X” in the row that corresponds to the freezer’s temperature.
5. If any out-of-range temp, see instructions to the right.
6. After each month has ended, save each month’s log for 3 years, unless state/local jurisdictions require a longer period.

Take action if temp is out of range—too warm (above 5°F) or too cold (below -58°F).
 1. Label exposed vaccine “do not use,” and store it under proper conditions as quickly as possible. Do not discard vaccines unless directed to by your state/local health department and/or the manufacturer(s).

2. Record the out-of-range temps and the room temp in the “Action” area on the bottom of the log.
3. Notify your vaccine coordinator, or call the immunization program at your state or local health department for guidance.
4. Document the action taken on the “Vaccine Storage Troubleshooting Record” on page 3.

Day of Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Staff Initials															
Exact Time	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM
Min/Max Temp (since previous reading)															
Danger! Temperatures above 5°F are too warm! Write any out-of-range temps and room temp on the lines below and call your state or local health department immediately!															
5°F															
4°F															
3°F															
2°F															
1°F															
0°F															
-1°F															
-2°F															
-3°F															
-4°F															
-5°F															
-58°F to -5°F															
Write any out-of-range temps (above 5°F or below -58°F) here.															
Room Temperature															

If you have a vaccine storage issue, also complete “Vaccine Storage Troubleshooting Record” found on page 3.

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Temperature Log for Freezer – Fahrenheit

DAYS 16–31

Month/Year _____ VFC PIN or other ID # _____

Page 2 of 3

Facility Name _____

Monitor temperatures closely!

1. Write your initials below in "Staff Initials," and note the time in "Exact Time."
2. Record temps twice each workday.
3. Record the min/max temps once each workday—preferably in the morning.
4. Put an "X" in the row that corresponds to the freezer's temperature.
5. If any out-of-range temp, see instructions to the right.
6. After each month has ended, save each month's log for 3 years, unless state/local jurisdictions require a longer period.

Take action if temp is out of range—too warm (above 5°F) or too cold (below -58°F).

1. Label exposed vaccine "do not use," and store it under proper conditions as quickly as possible. Do not discard vaccines unless directed to by your state/local health department and/or the manufacturer(s).
2. Record the out-of-range temps and the room temp in the "Action" area on the bottom of the log.
3. Notify your vaccine coordinator, or call the immunization program at your state or local health department for guidance.
4. Document the action taken on the "Vaccine Storage Troubleshooting Record" on page 3.

Day of Month	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Staff Initials																
Exact Time	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM
Min/Max Temp (since previous reading)																
Danger! Temperatures above 5°F are too warm! Write any out-of-range temps and room temp on the lines below and call your state or local health department immediately!																
5°F																
4°F																
3°F																
2°F																
1°F																
0°F																
-1°F																
-2°F																
-3°F																
-4°F																
-58°F to -5°F																
Write any out-of-range temps (above 5°F or below -58°F) here.																
Room Temperature																

If you have a vaccine storage issue, also complete "Vaccine Storage Troubleshooting Record" found on page 3.

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Vaccine Storage Troubleshooting Record (check one) ☐ Refrigerator ☐ Freezer

Page 3 of 3

Use this form to document any unacceptable vaccine storage event, such as exposure of refrigerated or frozen vaccines to temperatures that are outside the manufacturers' recommended storage ranges.

A fillable troubleshooting record (i.e., editable PDF or WORD document) can also be found at www.immunize.org/clinic/storage-handling.asp.

Date & Time of Event If multiple, related events occurred, see Description of Event below.		Storage Unit Temperature at the time the problem was discovered		Room Temperature at the time the problem was discovered		Person Completing Report	
Date:		Temp when discovered:		Temp when discovered:		Name:	
Time:		Minimum temp:	Maximum temp:	Comment (optional):		Title:	Date:
Description of Event <i>(If multiple, related events occurred, list each date, time, and length of time out of storage.)</i> <ul style="list-style-type: none"> General description (i.e., what happened?) Estimated length of time between event and last documented reading of storage temperature in acceptable range (35° to 46°F [2° to 8°C] for refrigerator; -58° to 5°F [-50° to -15°C] for freezer) Inventory of affected vaccines, including (1) lot #s and (2) whether purchased with public (for example, VFC) or private funds (Use separate sheet if needed, but maintain the inventory with this troubleshooting record.) At the time of the event, what else was in the storage unit? For example, were there water bottles in the refrigerator and/or frozen coolant packs in the freezer? Prior to this event, have there been any storage problems with this unit and/or with the affected vaccine? Include any other information you feel might be relevant to understanding the event. 							
Action Taken <i>(Document thoroughly. This information is critical to determining whether the vaccine might still be viable!)</i> <ul style="list-style-type: none"> When were the affected vaccines placed in proper storage conditions? (Note: Do not discard the vaccine. Store exposed vaccine in proper conditions and label it "do not use" until after you can discuss with your state/local health department and/or the manufacturer[s].) Who was contacted regarding the incident? (For example, supervisor, state/local health department, manufacturer—list all.) IMPORTANT: What did you do to prevent a similar problem from occurring in the future? 							
Results <ul style="list-style-type: none"> What happened to the vaccine? Was it able to be used? If not, was it returned to the distributor? (Note: For public-purchase vaccine, follow your state/local health department instructions for vaccine disposition.) 							

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Vaccine Storage Troubleshooting Record (check one) ☐ Refrigerator ☒ Freezer

Use this form to document any unacceptable vaccine storage event, such as exposure of refrigerated or frozen vaccines to temperatures that are outside the manufacturers' recommended storage ranges. A fillable troubleshooting record (i.e., editable pdf or WORD document) can also be found at www.immunize.org/clinic/storage-handling.asp

Date & Time of Event If multiple, related events occurred, see Description of Event below.	Storage Unit Temperature at the time the problem was discovered	Room Temperature at the time the problem was discovered	Person Completing Report
Date: 7/16/2013	Temp when discovered: 55°F	Temp when discovered: 77°F	Name: Nancy Nurse
Time: 8:00 am	Minimum temp: 2°F	Maximum temp: 57°F	Title: VFC Coordinator
Description of Event (If multiple, related events occurred, list each date, time, and length of time out of storage.) <ul style="list-style-type: none"> General description (i.e., what happened?) Estimated length of time between event & last documented reading of storage temperature in acceptable range (35° to 46°F [2° to 8°C] for refrigerator; -58° to 5°F [-50° to -15°C] for freezer) Inventory of affected vaccines, including (1) lot #s and (2) whether purchased with public (for example, VFC) or private funds (Use separate sheet if needed, but maintain the inventory with this troubleshooting record) At the time of the event, what else was in the storage unit? For example, were there water bottles in the refrigerator and/or frozen coolant packs in the freezer? Prior to this event, have there been any storage problems with this unit and/or with the affected vaccine? Include any other information you feel might be relevant to understanding the event. <p>When checked vaccine freezer (in lab) at 8:00 am on Tuesday, 7/16/2013, discovered freezer door slightly ajar. Digital readout on data logger read 55°F. Data logger located in center of freezer with probe in glycol. Review of computer readings (taken every 15 minutes) showed steady rise in temps from 2°F at 5:30 pm (7/15/2013) to 55°F reading discovered when arrived at clinic on Tuesday morning (7/16/2013). Readings hit 6°F at 11 pm (7/15) and 45°F at 2 am (7/16). Total time out of recommended storage temp of 5°F or below = 9 hours. (See attached document of continuous temp readings.) Freezer contained Varivax, ProQuad, and Zostavax (inventory attached).</p> <p>Frozen packs stored on freezer floor and shelves in door. No recent adjustments to temp controls and no previous temp excursions noted with this freezer before 7/15.</p>			
Action Taken (Document thoroughly. This information is critical to determining whether the vaccine might still be viable!) <ul style="list-style-type: none"> When were the affected vaccines placed in proper storage conditions? (Note: Do not discard the vaccine. Store exposed vaccine in proper conditions and label it "do not use" until after you can discuss with your state/local health department and/or the manufacturer[s].) Who was contacted regarding the incident? (For example, supervisor, state/local health department, manufacturer—list all.) IMPORTANT: What did you do to prevent a similar problem from occurring in the future? <p>Upon discovery, vaccines marked "Do Not Use" and stored in 2nd clinic freezer (in exam room #3) at 1°F. Also placed "Do Not Use" note on main freezer in lab. Notified Susie Supervisor about the issue. Contacted Victor Vaccine at My State Immunization Program at 8:30 am. Provided Victor with details of event and list of vaccines in freezer. Victor said to maintain vaccines in 2nd freezer and that he would check with Merck (manufacturer of all the affected vaccines) to determine next steps. Called Jim's Appliance Repair to examine freezer. Repairman replaced freezer door gasket and recommended removal of ~1/2 of freezer packs in door because size and weight of packs potentially interfered with door closing completely. No problems identified with thermostat or other mechanical components.</p> <p>Removed half of freezer packs located in shelf in door, per recommendation. Reset data logger on center shelf of freezer with probe in glycol. All staff received refresher training on ensuring freezer door is closed after each use, and a reminder sign was placed prominently on freezer door.</p>			
Results <ul style="list-style-type: none"> What happened to the vaccine? Was it able to be used? If not, was it returned to the distributor? (Note: For public-purchase vaccine, follow your state/local health department instructions for vaccine disposition.) <p>After repair, monitored temps in empty freezer for 1 week, per state requirements. Freezer maintained 0–2°F temps for entire week. Submitted repair documentation and data logger readings to Victor Vaccine for approval and ordered replacement vaccines. Victor had checked with manufacturer. After reviewing history and stability data, manufacturer stated vaccine was acceptable for continued use. Discussed entire situation with Susie Supervisor and clinic director, Dr. Immunize, who agreed on continued use of vaccine. Vaccine to be labeled as "use first."</p>			

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Temperature Log for Refrigerator – Celsius

DAYS 1–15

Month/Year _____ VFC PIN or other ID # _____ Page 1 of 3
Facility Name _____

Monitor temperatures closely!

1. Write your initials below in "Staff Initials," and note the time in "Exact Time."
2. Record temps twice each workday.
3. Record the min/max temps once each workday—preferably in the morning.
4. Put an "X" in the row that corresponds to the refrigerator's temperature.
5. If any out-of-range temp, see instructions to the right.
6. After each month has ended, save each month's log for 3 years, unless state/local jurisdictions require a longer period.

Take action if temp is out of range—too warm (above 8°C) or too cold (below 2°C).

1. Label exposed vaccine "do not use," and store it under proper conditions as quickly as possible. Do not discard vaccines unless directed to by your state/local health department and/or the manufacturer(s).
2. Record the out-of-range temps and the room temp in the "Action" area on the bottom of the log.
3. Notify your vaccine coordinator, or call the immunization program at your state or local health department for guidance.
4. Document the action taken on the "Vaccine Storage Troubleshooting Record" on page 3.

Day of Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Staff Initials															
Exact Time	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM
Min/Max Temp (since previous reading)															
Danger! Temperatures above 8°C are too warm! Write any out-of-range temps and room temp on the lines below and call your state or local health department immediately!															
TEMPERATURES	8°C														
	7°C														
	6°C														
	5°C														
	4°C														
	3°C														
	2°C														
Danger! Temperatures below 2°C are too cold! Write any out-of-range temps and room temp on the lines below and call your state or local health department immediately!															
ACTION	Write any out-of-range temps (above 8°C or below 2°C) here:														
	Room Temperature														

If you have a vaccine storage issue, also complete "Vaccine Storage Troubleshooting Record" found on page 3.

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Temperature Log for Refrigerator – Celsius

DAYS 16–31

Month/Year _____ VFC PIN or other ID # _____

Page 2 of 3

Facility Name _____

Monitor temperatures closely!

1. Write your initials below in “Staff Initials,” and note the time in “Exact Time.”
2. Record temps twice each workday.
3. Record the min/max temps once each workday—preferably in the morning.
4. Put an “X” in the row that corresponds to the refrigerator’s temperature.
5. If any out-of-range temp, see instructions to the right.
6. After each month has ended, save each month’s log for 3 years, unless state/local jurisdictions require a longer period.

Take action if temp is out of range—too warm (above 8°C) or too cold (below 2°C).

1. Label exposed vaccine “do not use,” and store it under proper conditions as quickly as possible. Do not discard vaccines unless directed to by your state/local health department and/or the manufacturer(s).
2. Record the out-of-range temps and the room temp in the “Action” area on the bottom of the log.
3. Notify your vaccine coordinator, or call the immunization program at your state or local health department for guidance.
4. Document the action taken on the “Vaccine Storage Troubleshooting Record” on page 3.

Day of Month	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Staff Initials																
Exact Time	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM
Min/Max Temp (since previous reading)																
Danger! Temperatures above 8°C are too warm! Write any out-of-range temps and room temp on the lines below and call your state or local health department immediately!																
TEMPERATURES	8°C															
	7°C															
	6°C															
	5°C															
	4°C															
	3°C															
	2°C															
Danger! Temperatures below 2°C are too cold! Write any out-of-range temps and room temp on the lines below and call your state or local health department immediately!																
ACTION	Write any out-of-range temps (above 8°C or below 2°C) here:															
	Room Temperature															

If you have a vaccine storage issue, also complete “Vaccine Storage Troubleshooting Record” found on page 3.

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Vaccine Storage Troubleshooting Record (check one) ☐ Refrigerator ☐ Freezer

Page 3 of 3

Use this form to document any unacceptable vaccine storage event, such as exposure of refrigerated vaccines to temperatures that are outside the manufacturers' recommended storage ranges.

A fillable troubleshooting record (i.e., editable PDF or WORD document) can also be found at www.immunize.org/clinic/storage-handling.asp.

Date & Time of Event If multiple, related events occurred, see Description of Event below.		Storage Unit Temperature at the time the problem was discovered		Room Temperature at the time the problem was discovered	Person Completing Report	
Date:	Temp when discovered:	Minimum temp:	Maximum temp:	Temp when discovered:	Name:	Date:
Description of Event <i>(If multiple, related events occurred, list each date, time, and length of time out of storage.)</i> <ul style="list-style-type: none"> General description (i.e., what happened?) Estimated length of time between event and last documented reading of storage temperature in acceptable range (35° to 46°F [2° to 8°C] for refrigerator; -58° to 5°F [-50° to -15°C] for freezer) Inventory of affected vaccines, including (1) lot #s and (2) whether purchased with public (for example, VFC) or private funds (Use separate sheet if needed, but maintain the inventory with this troubleshooting record.) At the time of the event, what else was in the storage unit? For example, were there water bottles in the refrigerator and/or frozen coolant packs in the freezer? Prior to this event, have there been any storage problems with this unit and/or with the affected vaccine? Include any other information you feel might be relevant to understanding the event. 						
Action Taken <i>(Document thoroughly. This information is critical to determining whether the vaccine might still be viable!)</i> <ul style="list-style-type: none"> When were the affected vaccines placed in proper storage conditions? (Note: Do not discard the vaccine. Store exposed vaccine in proper conditions and label it "do not use" until after you can discuss with your state/local health department and/or the manufacturer(s).) Who was contacted regarding the incident? (For example, supervisor, state/local health department, manufacturer—list all.) IMPORTANT: What did you do to prevent a similar problem from occurring in the future? 						
Results <ul style="list-style-type: none"> What happened to the vaccine? Was it able to be used? If not, was it returned to the distributor? (Note: For public-purchase vaccine, follow your state/local health department instructions for vaccine disposition.) 						

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Vaccine Storage Troubleshooting Record (check one) ☒ Refrigerator ☐ Freezer

Use this form to document any unacceptable vaccine storage event, such as exposure of refrigerated vaccines to temperatures that are outside the manufacturers' recommended storage ranges. A fillable troubleshooting record (i.e., editable pdf or WORD document) can also be found at www.immunize.org/clinic/storage-handling.asp

Date & Time of Event If multiple, related events occurred, see Description of Event below.		Storage Unit Temperature at the time the problem was discovered		Room Temperature at the time the problem was discovered	Person Completing Report	
Date: (see below)	Temp when discovered: 7°C	Minimum temp: 3°C	Maximum temp: 12°F	Temp when discovered: 25°C	Name: Nancy Nurse	Date: 6/24/13
Time: (see below)				Comment (optional): temp is approx	Title: VFC Coordinator	
Description of Event (If multiple, related events occurred, list each date, time, and length of time out of storage.) <ul style="list-style-type: none"> General description (i.e., what happened?) Estimated length of time between event & last documented reading of storage temperature in acceptable range (35° to 46°F [2° to 8°C] for refrigerator; -58° to 5°F [-50° to -15°C] for freezer) Inventory of affected vaccines, including (1) lot #'s and (2) whether purchased with public (for example, VFC) or private funds (Use separate sheet if needed, but maintain the inventory with this troubleshooting record) At the time of the event, what else was in the storage unit? For example, were there water bottles in the refrigerator and/or frozen coolant packs in the freezer? Prior to this event, have there been any storage problems with this unit and/or with the affected vaccine? Include any other information you feel might be relevant to understanding the event. <p>At 8 am on Monday (6/24/13) morning when clinic opened, identified 3 temperature excursions over the weekend in refrigerator with readings as high as 12°, 10° & 9°C in primary vaccine storage unit #1. Recordings taken every 15 min on calibrated digital data logger overnight. Data logger probe in glycol located in middle of refrigerator with vaccines.</p> <p>Total time out of range: approximately 3 hrs — maximum temp 12°F (see attached document of continuous temp readings)</p> <p>Inventory of vaccines: see attached</p> <p>Water bottles in refrigerator door. No vaccine stored in freezer. No problems with storage unit prior to Saturday night. Thunderstorms in area over weekend may have affected power.</p>						
Action Taken (Document thoroughly. This information is critical to determining whether the vaccine might still be viable.) <ul style="list-style-type: none"> When were the affected vaccines placed in proper storage conditions? (Note: Do not discard the vaccine. Store exposed vaccine in proper conditions and label it "do not use" until after you can discuss with your state/local health department and/or the manufacturer(s).) Who was contacted regarding the incident? (For example, supervisor, state/local health department, manufacturer—list all.) IMPORTANT: What did you do to prevent a similar problem from occurring in the future? <p>Vaccines currently stored appropriately at 7°C. Refrigerator and vaccines labeled "Do Not Use."</p> <p>My State Immunization Program contacted at 8:30 am. Spoke with Victor Vaccine. Provided Victor with details of event and list of vaccines.</p> <p>Vaccine to remain quarantined until we hear back from Victor.</p> <p>Called electric company and confirmed 2 short power outages during weekend.</p> <p>Checked refrigerator seals — called refrigerator maintenance company to replace seals.</p> <p>Checked plug on unit — placed tape over plug to prevent inadvertent dislodging. Plan to purchase plug guard.</p> <p>Plan to follow up with Immunization Program on data loggers with alarms that could be sent to coordinator and back-up phones.</p>						
Results <ul style="list-style-type: none"> What happened to the vaccine? Was it able to be used? If not, was it returned to the distributor? (Note: For public-purchase vaccine, follow your state/local health department instructions for vaccine disposition.) <p>Late on Monday, I talked with Victor regarding continued use of vaccine. Victor had checked with manufacturers which confirmed that vaccine is acceptable for use. He told me that vaccine could therefore be removed from quarantine. I discussed the entire situation with Susie Supervisor and Dr. Director (clinic medical director) who agreed that we could put vaccine back in use.</p>						

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Vaccine Storage Troubleshooting Record (check one) ☒ Refrigerator ☐ Freezer

Use this form to document any unacceptable vaccine storage event, such as exposure of refrigerated vaccines to temperatures that are outside the manufacturers' recommended storage ranges. A fillable troubleshooting record (i.e., editable pdf or WORD document) can also be found at www.immunize.org/clinic/storage-handling.asp

Date & Time of Event If multiple, related events occurred, see Description of Event below.	Storage Unit Temperature at the time the problem was discovered	Room Temperature at the time the problem was discovered	Person Completing Report
Date: 7/16/2013	Temp when discovered: -2°C	Temp when discovered: 25°C	Name: Nancy Nurse
Time: 8:00 am	Minimum temp: -2°C	Maximum temp: 6°C	Title: VFC Coordinator
Description of Event (If multiple, related events occurred, list each date, time, and length of time out of storage.) <ul style="list-style-type: none"> General description (i.e., what happened?) Estimated length of time between event & last documented reading of storage temperature in acceptable range (35° to 46°F [2° to 8°C] for refrigerator; -58° to -15°F [-50° to -15°C] for freezer) Inventory of affected vaccines, including (1) lot #s and (2) whether purchased with public (for example, VFC) or private funds (Use separate sheet if needed, but maintain the inventory with this troubleshooting record) At the time of the event, what else was in the storage unit? For example, were there water bottles in the refrigerator and/or frozen coolant packs in the freezer? Prior to this event, have there been any storage problems with this unit and/or with the affected vaccine? Include any other information you feel might be relevant to understanding the event. <p>When checked main clinic fridge (in lab) at 8:00 am on Tuesday, 7/16/2013, digital readout on data logger read -2°C. Data logger located in center of fridge with probe in glycol. Review of computer readings (taken every 15 minutes) showed steady drop in temps from 6°C at 8:15 pm (7/15/2013) to -2°C reading discovered when arrived at clinic on Tuesday morning (7/16/2013). Readings hit 1°C at 11 pm (7/15) and 0°C at 2 am (7/16). Total time out of recommended storage temps = 9 hours, with 6 hours at freezing or below (see attached document of continuous temp readings). Inventory of vaccines attached.</p> <p>Water bottles in refrigerator door and crisper area. No vaccines stored in freezer. No recent adjustments to temp controls and no previous temp excursions noted with this refrigerator before 7/15.</p>			
Action Taken (Document thoroughly. This information is critical to determining whether the vaccine might still be viable.) <ul style="list-style-type: none"> When were the affected vaccines placed in proper storage conditions? (Note: Do not discard the vaccine. Store exposed vaccine in proper conditions and label it "do not use" until after you can discuss with your state/local health department and/or the manufacturer(s).) Who was contacted regarding the incident? (For example, supervisor, state/local health department, manufacturer—list all.) IMPORTANT: What did you do to prevent a similar problem from occurring in the future? <p>Upon discovery, vaccines marked "Do Not Use" and stored in 2nd clinic fridge (in exam room #3 at 5°C). Also placed "Do Not Use" note on main fridge in lab. Notified Susie Supervisor about the issue. Contacted Victor Vaccine at My State Immunization Program at 8:30 am. Provided Victor with details of event and list of vaccines in fridge. Victor said to maintain vaccines in 2nd fridge and that he would check with manufacturers to determine next steps.</p> <p>Called Jim's Appliance. Repair to examine fridge. Repairman found and replaced faulty thermostat in unit.</p> <p>Reset data logger on center shelf in fridge with probe in glycol.</p>			
Results <ul style="list-style-type: none"> What happened to the vaccine? Was it able to be used? If not, was it returned to the distributor? (Note: For public-purchase vaccine, follow your state/local health department instructions for vaccine disposition.) <p>After fridge thermostat repaired, monitored temps in empty fridge for 1 week, per state requirements. Fridge maintained 3° to 4°C temps for entire week. Submitted repair documentation and data logger readings to Victor Vaccine for approval and ordered replacement vaccines. Victor had checked with manufacturers who confirmed that all vaccines in fridge EXCEPT MMR were no longer viable and should be returned per state policy guidelines. MMR may be used because pkg insert allows storage down to -50°C. Discussed entire situation with Susie Supervisor and clinic director, Dr. Director, who agreed on continued use of MMR. Will continue to monitor fridge closely to watch for pattern of temp fluctuations indicating potential problem with thermostat. If problems, contact Victor Vaccine for advice on purchasing new fridge meeting criteria for appropriate vaccine storage.</p>			

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www.immunize.org/catg.d/p3041.pdf • Item #P3041 (8/13)



Temperature Log for Freezer – Celsius

DAYS 1-15

Month/Year _____ VFC PIN or other ID # _____ Page 1 of 3
Facility Name _____

Monitor temperatures closely!

1. Write your initials below in "Staff Initials," and note the time in "Exact Time."
2. Record temps twice each workday.
3. Record the min/max temps once each workday—preferably in the morning.
4. Put an "X" in the row that corresponds to the freezer's temperature.
5. If any out-of-range temp, see instructions to the right.
6. After each month has ended, save each month's log for 3 years, unless state/local jurisdictions require a longer period.

Take action if temp is out of range—too warm (above -15°C) or too cold (below -50°C).
1. Label exposed vaccine "do not use," and store it under proper conditions as quickly as possible.
Do not discard vaccines unless directed to by your state/local health department and/or the manufacturer(s).

2. Record the out-of-range temps and the room temp in the "Action" area on the bottom of the log.
3. Notify your vaccine coordinator, or call the immunization program at your state or local health department for guidance.
4. Document the action taken on the "Vaccine Storage Troubleshooting Record" on page 3.

Day of Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Staff Initials															
Exact Time	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM
Min/Max Temp (since previous reading)															
Danger! Temperatures above -15°C are too warm! Write any out-of-range temps and room temp on the lines below and call your state or local health department immediately!															
ACCEPTABLE TEMPERATURES	-15°C														
	-16°C														
	-17°C														
	-18°C														
	-19°C														
	-20°C														
ACTION	-21°C														
	-22°C														
	-50°C to -23°C														
Write any out-of-range temps (above -15°C or below -50°C) here.															
Room Temperature															

If you have a vaccine storage issue, also complete "Vaccine Storage Troubleshooting Record" found on page 3.

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www.immunize.org/catg.d/p3037C.pdf • Item #P3038C (8/13)



Temperature Log for Freezer – Celsius

DAYS 16–31

Month/Year _____ VFC PIN or other ID # _____
Facility Name _____

Page 2 of 3

Monitor temperatures closely!

1. Write your initials below in “Staff Initials,” and note the time in “Exact Time.”
2. Record temps twice each workday.
3. Record the min/max temps once each workday—preferably in the morning.
4. Put an “X” in the row that corresponds to the freezer’s temperature.
5. If any out-of-range temp, see instructions to the right.
6. After each month has ended, save each month’s log for 3 years, unless state/local jurisdictions require a longer period.

Take action if temp is out of range—too warm (above -15°C) or too cold (below -50°C).
1. Label exposed vaccine “do not use,” and store it under proper conditions as quickly as possible.
Do not discard vaccines unless directed to by your state/local health department and/or the manufacturer(s).

2. Record the out-of-range temps and the room temp in the “Action” area on the bottom of the log.
3. Notify your vaccine coordinator, or call the immunization program at your state or local health department for guidance.
4. Document the action taken on the “Vaccine Storage Troubleshooting Record” on page 3.

Day of Month	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Staff Initials																
Exact Time	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM
Min/Max Temp (since previous reading)																
Danger! Temperatures above -15°C are too warm! Write any out-of-range temps and room temp on the lines below and call your state or local health department immediately!																
ACCEPTABLE TEMPERATURES																
-15°C																
-16°C																
-17°C																
-18°C																
-19°C																
-20°C																
-21°C																
-22°C																
-50°C to -23°C																
Write any out-of-range temps (above -15°C or below -50°C) here.																
Room Temperature																

If you have a vaccine storage issue, also complete “Vaccine Storage Troubleshooting Record” found on page 3.

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Vaccine Storage Troubleshooting Record (check one) ☐ Refrigerator ☐ Freezer

Page 3 of 3

Use this form to document any unacceptable vaccine storage event, such as exposure of refrigerated or frozen vaccines to temperatures that are outside the manufacturers' recommended storage ranges.

A fillable troubleshooting record (i.e., editable PDF or WORD document) can also be found at www.immunize.org/clinic/storage-handling.asp.

Date & Time of Event If multiple, related events occurred, see Description of Event below.		Storage Unit Temperature at the time the problem was discovered	Room Temperature at the time the problem was discovered	Person Completing Report
Date:	Temp when discovered:	Minimum temp:	Maximum temp:	Name:
Time:	Temp when discovered:	Minimum temp:	Maximum temp:	Title:
Description of Event <i>(If multiple, related events occurred, list each date, time, and length of time out of storage.)</i> <ul style="list-style-type: none"> General description (i.e., what happened?) Estimated length of time between event and last documented reading of storage temperature in acceptable range (35° to 46°F [2° to 8°C] for refrigerator; -58° to 5°F [-50° to -15°C] for freezer) Inventory of affected vaccines, including (1) lot #s and (2) whether purchased with public (for example, VFC) or private funds (Use separate sheet if needed, but maintain the inventory with this troubleshooting record.) At the time of the event, what else was in the storage unit? For example, were there water bottles in the refrigerator and/or frozen coolant packs in the freezer? Prior to this event, have there been any storage problems with this unit and/or with the affected vaccine? Include any other information you feel might be relevant to understanding the event. 				
Action Taken <i>(Document thoroughly. This information is critical to determining whether the vaccine might still be viable!)</i> <ul style="list-style-type: none"> When were the affected vaccines placed in proper storage conditions? (Note: Do not discard the vaccine. Store exposed vaccine in proper conditions and label it "do not use" until after you can discuss with your state/local health department and/or the manufacturer[s].) Who was contacted regarding the incident? (For example, supervisor, state/local health department, manufacturer—list all.) IMPORTANT: What did you do to prevent a similar problem from occurring in the future? 				
Results <ul style="list-style-type: none"> What happened to the vaccine? Was it able to be used? If not, was it returned to the distributor? (Note: For public-purchase vaccine, follow your state/local health department instructions for vaccine disposition.) 				

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Vaccine Storage Troubleshooting Record (check one) ☐ Refrigerator ☒ Freezer

Use this form to document any unacceptable vaccine storage event, such as exposure of refrigerated or frozen vaccines to temperatures that are outside the manufacturers' recommended storage ranges. A fillable troubleshooting record (i.e., editable pdf or WORD document) can also be found at www.immunize.org/clinic/storage-handling.asp

Date & Time of Event If multiple, related events occurred, see Description of Event below.	Storage Unit Temperature at the time the problem was discovered	Room Temperature at the time the problem was discovered	Person Completing Report
Date: 7/16/2013	Temp when discovered: 13°C	Temp when discovered: 25°C	Name: Nancy Nurse
Time: 8:00 am	Minimum temp: -17°C	Maximum temp: 14°C	Title: VFC Coordinator
Description of Event (If multiple, related events occurred, list each date, time, and length of time out of storage.) <ul style="list-style-type: none"> General description (i.e., what happened?) Estimated length of time between event & last documented reading of storage temperature in acceptable range (35° to 46°F [2° to 8°C] for refrigerator; -58° to 5°F [-50° to -15°C] for freezer) Inventory of affected vaccines, including (1) lot #s and (2) whether purchased with public (for example, VFC) or private funds (Use separate sheet if needed, but maintain the inventory with this troubleshooting record) At the time of the event, what else was in the storage unit? For example, were there water bottles in the refrigerator and/or frozen coolant packs in the freezer? Prior to this event, have there been any storage problems with this unit and/or with the affected vaccine? Include any other information you feel might be relevant to understanding the event. <p>When checked vaccine freezer (in lab) at 8:00 am on Tuesday, 7/16/2013, discovered freezer door slightly ajar. Digital readout on data logger read 13°C. Data logger located in center of freezer with probe in glycol. Review of computer readings (taken every 15 minutes) showed steady rise in temps from -17°C at 5:30 pm (7/15/2013) to 13°C reading discovered when arrived at clinic on Tuesday morning (7/16/2013). Readings hit -14°C at 11 pm (7/15) and 7°C at 2 am (7/16). Total time out of recommended storage temp of -15°C or below = 9 hours. (See attached document of continuous temp readings.) Freezer contained Varivax, ProQuad, and Zostavax (inventory attached).</p> <p>Frozen packs stored on freezer floor and shelves in door. No recent adjustments to temp controls and no previous temp excursions noted with this freezer before 7/15.</p>			
Action Taken (Document thoroughly. This information is critical to determining whether the vaccine might still be viable.) <ul style="list-style-type: none"> When were the affected vaccines placed in proper storage conditions? (Note: Do not discard the vaccine. Store exposed vaccine in proper conditions and label it "do not use" until after you can discuss with your state/local health department and/or the manufacturer[s].) Who was contacted regarding the incident? (For example, supervisor, state/local health department, manufacturer—list all.) IMPORTANT: What did you do to prevent a similar problem from occurring in the future? <p>Upon discovery, vaccines marked "Do Not Use" and stored in 2nd clinic freezer (in exam room #3) at -17°C. Also placed "Do Not Use" note on main freezer in lab. Notified Susie Supervisor about the issue. Contacted Victor Vaccine at My State Immunization Program at 8:30 am. Provided Victor with details of event and list of vaccines in freezer. Victor said to maintain vaccines in 2nd freezer and that he would check with Merck (manufacturer of all the affected vaccines) to determine next steps. Called Jim's Appliance Repair to examine freezer. Repairman replaced freezer door gasket and recommended removal of ~1/2 of freezer packs in door because size and weight of packs potentially interfered with door closing completely. No problems identified with thermostat or other mechanical components.</p> <p>Removed half of freezer packs located in shelf in door, per recommendation. Reset data logger on center shelf of freezer with probe in glycol. All staff received refresher training on ensuring freezer door is closed after each use, and a reminder sign was placed prominently on freezer door.</p>			
Results <ul style="list-style-type: none"> What happened to the vaccine? Was it able to be used? If not, was it returned to the distributor? (Note: For public-purchase vaccine, follow your state/local health department instructions for vaccine disposition.) <p>After repair, monitored temps in empty freezer for 1 week, per state requirements. Freezer maintained -18° to -17°C temps for entire week. Submitted repair documentation and data logger readings to Victor Vaccine for approval and ordered replacement vaccines. Victor had checked with manufacturer. After reviewing history and stability data, manufacturer stated vaccine was acceptable for continued use. Discussed entire situation with Susie Supervisor and clinic director, Dr. Immunize, who agreed on continued use of vaccine. Vaccine to be labeled as "use first."</p>			

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www.immunize.org/catg.d/p3041.pdf • Item #P3041 (8/13)

Don't Be Guilty of These Preventable Errors in Vaccine Storage and Handling!

*Do you see your clinic or practice making any of these frequently reported errors in vaccine storage and handling? Although some of these errors are much more serious than others, none of them should occur. Be sure your healthcare setting is not making any of these **preventable** errors.*

ERROR: Designating only one person, rather than at least two, to be responsible for storage and handling of vaccines

- Everyone in the office should know the basics of vaccine handling, including what to do when a shipment arrives and what to do in the event of an equipment failure or power outage.
- Train at least one back-up person. The back-up and primary persons should be equally familiar with all aspects of vaccine storage and handling, including knowing how to handle vaccines when they arrive, properly record refrigerator and freezer temperatures, what to do when an out-of-range temperature occurs, and how to appropriately respond to an equipment problem or power outage.

ERROR: Storing vaccine inappropriately

- Be sure all office staff (especially persons involved in receiving vaccine shipments) understand the importance of properly storing vaccines immediately after they arrive.
- Know which vaccines should be refrigerated and which should be frozen. Storage information is found in the package insert. For quick reference, post IAC's *Vaccine Handling Tips* (www.immunize.org/catg.d/p3048.pdf) on the refrigerator and freezer.
- Always store vaccines (and thermometers) in the body of the refrigerator – not in the vegetable bins, on the floor, next to the walls, in the door, or near the cold air outlet from the freezer. The temperature in these areas may differ significantly from the temperature in the body of the unit.
- Don't over-pack the unit. Place the vaccine packages in such a way that air can circulate around the compartment.
- Always store vaccines in their original packaging.

ERROR: Using the wrong type of equipment

STORAGE UNITS

- CDC recommends storing vaccines in separate, self-contained units that only refrigerate or only freeze. If a combination refrigerator/freezer must be used, only refrigerated vaccines should be stored in the unit, and a separate stand-alone freezer should be used for frozen vaccines.
- Never store vaccines in a "dormitory-style" unit (i.e., a small refrigerator-freezer unit with one exterior door and a freezer compartment inside the refrigerator). These units cannot maintain stable temperatures.

THERMOMETERS

- Use only calibrated thermometers that have a Certificate of Traceability and Calibration Testing. Ideally, you should use a "continuous read" thermometer that records temperatures all day and all night.
- Place the thermometer's temperature probe in glycol so that you are not just measuring air temperature, which is subject to fluctuation when you open the door.

For more detailed information, see the *Vaccine Storage Equipment* section of CDC's *Vaccine Storage and Handling Toolkit* (www.cdc.gov/vaccines/recs/storage/toolkit).

ERROR: Inadvertently leaving the refrigerator or freezer door open or having inadequate seals

- Unfortunately, too much vaccine is lost every year because storage unit doors were left open. Remind staff to *completely* close the door every time they open the refrigerator or freezer.
- Check the seals on the doors on a regular schedule, such as when you're taking inventory. If there is any indication the door seal may be cracked or not sealing properly, have it replaced. (This is much less costly than replacing a box of pneumococcal conjugate or varicella vaccine!)

ERROR: Storing food and drinks in the vaccine refrigerator

- Frequent opening of the refrigerator door to retrieve food items can adversely affect the internal temperature of the unit and damage vaccines. Store only vaccines in the designated units.

CONTINUED ON THE NEXT PAGE ►

ERROR: Inadvertently cutting the power supply to the storage units

- Be sure everyone in your office, including the janitorial staff, understands that very expensive and fragile vaccines are being stored in the refrigerator and freezer.
- Post a *Do Not Unplug* sign (www.immunize.org/catg.d/p2090.pdf) next to electrical outlets for the refrigerator and freezer, and a *Do Not Stop Power* warning label (www.immunize.org/catg.d/p2091.pdf) by the circuit breaker for the electrical outlets.

ERROR: Recording temperatures only once per day

- Refrigerator and freezer temperatures should be checked at the beginning and end of each workday.
- Record the temperatures you observed on an appropriate log. IAC has temperature logs (www.immunize.org/handouts/temperature-logs.asp) available in both Fahrenheit and Celsius formats.
- Record temperatures for ALL units being used to store vaccine. Don't forget to check temperatures for both the refrigerator and freezer.

ERROR: Documenting out-of-range temperatures on vaccine temperature logs but not taking action

- If you find out-of-range temperatures...do something! The viability of your vaccine – and the protection of your patients – is at stake.
- Guidance on what to do may be found on IAC's temperature logs (www.immunize.org/handouts/temperature-logs.asp) and Vaccine Storage Troubleshooting Record (www.immunize.org/catg.d/p3041.pdf).
- Have an Emergency Response Plan and trained staff in place before a problem occurs. For help in developing a plan, see the Checklist of Resources for the Emergency Vaccine Retrieval and Storage Plan in CDC's Vaccine Storage and Handling Toolkit (www.cdc.gov/vaccines/recs/storage/toolkit).

ERROR: Discarding temperature logs too soon

Keep your temperature logs for at least 3 years. Why?

- You can track recurring problems as the storage unit ages.
- If out-of-range temperatures have been documented, you can determine how long and how often this has been occurring.
- This can be a great way to demonstrate why you need a new refrigerator or freezer!

ERROR: Not using vaccine with the soonest expiration date first

When unloading a new shipment of vaccine:

- Move vaccine with the shortest expiration date to the front of the unit, making it easier for staff to access this vaccine first.
- Mark the "older" vaccine to be used first.

ERROR: Dealing inappropriately with expired vaccines

- Carefully monitor your usage to ensure viable vaccines don't expire! As discussed above, place vaccines with the shortest expiration dates at the front of the unit.
- If you discover expired vaccines, immediately remove them from the unit so that they are not inadvertently administered.

ERROR: Discarding multidose vials prematurely

- Almost all multidose vials of vaccines contain a preservative and can be used until the expiration date on the vial, unless there is actual contamination or the vials are not stored under appropriate conditions. However, multidose vials of reconstituted vaccine (e.g., meningococcal polysaccharide and yellow fever) must be used within a defined period after reconstitution. Refer to the package inserts for information.
- The Joint Commission has clarified that vaccines are an exception to its usual "28-day rule" for use of medications in multidose vials. Providers are directed to follow guidance from CDC and vaccine manufacturers.

Emergency Response Worksheet

What to do in case of a power failure or other event that results in vaccine storage outside of the recommended temperature range

Follow these procedures:

1. Close the door tightly.
2. Ensure the vaccine is kept at appropriate temperatures. Make sure the refrigerator or freezer is plugged in and working properly, or move the vaccines into proper storage conditions as quickly as possible.
3. Do NOT discard the affected vaccines unless directed to by your state/local health department and/or the manufacturer(s). Label the vaccines "Do Not Use" so that the potentially compromised vaccines can be easily identified.
4. Notify the state/local health department or call the manufacturer (see manufacturers' phone numbers below).
5. Document the inventory of affected vaccines below and document the circumstances of the event and the actions taken on the *Vaccine Storage Troubleshooting Record* (see www.immunize.org/catg.d/p3041.pdf).

Vaccines Stored in Refrigerator

Vaccine	Manufacturer	Lot #	Expiration Date	# of Doses (i.e., not # of vials)

Vaccines Stored in Freezer

Vaccine	Manufacturer	Lot #	Expiration Date	# of Doses (i.e., not # of vials)

Important Contact Information:

Vaccine Manufacturers

Emergent BioSolutions ★ ₁	(877) 246-8472	Merck & Co., Inc.	(800) 444-2080	Sanofi Pasteur	(800) 822-2463
GlaxoSmithKline	(866) 475-8222	PaxVax ★ ₂	(800) 533-5899	Seqirus	
Massachusetts Biological Labs	(617) 474-3000	Pfizer Inc.	(800) 505-4426	- Afluria	(888) 435-8633
MedImmune, Inc.	(877) 633-4411	Protein Sciences Corp.	(800) 488-7099	- Fludax, Flucelvax, Fluvirin	(855) 358-8966
				Valneva ★ ₃	(301) 556-4500

★Manufacturer for less commonly used vaccine:

1. anthrax
2. typhoid
3. Japanese encephalitis

Health Departments

Local Health Department phone _____ State Health Department phone _____

Adapted by the Immunization Action Coalition, courtesy of the Michigan Department of Community Health

Technical content reviewed by the Centers for Disease Control and Prevention

IMMUNIZATION ACTION COALITION Saint Paul, Minnesota • 651-647-9009 • www.vaccineinformation.org • www.immunize.org

www.immunize.org/catg.d/p3051.pdf • Item #P3051 (5/16)

Checklist for Safe Vaccine Storage and Handling

*Are you doing everything you should to safeguard your vaccine supply?
Review this list to see where you might make improvements in your vaccine
management practices. Check each listed item with either ☐ YES or ☐ NO.*

Establish Storage and Handling Policies

- ☐ YES ☐ NO 1. We have designated a primary vaccine coordinator and at least one alternate coordinator to be in charge of vaccine storage and handling at our facility.
- ☐ YES ☐ NO 2. Both the primary and alternate vaccine coordinator(s) have completely reviewed either CDC's Vaccine Storage & Handling Toolkit (www.cdc.gov/vaccines/recs/storage/toolkit/storage-handling-toolkit.pdf) or equivalent training materials offered by our state or local health department's immunization program.
- ☐ YES ☐ NO 3. We have detailed, up-to-date, written policies for general vaccine management, including policies for routine activities and an emergency vaccine retrieval and storage plan for power outages and other problems. Our policies are based on CDC's Vaccine Storage & Handling Toolkit and/or on instruction from our state or local health department's immunization program.
- ☐ YES ☐ NO 4. We review these policies with all staff annually and with new staff, including temporary staff, when they are hired.

Log In New Vaccine Shipments

- ☐ YES ☐ NO 5. We maintain a vaccine inventory log that we use to document the following:
- ☐ YES ☐ NO a. Vaccine name and number of doses received
- ☐ YES ☐ NO b. Date we received the vaccine
- ☐ YES ☐ NO c. Condition of vaccine when we received it
- ☐ YES ☐ NO d. Vaccine manufacturer and lot number
- ☐ YES ☐ NO e. Vaccine expiration date

Use Proper Storage Equipment

- ☐ YES ☐ NO 6. We store vaccines in separate, self-contained units that refrigerate or freeze only. If we must use a household-style combination unit, we use it only for storage of our refrigerated vaccines, maintaining frozen vaccines in a separate stand-alone freezer.
- ☐ YES ☐ NO 7. We store vaccines in units with enough room to maintain the year's largest inventory without crowding.
- ☐ YES ☐ NO 8. We never store any vaccines in a dormitory-style unit (a small combination freezer-refrigerator unit with the freezer compartment inside the refrigerator).
- ☐ YES ☐ NO 9. We use only calibrated thermometers that have a Certificate of Traceability and Calibration Testing* ("Report of Calibration") and are calibrated every 1 to 2 years from the last calibration testing date or according to the manufacturer's suggested timeline.
- ☐ YES ☐ NO 10. We have planned back-up storage unit(s) in the event of a power failure or other unforeseen event.

*Certificate of Traceability and Calibration Testing ("Report of Calibration") with calibration measurements traceable to a laboratory with accreditation from the International Laboratory Accreditation Cooperations (ILAC) Mutual Recognition Arrangement (MRA) signatory body.

continued on page 2 ►

Ensure Optimal Operation of Storage Units

- ☐ YES ☐ NO 11. We have a “Do Not Unplug” sign (e.g., www.immunize.org/catg.d/p2090.pdf) next to the electrical outlets for the refrigerator and freezer and a “Do Not Stop Power” warning label (e.g., www.immunize.org/catg.d/p2091.pdf) by the circuit breaker for the electrical outlets. Both signs include emergency contact information.
- ☐ YES ☐ NO 12. We perform regular maintenance on our vaccine storage units to assure optimal functioning. For example, we keep the units clean, dusting the coils and cleaning beneath the units every 3–6 months.

Maintain Correct Temperatures

- ☐ YES ☐ NO 13. We always keep at least one accurate calibrated thermometer (+/-1°F [+/-0.5°C]) with the vaccines in the refrigerator and a separate calibrated thermometer with the vaccines in the freezer.
- ☐ YES ☐ NO 14. We use a thermometer that
- ☐ YES ☐ NO a. uses an active display to provide continuous monitoring information
 - ☐ YES ☐ NO b. is digital and has a probe in a glycol-filled bottle
 - ☐ YES ☐ NO c. includes an alarm for out-of-range temperatures
 - ☐ YES ☐ NO d. has a resettable (automatic or manual) min/max display (applies only to thermometers that have a data logger)
 - ☐ YES ☐ NO e. is capable of showing the current temperature, as well as minimum and maximum temperatures
 - ☐ YES ☐ NO f. can measure temperatures within +/-1°F (+/-0.5°C)
 - ☐ YES ☐ NO g. has a low-battery indicator
- ☐ YES ☐ NO 15. We maintain the refrigerator temperature at 35–46°F (2–8°C), and we aim for 40°F (5°C).
- ☐ YES ☐ NO 16. We maintain the freezer at an average temperature of +5°F (-15°C) or colder, but no colder than -58°F (-50°C).
- ☐ YES ☐ NO 17. We keep extra containers of water in the refrigerator (e.g., in the door and/or on the floor of the unit where the vegetable bins were located) to help maintain cool temperatures. We keep ice packs or ice-filled containers in the freezer to help maintain cold temperatures.

Maintain Daily Temperature Logs

- ☐ YES ☐ NO 18. On days when our practice is open, we visually inspect the vaccine storage unit twice a day (first thing in the morning and right before our facility closes) and document refrigerator and freezer temperatures on the appropriate log. (See selections at www.immunize.org/clinic/storage-handling.asp.)
- ☐ YES ☐ NO 19. We document the minimum and maximum temperature readings in the refrigerator and freezer once each day, preferably in the morning.
- ☐ YES ☐ NO 20. We consistently record temperatures on the log either in Fahrenheit or Celsius. We never mix temperature scales when we record our temperatures.
- ☐ YES ☐ NO 21. If the temperature log prompts us to insert an “x” by the temperature that’s preprinted on the form, we do not attempt to write in the actual temperature.
- ☐ YES ☐ NO 22. We follow the directions on the temperature log to call appropriate personnel if the temperature in a storage unit goes out of range.
- ☐ YES ☐ NO 23. If out-of-range temperatures occur in the unit, we complete the Vaccine Storage Troubleshooting Record (www.immunize.org/catg.d/p3041.pdf) to document actions taken when the problem was discovered and what was done to prevent a recurrence of the problem.
- ☐ YES ☐ NO 24. Trained staff (other than staff designated to record the temperatures) review the temperature logs weekly.
- ☐ YES ☐ NO 25. We keep the temperature logs on file for at least 3 years.

continued on page 3 ►

Technical content reviewed by the Centers for Disease Control and Prevention

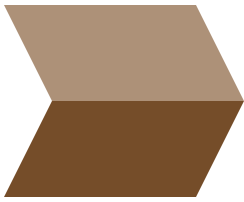
Store Vaccines Correctly

- ☐ YES ☐ NO 26. We post signs (e.g., www.immunize.org/catg.d/p3048.pdf) on the doors of the refrigerator and freezer that indicate which vaccines should be stored in the refrigerator and which in the freezer.
- ☐ YES ☐ NO 27. We do not store any food or drink in any vaccine storage unit.
- ☐ YES ☐ NO 28. We store vaccines in the middle of the refrigerator or freezer (away from walls and vents), leaving room for air to circulate around the vaccine. We never store vaccine in the doors.
- ☐ YES ☐ NO 29. We have removed all vegetable and deli bins from the storage unit, and we do not store vaccines in these empty areas.
- ☐ YES ☐ NO 30. If we must use a combination refrigerator-freezer unit, we store vaccines only in the refrigerator section of the unit. We do not place vaccines in front of the cold-air outlet that leads from the freezer to the refrigerator (often near the top shelf). In general, we try to avoid storing vaccines on the top shelf, and we place water bottles in this location.
- ☐ YES ☐ NO 31. We check vaccine expiration dates and rotate our supply of each type of vaccine so that vaccines with the shortest expiration dates are located close to the front of the storage unit, facilitating easy access.
- ☐ YES ☐ NO 32. We store vaccines in their original packaging in clearly labeled uncovered containers.

Take Emergency Action As Needed

33. In the event that vaccines are exposed to improper storage conditions, we take the following steps:
- ☐ YES ☐ NO a. We restore proper storage conditions as quickly as possible. If necessary, we label the vaccine “Do Not Use” and move it to a unit where it can be stored under proper conditions. We do not discard the vaccine before discussing the circumstances with our state / local health department and/or the appropriate vaccine manufacturers.
- ☐ YES ☐ NO b. We follow the Vaccine Storage Troubleshooting Record’s (www.immunize.org/catg.d/p3041.pdf) instructions for taking appropriate action and documenting the event. This includes recording details such as the length of time the vaccine was out of appropriate storage temperatures and the current room temperature, as well as taking an inventory of affected vaccines.
- ☐ YES ☐ NO c. We contact our clinic supervisor or other appropriate clinic staff to report the incident. We contact our state / local health department and / or the appropriate vaccine manufacturers for consultation about whether the exposed vaccine can still be used.
- ☐ YES ☐ NO d. We address the storage unit’s mechanical or electrical problems according to guidance from the unit’s manufacturer or a qualified repair service.
- ☐ YES ☐ NO e. In responding to improper storage conditions, we do not make frequent or large changes in thermostat settings. After changing the setting, we give the unit at least a day to stabilize its temperature.
- ☐ YES ☐ NO f. We do not use exposed vaccines until our state / local health department’s immunization program or the vaccine manufacturer has confirmed that the vaccine is acceptable for use. We review this information with our clinic medical director before returning the vaccine to our supply. If the vaccine is not acceptable for use, we follow our state / local health department instructions for vaccine disposition.

If we answer ☐ YES to all of the above, we give ourselves a pat on the back! If not, we assign someone to implement needed changes!



3 Communicating With Parents About Vaccines

Introduction

All health care professionals providing care to newborns, infants, children, and adolescents meet daily with parents who have concerns about vaccines to be administered. Some parents have questions about things they have heard or request a nonstandard schedule; some want to avoid particular ingredients, particular vaccines, or all vaccines. During a busy day filled with the care of well and sick children, it is a challenge to address all the concerns that are raised.

The following section presents

1. Resources health care professionals can use to address common concerns of parents
2. Resources to provide to parents to answer their questions
3. A sample of a form prepared by the American Academy of Pediatrics (AAP) to document parental refusal to vaccinate

Please note that the federal requirements for providing Centers for Disease Control and Prevention (CDC) Vaccine Information Statements (VISs) are provided in Topic 9 of this guide.

Learning Objectives

On completion of this unit, the health care professional will be able to

- Describe 2 or more keys to the vaccine communication framework.
- Respond accurately and succinctly to 3 or more common parent concerns about vaccines.
- Appropriately use the AAP Refusal to Vaccinate form.
- Employ effective vaccine communication techniques for parents and adolescents.

Please use this text box to add your practice's specific policies on this topic and any other notes you wish to include in your final document.

About Communicating With Parents

Vaccination effectiveness and complacency. Immunization is widely recognized as one of the most important public health advances. Health care professionals have seen the characteristics of pediatric practice change as vaccines have been introduced. For example, compared with the late 20th century, today far fewer children are hospitalized with rotavirus and invasive pneumococcal disease. In fact, vaccination has led to the decline in incidence of diseases from each of the vaccine-preventable infections. In the future, the number of cases of cervical and oropharyngeal cancer and other sequelae of human papillomavirus (HPV) are expected to decrease, too. The effectiveness of vaccination has led to such a decrease in disease incidence that some parents conclude at least some vaccines are no longer necessary.

Types of parental immunization attitudes. A study published in 2005 in the *American Journal of Health Behavior* (Gust D, Brown C, Sheedy K, Hibbs B, Weaver D, Nowak G. Immunization attitudes and beliefs among parents: beyond a dichotomous perspective. 2005;29[1]:81–92) described different types of parents and their beliefs about vaccines.

Parent Type	Belief About Vaccines	Percentage of Parents
Immunization advocates	Strongly agree vaccines are necessary and safe	33%
Go along to get alongs	Agree vaccines are necessary and safe	26%
Health advocates	Agree vaccines are necessary but are less sure about their safety	25%
Fence-sitters	Slightly agree that vaccines are necessary and safe	13%
Worrieds	Slightly disagree that vaccines are necessary and strongly disagree that vaccines are safe	3%

A framework for communication. A study published in the April 2010 *Pediatrics* (Freed GL, Clark SJ, Butchart AT, Singer DC, Davis MM. Parental vaccine safety concerns in 2009. 2010;125[4]:654–659) showed that 12% of parents had refused at least one vaccine. This study also found that most parents listen to their physician's recommendations. Following are keys to the vaccine communication framework.

- The entire health care team should give a strong recommendation for all recommended vaccines, including those for adolescents, such as HPV.
- Health care professionals should be prepared to address concerns, asking parents what questions they have about each vaccine being delayed or refused.
- Office staff should give parents VISs from the CDC to provide objective information about the benefits and risks of vaccines. (Distribution of VISs is legally required.)
- Common and rare adverse events can be described using the VISs.

Discussion within this framework can provide opportunities to correct misinformation about vaccines.

Motivational interviewing. Speaking with adolescents and their parents about vaccines may require a different skill set than speaking with parents of younger children. Although evidence is scant, one technique that may be effective is motivational interviewing (MI), “a collaborative, person-centered form of guiding to elicit and strengthen motivation for change.” After a strong presumptive recommendation for adolescents to receive vaccines is met with hesitation, MI may tap into a parent's own desires for his or her adolescent to be healthy and protected from disease. This may influence the parent's decision about vaccines. See the Tools and Resources section for MI tools and information.

Cultural sensitivity. People from some cultures may have reasons for vaccine hesitancy regarding specific vaccines. For example, parents from some groups may be particularly concerned that accepting HPV vaccine implies acceptance of adolescent sexual activity; this concern may lead to HPV vaccination refusal. When communicating with families, explain the vaccine benefits (eg, cancer prevention) in a way that acknowledges their values and concerns without challenging cultural beliefs. See the Tools and Resources section for cultural competence tools and information.

What doesn't work in vaccine communication. An April 2014 study in *Pediatrics* (Nyhan B, Reifler J, Richey S, Freed GL. Effective messages in vaccine promotion: a randomized trial. 2014;133[4]:e835–e842) found that some information provided to parents can have unintended results.

- Pro-vaccine messages didn't always work as intended.
 - Effectiveness of messages may depend on the receiver's attitude of the message.
 - Corrective messages intended to clarify misperceptions about some vaccine adverse events actually reduced intent to vaccinate among parents.
- Presenting information about the dangers of disease increased misperceptions about vaccines.

Addressing Common Concerns

Below are some of the common concerns that parents have with vaccinating their child, as well as facts and information you can use to help calm those concerns.

1. Too Many/Too Soon

Many parents have concerns that giving too many vaccines too soon may overwhelm a baby's immune system. Although young babies receive vaccines covering a lot of antigens, the vaccines are given at this time because babies are most at risk for many vaccine-preventable infections. We must never forget that vaccines prevent infections that can lead to death or cause, for example, liver damage, cardiac disease, or hearing loss, all of which can last a lifetime. Many vaccines are given to babies in series of doses (eg, diphtheria and tetanus toxoids and acellular pertussis [DTaP], *Haemophilus influenzae* type b [Hib],

inactivated polio virus) to build up immunity, so delaying early doses can lead to absence of protection in the first year of life. Many studies have been done to ensure that giving recommended vaccines at the same visit is safe (ie, neither overstimulates nor shuts down the immune system) and effective. In fact, a baby is exposed to antigens every time he eats, puts a toy in his mouth, or plays on the floor; normal life leads to exposure with many more antigens on a daily basis than the number given in vaccines.

2. Too Many at Once (Desire for Nonstandard Schedules)

Some parents would prefer to spread out their children's vaccinations, believing such an "alternative schedule" is safer. It is recommended that health care professionals work with these parents to make sure immunizations are provided to achieve full protection as early as possible. The article "The Problem With Dr Bob's Alternative Vaccine Schedule" (Offit PA, Moser CA. *Pediatrics*. 2009;123[1]:e164–e169) provides a clear analysis of the problem and can be given to parents to read. Reasons for giving vaccines on the recommended schedule include

- The recommended schedule protects our children when they are most vulnerable to diseases the vaccines prevent. Nonstandard schedules that spread out the timing of vaccinations or start when a child is older leave babies vulnerable.
- Effectiveness and safety of the recommended schedule have been documented in many studies. Nonstandard schedules have not been tested for effectiveness and safety.

It is important to document the parent's request for a nonstandard schedule and discussion of its risks as described above. It is also necessary to have a recall system to make sure that families who delay return for needed vaccines. See Topic 6 for more information on reminder and recall systems.

3. Vaccine Ingredients

Understandably, parents want to know what is in their children's vaccines.

Antigens are substances in vaccines that stimulate the body's immune response to make antibodies, which protect against infection. Vaccines contain antigens designed to stimulate the immune system to make antibodies that will protect the body if it comes into contact with illness-causing germs. Some of the antigens in vaccines are killed (eg, injectable influenza vaccine) and others are alive (eg, nasal spray influenza vaccine).

An **adjuvant** is an addition to a vaccine that helps increase the body's immune response to the vaccine antigen. Adjuvants make it possible to use smaller antigen amounts and to decrease the number of doses needed. Aluminum-based adjuvants have been used safely in some vaccines in the United States for more than 70 years. Aluminum is in our air, water, and food, including human (breast) milk and infant formula. In fact, the amount of aluminum in all recommended vaccines is similar to that found in approximately 33 oz of infant formula. Vaccines that contain aluminum are those that prevent diphtheria, tetanus, and pertussis; hepatitis A; hepatitis B; Hib; HPV; and pneumococcal infection.

Thimerosal is a mercury-based preservative that has been used to prevent contamination of vaccines with bacteria and fungi. Some parents worried that thimerosal used in vaccines would lead to autism spectrum disorder, so many scientific studies were done to assess this. They have shown there is no link between thimerosal and autism. Today, although thimerosal is used in the manufacturing of some vaccines, it is removed so childhood vaccines—with the exception of some influenza vaccines—do not contain detectable amounts of thimerosal. (It should be noted that live vaccines such as measles-mumps-rubella [MMR] and varicella do not contain any thimerosal because it would kill the vaccine virus, and to prevent contamination, thimerosal is still used in multidose vials of vaccine. Injectable influenza vaccine in multidose vials contains thimerosal, but single-dose syringes without thimerosal are also available.) Although thimerosal was removed from vaccines in 2001, unfortunately, rates of autism have actually increased since then. For more information on thimerosal, see the Institute for Vaccine Safety Web page: (www.vaccinesafety.edu/cc-thim.htm).

4. Autism

Some parents fear that vaccines might be a cause of autism. Pediatricians can assure parents that no scientific studies have shown a relationship between MMR or any other vaccine and autism. In 1998, Andrew Wakefield, a British physician, published a paper about 8 children who reportedly developed autism after receiving MMR vaccine. Because of falsification of data in the article, it was retracted from the journal in which it was published, but immunization rates in the United Kingdom had already dropped. Since then, scientific studies comparing vaccinated and unvaccinated children have not found a relationship between vaccination and autism. Scientific studies investigating a link between thimerosal and autism have similarly not shown a link between thimerosal in vaccination and autism; during the past decade, despite removal of thimerosal from most childhood vaccines, the rate of autism has continued to rise.

5. Vaccinations Hurt Too Much

No one likes to cause children discomfort. Even though a shot may hurt briefly, vaccination is better than having a serious disease such as meningitis or cancer. Talk with nursing staff about ways to reduce pain during vaccination (eg, stroking or applying pressure to the patient's skin before the shot). The AAP does not recommend the routine preemptive administration of acetaminophen because of concern it could have a detrimental effect on the immune response to the vaccines being administered. Consider offering medication to numb the skin. See Canadian guidelines for reducing vaccination pain at www.cmaj.ca/content/early/2015/08/24/cmaj.150391.

6. Why Is More Than One Dose Needed?

With many vaccines, more than 1 dose is needed for the body to build up or sustain immunity. In these cases, several priming or booster doses are needed for full protection.

7. My Child Will Not Be Exposed to This Infection

Hepatitis B. Many parents believe that their children will not be exposed to certain diseases. For example, parents do not understand why hepatitis B vaccine (HepB vaccine) is recommended for their infant, who is not sexually active nor using intravenous drugs, typical behaviors that spread the virus. Let parents know it is important to start the HepB vaccine series at birth because close contacts, who may not know they are infected, can spread this highly contagious virus. Early infection can lead to serious and chronic liver disease. Three properly spaced vaccinations are important to prevent this disease.

Human papillomavirus. Parents of 11- to 12-year-olds may balk at giving HPV vaccine because it's difficult to imagine their child engaging in sexual activity. Let parents know the AAP recommends HPV vaccination at 11 to 12 years of age for an important reason: it works better at this age. The immune system of an 11- to 12-year-old responds better to HPV vaccine than that of an older teen, and a teen needs to complete the vaccine series before coming into contact with the virus to be fully protected.

One study found that young women who had just one sexual partner are at high risk of infection with HPV. This indicates it is important that adolescents receive the full series before their sexual debut. Even those who wait until marriage or have only one partner in the future could still be exposed to HPV. Using condoms can prevent pregnancy and several sexually transmitted infections, but HPV can be spread by intimate skin-to-skin contact and oral sex, not just sexual intercourse. Condoms cover only a limited amount of skin, and HPV can be spread even if a condom is used every time a person has sex. To ensure the best HPV protection, parents should have their children vaccinated at age 11 to 12 years. Always give a strong recommendation for the HPV vaccine. It is not necessary to mention sexual activity unless a parent specifically asks about it.

8. Vaccination Will Lead My Child to Engage in Sexual Activity (HPV)

Parents want their children to be mature before engaging in sexual activity. Let them know you agree and understand their concern. Studies show that, compared with children not vaccinated against HPV, children who receive HPV vaccine are not more likely to have sex or have sex earlier. This tells us that children do not see HPV vaccination as a license to have sex.

9. My Son Doesn't Need This Vaccine (HPV)

Human papillomavirus vaccine prevents cervical cancer, which only females can get. Human papillomavirus vaccine can also protect both males and females from infection with the HPV types that most commonly cause oropharyngeal cancer, as well as cancers of the genitals and anus, and genital warts. Notably, a preteen boy who receives HPV vaccine can protect his future partner because he will not be infected and so will not spread the virus. Explain to parents that males and females infected with HPV often have no symptoms so they don't know they can spread the infection. There is effective HPV cancer screening for the female cervix but no such screening for the oropharynx.

Resources used to verify these statements were found through www.immunize.org, www.cdc.gov, www.fda.gov, and the following journals: *Pediatrics*, *Disease Markers*, *Journal of Infectious Diseases*, and *Clinical Therapeutics*.

Key Facts

- Vaccine Information Statements need to be provided to a parent or legal representative every time a vaccine is given. They are available from the CDC and Immunization Action Coalition (IAC) Web sites. Translated VIS sheets are available in a number of languages from the IAC Web site (www.immunize.org/vis). Remember that it is important that parents or legal representatives understand the content of any VIS sheets they are given.
- Every discussion of vaccine risk and benefit and the risks of not vaccinating needs to be documented in the chart. For parents who decline or delay vaccination, the AAP offers a Refusal to Vaccinate form, to sign after discussion. The topic can be approached each year, and if parents decline, the form can be updated annually. Refusal is reversible and should not prevent discussion of vaccines at future visits. The form is accompanied by a list of resources for parents.
- The pediatrician should strongly recommend each routine vaccine, including HPV.

Tools and Resources

Organization	Category	Title	Link
Web Links From Key Organizations			
AAP	Autism	Causes of Autism (video)	www.aap.org/en-us/about-the-aap/aap-press-room/aap-press-room-media-center/Pages/Causes-of-Autism.aspx
AAP	Autism	"Autism Spectrum Disorder"	www.healthychildren.org/English/health-issues/conditions/Autism/Pages/Autism-Spectrum-Disorder.aspx
AAP	Autism Thimerosal	<i>Vaccine Safety: Examine the Evidence</i> (PDF)	www.aap.org/en-us/Documents/immunization_vaccine_studies.pdf
AAP	Hesitancy VISI Liability	"Immunization: Communicating with Families"	www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/immunization/Pages/communicating-parents.aspx
AAP	Vaccine ingredients	"Vaccine Ingredients: Frequently Asked Questions"	www.healthychildren.org/English/safety-prevention/immunizations/Pages/Vaccine-Ingredients-Frequently-Asked-Questions.aspx
AAP	Autism	"Emphasizing MMR Vaccine's Benefits for Children Increases Parents' Intent to Immunize"	www.healthychildren.org/English/news/Pages/Emphasizing-MMR-Vaccines-Benefits-for-Children-Increases-Parents-Intent-to-Immunize.aspx
AAP	Schedule	"Why So Many Vaccinations?"	www.healthychildren.org/English/safety-prevention/immunizations/Pages/Why-So-Many-Vaccinations.aspx
CDC	Vaccine safety	"Common Vaccine Safety Concerns"	www.cdc.gov/vaccinesafety/Concerns
CDC	HPV	<i>Epidemiology and Prevention of Vaccine-Preventable Diseases</i> , 13th Edition (the "Pink Book"): "Human Papillomavirus" (PDF)	www.cdc.gov/vaccines/pubs/pinkbook/downloads/hpv.pdf
CDC	Miscellaneous	"Provider Resources for Vaccine Conversations with Parents"	www.cdc.gov/vaccines/hcp/conversations
IAC	VIS	"Vaccine Information Statements"	www.immunize.org/vis
IAC	Vaccine concerns	"Talking about Vaccines"	www.immunize.org/talking-about-vaccines
IAC	State laws and mandates	"State Information"	www.immunize.org/laws
IAC	Miscellaneous	"Ask the Experts"	www.immunize.org/askexperts
IAC	Miscellaneous	"Vaccine-Related Journal Articles"	www.immunize.org/journalarticles
CHOP	Vaccine safety	"Vaccine Safety"	www.chop.edu/centers-programs/vaccine-education-center/vaccine-safety#.VvGJQBIRJ3k
CHOP	Vaccine ingredients	"Vaccine Ingredients"	www.chop.edu/centers-programs/vaccine-education-center/vaccine-ingredients#.VvGJcRIRJ3k
CHOP	Autism	"Vaccines and Autism"	www.chop.edu/centers-programs/vaccine-education-center/vaccines-and-other-conditions/vaccines-autism#.VvGJxBlrJ3k
Institute for Vaccine Safety	Vaccine safety	"Thimerosal in Vaccines"	www.vaccinesafety.edu/cc-thim.htmlh
Shot By Shot	Vaccine communication	"Why Use a Story?"	www.shotbyshot.org/use-a-story
Shot By Shot	HPV and cervical cancer	"Story Gallery"	www.shotbyshot.org/story-gallery/#Cervical Cancer and HPV

Tools and Resources

Organization	Category	Title	Link
Additional Useful Web Links			
MI	Vaccine communication	Motivationalinterview.org: "Interaction Techniques"	http://motivationalinterview.net/clinical/interaction.html
MSH	Vaccine communication	The Provider's Guide to Quality & Culture	http://erc.msh.org/mainpage.cfm?file=1.0.htm&module=provider&language=English&ggroup=&mgroup
HRSA	Vaccine communication	"Culture, Language and Health Literacy"	www.hrsa.gov/culturalcompetence/index.html
<i>Clinical Therapeutics</i>	Pain	<i>Clinical Therapeutics</i> : "Physical Interventions and Injection Techniques for Reducing Injection Pain During Routine Childhood Immunization: Systematic Review of Randomized Controlled Trials and Quasi-randomized Controlled Trials"	www.clinicaltherapeutics.com/article/S0149-2918%2809%2900263-X/abstract
Articles in <i>Pediatrics</i> (http://pediatrics.aappublications.org) (Log-in may be required.)			
AAP	Autism	"On-time Vaccine Receipt in the First Year Does Not Adversely Affect Neuropsychological Outcomes"	http://pediatrics.aappublications.org/content/125/6/1134.full
AAP	Schedule	"The Problem With Dr Bob's Alternative Vaccine Schedule"	http://pediatrics.aappublications.org/content/123/1/e164.full
AAP	HPV	"Sexual Activity–Related Outcomes After Human Papillomavirus Vaccination of 11- to 12-Year-Olds"	http://pediatrics.aappublications.org/content/early/2012/10/10/peds.2012-1516.abstract
Information for Parents on <i>HealthyChildren.org</i> (official AAP Web site for parents) (www.healthychildren.org)			
AAP	HPV	"Human Papillomavirus (HPV)"	www.healthychildren.org/English/health-issues/vaccine-preventable-diseases/Pages/Human-Papillomavirus-%28HPV%29.aspx
AAP	HPV	"Vaccinating Your Preteen: Addressing Common Concerns"	www.healthychildren.org/English/safety-prevention/immunizations/Pages/Vaccinating-Your-Preteen-Addressing-Common-Concerns.aspx
Documents Included in the AAP Immunization Training Guide			
AAP	Vaccine hesitancy	"Vaccine-Hesitant Parents"	www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/immunization/Pages/vaccine-hesitant-parents.aspx
AAP	Vaccine hesitancy	<i>Documenting Parental Refusal to Have Their Children Vaccinated</i> (PDF)	www.aap.org/en-us/Documents/immunization_refusaltovaccinate.pdf
AAP	Thimerosal	"Vaccine Ingredients: Frequently Asked Questions"	www.healthychildren.org/English/safety-prevention/immunizations/Pages/Vaccine-Ingredients-Frequently-Asked-Questions.aspx
CDC	Communication	<i>Talking with Parents about Vaccines for Infants: Strategies for Health Care Professionals</i> (PDF)	www.cdc.gov/vaccines/hcp/patient-ed/conversations/downloads/talk-infants-bw-office.pdf
IAC	Autism	<i>MMR Vaccine Does Not Cause Autism: Examine the Evidence!</i> (PDF)	www.immunize.org/catg.d/p4026.pdf Acquired from http://www.immunize.org/catg.d/p4026.pdf on April 29, 2016. We thank the Immunization Action Coalition.

Abbreviations: AAP, American Academy of Pediatrics; CDC, Centers for Disease Control and Prevention; CHOP, Children's Hospital of Philadelphia; HPV, human papillomavirus; HRSA, Health Resources and Services Administration; IAC, Immunization Action Coalition; MI, motivational interviewing; VIS, Vaccine Information Statement.

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Immunization

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Vaccine-Hesitant Parents

Updated 10/2015

Parents want to do what is best for their child, even those who ask questions. While every parent is different and not all methods of communicating work for every parent or physician, below is a brief review of parental immunization attitudes and communication methods that have worked to reassure parents in some circumstances. To begin:

- Listen to parents' concerns and acknowledge them in a non-confrontational manner. Allowing parents to express their concerns will increase their willingness to listen to the pediatrician's views.
- Promote partnerships with parents in decision-making and personalize these relationships. Provide the important information first. Make sure the parent understands the information. Clarify and reaffirm parents' correct beliefs about immunization and modify misconceptions.
- Discuss the benefits of vaccines and the possibility of adverse events. Be open about what is known about immunizations and what is not known. Provide parents with Vaccine Information Statements, educational resources, and reliable Web sites. Personalize the information provided to parents based on cultural beliefs, vaccine concerns, and literacy level.
- Stress the number of lives saved by immunization, as a positive approach, rather than focusing on the number of deaths from not immunizing.
- Discuss state laws for school entry and the rationale for them. Some parents disagree with mandatory immunization and resist immunization because they believe their rights as parents are being taken away. Explain that vaccines benefit individual children and communities through herd immunity.
- Provider attitudes and beliefs about vaccine safety have been linked to vaccination coverage in preschool

children. The majority of parents believe immunization is important and trust pediatricians as the most important source of immunization information.

Kimmel SR, Wolfe RM. Communicating the benefits and risks of vaccines. *The Journal of Family Practice*. 2005; 54:S51-S57
Zhang J, Yu KF. What's the relative risk? A method of correcting the odds ratio in cohort studies of common outcomes. *JAMA*. 1998; 280:1690-1691

Types of parental immunization attitudes:

Parent Type	Belief about vaccines	Percentage of Parents
Immunization Advocates	Strongly agree vaccines are necessary and safe	33%
Go Along to Get Alongs	Agree vaccines are necessary and safe	26%
Health Advocate	Agree vaccines are necessary but are less sure about their safety	25%
Fence-sitters	Who slightly agree that vaccines are necessary and safe	13%
Worrieds	Slightly disagree that vaccines are necessary and strongly disagree that vaccines are safe	3%

Gust, et al. *American Journal of Health Behavior*, 2005. <http://www.ncbi.nlm.nih.gov/pubmed/15604052>

Key points to consider:

- Parents from all groups include their health care provider as a source of information to help decide about their child's health care.
- Most parents still vaccinate their children, despite concerns.

Strategies for Talking to Parents:

Presumptive Vs. Participatory Recommendations

Researchers found that pediatricians who provided a "presumptive recommendation" – informed parents that shots were due, rather than a "participatory recommendation" – asking what the parent thought about shots, were more likely to see parents accept vaccines.

Opel, et al. The Architecture of Provider-Parent Vaccine Discussions at Health Supervision Visits. 2013. *Pediatrics*, 134, 139, 2013-2037. <http://pediatrics.aappublications.org/content/early/2013/10/30/peds.2013-2037.abstract>.

Examples

Participatory:

- "Do you want to vaccinate your child today?"
- "What do you think about vaccines?"
- "Would you like to hear about the vaccines we offer for today's visit?"

Presumptive:

- "Today your child is due for 2 vaccines. We will be giving MMR and Varicella."
- "It's time for an annual influenza vaccine. Your child is old enough to receive either the inactivated shot or the live nasal spray."

CASE*

CASE is an acronym for Corroborate, About Me, Science, Explain/Advise.

- **Corroborate:** Acknowledge the parents' concern and find some point on which you can agree. Set the tone for a respectful, successful talk.
- **About Me:** Describe what you have done to build your knowledge base and expertise.
- **Science:** Describe what the science says.
- **Explain/Advise:** Give your advice to patient, based on the science.

*Developed by [Alison Singer, MBA, Autism Science Foundation](#).

Example:

Parent Question: Do vaccines cause autism?

CASE Response:

- **Corroborate:** I understand why you might think this. There is a lot of information online and in the news about vaccines and autism.
- **About Me:** I like to make sure that I always have the most up-to-date information on this topic so I can inform families about what we do know about vaccines and autism, so I've researched this thoroughly.
- **Science:** The scientific evidence does not show any link between vaccines and autism. There have been several studies that have looked for a connection, but none has been seen. The CDC, the AAP, the National Institutes for Health, and the Institute of Medicine agree that vaccines do not cause autism.
- **Explain/Advise:** But vaccines are critical to maintaining health and wellbeing. They prevent diseases that cause real harm. Choosing not to vaccinate does not protect children from autism, but does leave them open to diseases. I would recommend that your child receive these vaccines today.

View videos demonstrating this model:

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Documenting Parental Refusal to Have Their Children Vaccinated

All parents and patients should be informed about the risks and benefits of preventive and therapeutic procedures, including vaccination. In the case of vaccination, the American Academy of Pediatrics (AAP) strongly recommends and federal law mandates that this discussion include the provision of the Vaccine Information Statements (VISs). Despite our best efforts to educate parents about the effectiveness of vaccines and the realistic chances of vaccine-associated adverse events, some will decline to have their children vaccinated. This often results from families misinterpreting or misunderstanding information presented by the media and on unmonitored and biased Web sites, causing substantial and often unrealistic fears.

Within a 12-month period, 74% of pediatricians report encountering a parent who refused or delayed one or more vaccines. A 2011 survey of children six months to six years of age reported that 13% of parents followed an alternative vaccination schedule. Of these, 53% refused certain vaccines and 55% delayed some vaccines until the child was older. Seventeen percent reported refusing all vaccines. In a 2009 survey, 11.5% of parents of children 17 years and younger reported refusing at least one vaccine. The use of this or a similar form in concert with direct and non-condescending discussion can demonstrate the importance you place on appropriate immunizations, focuses parents' attention on the unnecessary risk for which they are accepting responsibility, and may in some instances induce a wavering parent to accept your recommendations.

Providing parents (or guardians) with an opportunity to ask questions about their concerns regarding recommended childhood immunizations, attempting to understand parents' reasons for refusing one or more vaccines, and maintaining a supportive relationship with the family are all part of a good risk management strategy. The AAP encourages documentation of the health care provider's discussion with parents about the serious risks of what could happen to an unimmunized or under-immunized child. Provide parents with the appropriate VIS for each vaccine at each immunization visit and answer their questions. For parents who refuse one or more recommended immunizations, document your conversation and the provision of the VIS(s), have a parent sign the Refusal to Vaccinate form, and keep the form in the patient's medical record. The AAP also recommends that you revisit the immunization discussion at each subsequent appointment and carefully document the discussion, including the benefits to each immunization and the risk of not being age-appropriately immunized. For unimmunized or partially immunized children, some physicians may want to flag the chart to be reminded to revisit the immunization discussion, as well as to alert the provider about missed immunizations when considering the evaluation of future illness, especially young children with fevers of unknown origin.

This form may be used as a template to document that the health care provider had a discussion with the parent signing the form about the risks of failing to immunize the child. It is not intended as a substitute for legal advice from a qualified attorney as differing state laws and factual circumstances will impact the outcome. While it may be modified to reflect the particular circumstances of a patient, family, or medical practice, practices may want to consider obtaining advice from a qualified attorney. If a parent refuses to sign the refusal form such refusal along with the name of a witness to the refusal should be documented in the medical record.

The AAP Section on Infectious Diseases and other contributing sections and committees hope this form will be helpful to you as you deal with parents who refuse immunizations. It is available on the AAP Web site on the Section on Infectious Diseases Web site (<http://www2.aap.org/sections/infectdis/resources.cfm>), and the Web site for the AAP Childhood Immunization Support Program (<http://www2.aap.org/immunization/pediatricians/refusaltovaccinate.html>).

Sincerely,

/s/

Tina Tan, MD, FAAP

Chairperson

AAP Section on Infectious Diseases

/s/

Ed Rothstein, MD, FAAP

AAP Section on Infectious Diseases

Refusal to Vaccinate

Child's Name _____ Child's ID# _____

Parent's/Guardian's Name _____

My child's doctor/nurse, _____, has advised me that my child (named above) should receive the following vaccines:

Recommended	Declined
<input type="checkbox"/> Hepatitis B vaccine	<input type="checkbox"/>
<input type="checkbox"/> Diphtheria, tetanus, acellular pertussis (DTaP or Tdap) vaccine	<input type="checkbox"/>
<input type="checkbox"/> Diphtheria tetanus (DT or Td) vaccine	<input type="checkbox"/>
<input type="checkbox"/> <i>Haemophilus influenzae</i> type b (Hib) vaccine	<input type="checkbox"/>
<input type="checkbox"/> Pneumococcal conjugate or polysaccharide vaccine	<input type="checkbox"/>
<input type="checkbox"/> Inactivated poliovirus (IPV) vaccine	<input type="checkbox"/>
<input type="checkbox"/> Measles-mumps-rubella (MMR) vaccine	<input type="checkbox"/>
<input type="checkbox"/> Varicella (chickenpox) vaccine	<input type="checkbox"/>
<input type="checkbox"/> Influenza (flu) vaccine	<input type="checkbox"/>
<input type="checkbox"/> Meningococcal conjugate or polysaccharide vaccine	<input type="checkbox"/>
<input type="checkbox"/> Hepatitis A vaccine	<input type="checkbox"/>
<input type="checkbox"/> Rotavirus vaccine	<input type="checkbox"/>
<input type="checkbox"/> Human papillomavirus (HPV) vaccine	<input type="checkbox"/>
<input type="checkbox"/> Other _____	<input type="checkbox"/>

I have been provided with and given the opportunity to read each Vaccine Information Statement from the Centers for Disease Control and Prevention explaining the vaccine(s) and the disease(s) it prevents for each of the vaccine(s) checked as recommended and which I have declined, as indicated above. I have had the opportunity to discuss the recommendation and my refusal with my child's doctor or nurse, who has answered all of my questions about the recommended vaccine(s). A list of reasons for vaccinating, possible health consequences of non-vaccination, and possible side effects of each vaccine is available at www.cdc.gov/vaccines/pubs/vis/default.htm. I understand the following:

- The purpose of and the need for the recommended vaccine(s).
- The risks and benefits of the recommended vaccine(s).

- That some vaccine-preventable diseases are common in other countries and that my unvaccinated child could easily get one of these diseases while traveling or from a traveler.
- If my child does not receive the vaccine(s) according to the medically accepted schedule, the consequences may include
 - Contracting the illness the vaccine is designed to prevent (the outcomes of these illnesses may include one or more of the following: certain types of cancer, pneumonia, illness requiring hospitalization, death, brain damage, paralysis, meningitis, seizures, and deafness; other severe and permanent effects from these vaccine-preventable diseases are possible as well).
 - Transmitting the disease to others (including those too young to be vaccinated or those with immune problems), possibly requiring my child to stay out of child care or school and requiring someone to miss work to stay home with my child during disease outbreaks.
- My child's doctor and the American Academy of Pediatrics, the American Academy of Family Physicians, and the Centers for Disease Control and Prevention all strongly recommend that the vaccine(s) be given according to recommendations.

Nevertheless, I have decided at this time to decline or defer the vaccine(s) recommended for my child, as indicated above, by checking the appropriate box under the column titled "Declined." I know that failure to follow the recommendations about vaccination may endanger the health or life of my child and others with whom my child might come into contact. I therefore agree to tell all health care professionals in all settings what vaccines my child has not received because he or she may need to be isolated or may require immediate medical evaluation and tests that might not be necessary if my child had been vaccinated.

I know that I may readdress this issue with my child's doctor or nurse at any time and that I may change my mind and accept vaccination for my child any time in the future.

I acknowledge that I have read this document in its entirety and fully understand it.

Parent/Guardian Signature: _____ Date: _____

Witness: _____ Date: _____

I have had the opportunity to rediscuss my decision not to vaccinate my child and still decline the recommended immunizations.

Parent's Initials: _____ Date: _____ Parent's Initials: _____ Date: _____



Parental Refusal to Accept Vaccination: Resources for Pediatricians

The following are some of the resources available to help pediatricians develop a productive dialogue with vaccine-hesitant parents and answer questions about vaccine risks and benefits:

Web Sites

1. **AAP Childhood Immunization Support Program (CISP)**
Information for providers and parents.
www.aap.org/immunization
www2.aap.org/immunization/pediatricians/refusaltovaccinate.html
2. **Immunization Action Coalition (IAC)**
The IAC works to increase immunization rates by creating and distributing educational materials for health professionals and the public that enhance the delivery of safe and effective immunization services. The IAC "Unprotected People Reports" are case reports, personal testimonies, and newspaper and journal articles about people who have suffered or died from vaccine-preventable diseases.
www.immunize.org/reports
3. **Centers for Disease Control and Prevention (CDC) National Immunization Program**
Information about vaccine safety.
www.cdc.gov/vaccines/hcp.htm
4. **National Network for Immunization Information (NNii)**
Includes information to help answer patients' questions and provide the facts about immunizations.
<http://www.immunizationinfo.org/professionals>
5. **Vaccine Education Center at Children's Hospital of Philadelphia**
Information for parents includes "Vaccine Safety FAQs" and "A Look at Each Vaccine."
www.vaccine.chop.edu
6. **Institute for Vaccine Safety, Johns Hopkins Bloomberg School of Public Health**
Provides an independent assessment of vaccines and vaccine safety to help guide decision-makers and educate physicians, the public, and the media about key issues surrounding the safety of vaccines.
www.vaccinesafety.edu
7. **Immunize Canada**
Immunize Canada aims to meet the goal of eliminating vaccine-preventable disease through education, promotion, advocacy, and media relations. It includes resources for parents and providers.
www.immunize.cpha.ca/en/default.aspx
8. **Sample office policy/letter to parents about refusal to vaccinate**

Journal Articles

1. Offit PA, Jew RK. Addressing parents' concerns: do vaccines contain harmful preservatives, adjuvants, additives, or residuals? *Pediatrics*. 2003;112(6 Pt 1):1394–1397
2. Offit PA, Quarles J, Gerber MA, et al. Addressing parents' concerns: do multiple vaccines overwhelm or weaken the infant's immune system? *Pediatrics*. 2002;109(1):124–129
3. Diekema DS, American Academy of Pediatrics Committee on Bioethics. Responding to parental refusals of immunization of children. *Pediatrics*. 2005;115(5):1428–1431

Books

1. American Academy of Pediatrics. *Red Book: 2012 Report of the Committee on Infectious Diseases*. Pickering LK, Baker CJ, Long SS, Kimberlin DW, eds. 29th ed. Elk Grove Village, IL: American Academy of Pediatrics; 2012
2. Marshall GS. *The Vaccine Handbook: A Practical Guide for Clinicians*. 5th ed. West Islip, NY: Professional Communications, Inc; 2015

Handout

1. Immunization Action Coalition. Reliable sources of immunization information: where to go to find answers! <http://www.immunize.org/catg.d/p4012.pdf>. Accessed October 17, 2012

Reliable Immunization Resources for Parents

Web Sites

1. **Centers for Disease Control and Prevention (CDC) Vaccine Information Statements**
Provide possible health consequences of non-vaccination and possible side effects of each vaccine.
www.cdc.gov/vaccines/pubs/vis/default.htm
2. **AAP Childhood Immunization Support Program (CISP)**
Information for providers and parents.
www.aap.org/immunization
3. **Why Immunize?**
A description of the individual diseases and the benefits expected from vaccination.
www2.aap.org/immunization/families/faq/whyimmunize.pdf
4. **Pennsylvania Immunization Education Program of Pennsylvania Chapter, AAP**
Includes answers to common vaccine questions and topics, such as addressing vaccine safety concerns; evaluating anti-vaccine claims; sources of accurate immunization information on the Web; and talking with parents about vaccine safety.
www.paiep.org
5. **CDC For Parents: Vaccines for Your Children**
Information about vaccine safety.
www.cdc.gov/vaccines/parents/index.html
6. **National Network for Immunization Information (NNii)**
Includes information to help answer patients' questions and provide the facts about immunizations.
www.immunizationinfo.org/parents
7. **Vaccine Education Center at Children's Hospital of Philadelphia**
Information for parents includes "Vaccine Safety FAQs" and "A Look at Each Vaccine."
www.vaccine.chop.edu
8. **Institute for Vaccine Safety, Johns Hopkins Bloomberg School of Public Health**
Provides an independent assessment of vaccines and vaccine safety to help guide decision-makers and educate physicians, the public, and the media about key issues surrounding the safety of vaccines.
www.vaccinesafety.edu
9. **Immunize Canada**
Immunize Canada aims to meet the goal of eliminating vaccine-preventable disease through education, promotion, advocacy, and media relations. It includes resources for parents and providers.
<http://immunize.cpha.ca/en/default.aspx>
10. **Vaccinate Your Baby**
This Every Child By Two site serves as a central resource of vaccine information for parents. The site links to the latest research and studies about vaccines, an interactive timeline on the benefits of vaccines, information about vaccine safety and ingredients, and the importance of adhering to the recommended schedule.
www.vaccinateyourbaby.org

Books

1. American Academy of Pediatrics. *Immunizations and Infectious Diseases: An Informed Parent's Guide*. Fisher MC, ed. Elk Grove Village, IL: American Academy of Pediatrics; 2006
2. Myers MG, Pineda D. *Do Vaccines Cause That?! A Guide for Evaluating Vaccine Safety Concerns*. Galveston, TX: Immunizations for Public Health; 2008
3. Offit PA. *Autism's False Prophets: Bad Science, Risky Medicine, and the Search for a Cure*. New York, NY: Columbia University Press; 2008
4. Offit PA. *Deadly Choices: How the Anti-Vaccine Movement Threatens Us All*. New York, NY: Basic Books; 2011
5. Mnookin S. *The Panic Virus: A True Story of Medicine, Science, and Fear*. New York, NY: Simon and Schuster; 2011
6. Offit PA, Moser CA. *Vaccines and Your Child: Separating Fact from Fiction*. New York, NY: Columbia University Press; 2011



Healthy Children (/English) > Safety & Prevention (<https://www.healthychildren.org/English/safety-prevention>) > Immunizations (<https://www.healthychildren.org/English/safety-prevention/immunizations>) > Vaccine Ingredients: Frequently Asked Questions

SAFETY & PREVENTION

Vaccine Ingredients: Frequently Asked Questions

Q. What ingredients are in vaccines?

All vaccines contain antigens. Antigens make vaccines work. They prompt the body to create the immune response needed to protect against infection. Antigens come in several forms. The form used in a vaccine is chosen because studies show it is the best way to protect against a particular infection.



Antigen forms include:

- **Weakened live viruses.** They are too weak to cause disease but can still prompt an immune response. Measles, mumps, rubella, rotavirus, chickenpox, and one type of influenza vaccine contain weakened live viruses.
- **Inactivated (or killed) viruses.** These viruses cannot cause even a mild form of the disease, but the body still recognizes the virus and creates an immune response to protect itself. The polio, hepatitis A, influenza ([/English/safety-prevention/immunizations/pages/Inactivated-Influenza-Vaccine-What-You-Need-to-Know.aspx](https://www.healthychildren.org/English/safety-prevention/immunizations/pages/Inactivated-Influenza-Vaccine-What-You-Need-to-Know.aspx)) and rabies vaccines contain inactivated viruses.
- **Partial viruses.** These are made up of the specific part of the dead virus that will prompt a protective immune response. Some vaccines are made this way including the hepatitis B and HPV vaccine.
- **Partial bacteria.** are made up of the specific part of the dead bacteria that will prompt a protective immune response. Some vaccines are made this way including the Hib, pneumococcal, meningococcal ([/English/safety-prevention/immunizations/pages/Meningococcal-Vaccines-What-You-Need-to-Know.aspx](https://www.healthychildren.org/English/safety-prevention/immunizations/pages/Meningococcal-Vaccines-What-You-Need-to-Know.aspx)), diphtheria, tetanus and pertussis (whooping cough) vaccines.

Vaccines also contain other ingredients, which help make them safer and more effective. They include:

- **Preservatives.** They keep the vials from getting contaminated with germs.
- **Adjuvants.** They help the body create a better immune response. These are aluminum salts.
- **Additives.** They help the vaccine stay effective while being stored. Additives include gelatin, albumin, sucrose, lactose, MSG and glycine.
- **Residuals of the vaccine production process.** Some ingredients are needed to make the vaccine. Although these ingredients are removed, tiny (residual) amounts are left in the final product. Depending on how the vaccine is made, it may include tiny amounts of antibiotics (neomycin), egg protein or yeast protein.

Q. Are these other ingredients in vaccines safe?

A. Yes.

Q. Why are these other ingredients in vaccines?

A. Each ingredient has a specific function in a vaccine. These ingredients have been studied and are safe for humans in the amount used in vaccines. This amount is much less than children encounter in their environment, food and water.

- **Aluminum salts.** Aluminum salts help your body create a better immune response to vaccines. Aluminum salts are necessary to make some of the vaccines we use more effective. Without an adjuvant like aluminum, people could need more doses of shots to be protected. Everyone is exposed to aluminum because there is much aluminum in the earth's crust. It's present in our food, air and water, including breast milk and formula. The amount of aluminum in vaccines is similar to that found in 33 ounces of infant formula. Aluminum has been used and studied in vaccines for 75 years and is safe.
- **Formaldehyde.** Formaldehyde is used to detoxify diphtheria and tetanus toxins or to inactivate a virus. The tiny amount which may be left in these vaccines is safe. Vaccines are not the only source of formaldehyde your baby is exposed to. Formaldehyde is also in products like paper towels, mascara and carpeting. Our bodies normally have formaldehyde in the blood stream and at levels higher than in vaccines.
- **Antibiotics.** Antibiotics, such as neomycin, are present in some vaccines to prevent bacterial contamination when the vaccine is made. Trace amounts of antibiotics in vaccines rarely, if ever, cause allergic reactions.
- **Egg protein.** Influenza and yellow fever vaccines are produced in eggs, so egg proteins are present in the final product and can cause allergic reaction. Measles and mumps vaccines are made in chick embryo cells in culture, not in eggs. The much smaller amount of remaining egg proteins found in the MMR (measles, mumps, rubella) vaccine does not usually cause a reaction in egg allergic children.
- **Gelatin.** Some vaccines contain gelatin to protect them against freeze-drying or heat. People with severe allergies to gelatin should avoid getting gelatin-containing vaccines.

Q. Do vaccines contain antifreeze?

A: No. Antifreeze is typically made of ethylene glycol, which is unsafe. Confusion has arisen, because polyethylene glycol (a chemical used in antifreeze and personal care products like skin creams and toothpaste) is used in vaccines and is safe. It is used to inactivate the influenza virus in some influenza vaccines. It is also used to purify other vaccines.

Q. Do vaccines contain mercury?

A: Almost all childhood vaccines do NOT contain any mercury. Methylmercury, which is found in fish and other animals (including humans) can be toxic and lead to adverse effects in humans. Thimerosal, a mercury-based preservative, was removed from most childhood vaccines in 2001. Thimerosal contains a different form of mercury called ethylmercury, which is processed by the body very differently than methylmercury, and is not associated with the same adverse effects. It is still present in some influenza vaccines. Thimerosal is still used in the manufacture of some vaccines to prevent contamination. The thimerosal is removed at the end of the manufacturing process. In some cases, a tiny amount of thimerosal remains. The remaining amount is so small, that it is not possible for it to have any effect. Valid scientific studies have shown there is no link between thimerosal and autism. In fact, autism rates have actually increased since thimerosal was removed from childhood vaccines. The American Academy of Pediatrics (AAP), the American Medical Association (AMA), the CDC, and the Institute of Medicine (IOM) agree that science does not support a link between thimerosal in vaccines and autism. For the IOM report, go to <http://www.iom.edu/CMS/3793/4705/4717.aspx> (<http://www.iom.edu/Reports/2001/Immunization-Safety-Review-Thimerosal---Containing-Vaccines-and-Neurodevelopmental-Disorders.aspx>).

Q. Do vaccines contain fetal tissue?

A. No. A few vaccines involve growing the viruses in human cell culture. Two cell lines provide the cultures needed for producing vaccines. These lines were developed from two fetuses in the 1960s. The fetuses were aborted for medical reasons, not for the purpose of producing vaccines. These cell lines have an indefinite life span, meaning that no new aborted fetuses are ever used. No fetal tissue is included in the vaccines, either, so children are not injected with any part of an aborted fetus.

Q. Should vaccines be "greener"?

A. The amount of each additive used in vaccines is very small. In fact, we are exposed to much higher levels of these chemicals in our everyday lives. In vaccines, these ingredients are used to make the vaccine safer and more effective. Each vaccine is tested many times ([/English/safety-prevention/immunizations/pages/Vaccine-Hot-Lots.aspx](https://www.healthychildren.org/English/safety-prevention/immunizations/pages/Vaccine-Hot-Lots.aspx)) to make sure it is safe and works. Taking ingredients out might affect the ability of the vaccine to protect a child. Research is always being done to make sure that ingredients in vaccines continue to be the safest and best available for children.

Last Updated 11/21/2015

Source Questions and Answers About Vaccine Ingredients (Copyright © 2013 American Academy of Pediatrics)

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Reviewed March 2012

Talking with Parents about Vaccines for Infants

Strategies for Health Care Professionals

Immunization professionals and parents agree: times have changed.

Because of questions or concerns about vaccines, well-child visits can be stressful for parents. As their infant's health care provider, you remain parents' most trusted source of information about vaccines. This is true even for parents with the most questions and concerns. Your personal relationship uniquely qualifies you to help support parents in understanding and choosing vaccinations.

However, time for infant health evaluation at each well visit is at a premium, as you check physical, cognitive, and other milestones and advise parents on what to expect in the coming months. Therefore, making time to talk about vaccines may be stressful for *you*. But when an infant is due to receive vaccines, nothing is more important than making the time to assess the parents' information needs as well as the role they desire to play in making decisions for their child's health, and then following up with communication that meets their needs.

When it comes to communication, you may find that similar information—be it science or anecdote or some mix of the two—works for most parents you see. But keep a watchful eye to be sure that you are connecting with each parent to maintain trust and keep lines of communication open.

We hope that these brief reminders—and the materials that you, your staff, and parents can find on our website— will help ensure your continued success in immunizing infants and children. Success may mean that all vaccines are accepted when you recommend them, or that some vaccines are scheduled for another day. If a parent refuses to vaccinate, success may simply mean keeping the door open for future discussions about choosing vaccination.



THIS RESOURCE COVERS:

- What you may hear from parents about their vaccine safety questions and how to effectively address them
- Proven communication strategies and tips for having a successful vaccine conversation with parents
- This brochure is part of a comprehensive set of educational materials for health care professionals and parents available at <http://www.cdc.gov/vaccines/conversations>

Nurses, physician assistants, and other office staff play a key role in establishing and maintaining a practice-wide commitment to communicating effectively about vaccines and maintaining high vaccination rates: from providing parents with educational materials, to being available to answer their questions, to making sure that families who may opt for extra visits for vaccines make and keep vaccine appointments.

What You May Hear From Parents

As you plan for responding to parents' concerns, it may be useful to think of parental questions in the following categories.

Questions about whether vaccines cause autism

Parents may encounter poorly designed and conducted studies, misleading summaries of well-conducted studies, or anecdotes made to look like science—claiming that vaccines cause autism. Many rigorous studies show that there is no link between MMR vaccine or thimerosal and autism. Visit <http://www.cdc.gov/vaccines/conversations> for more information to help you answer parents' questions on these two issues. If parents raise other possible hypotheses linking vaccines to autism, four items are key: (1) patient and empathetic reassurance that you understand that their infant's health is their top priority, and it also is your top priority, so putting children at risk of vaccine-preventable diseases without scientific evidence of a link between vaccines and autism is a risk you are not willing to take; (2) your knowledge that the onset of regressive autism symptoms often coincides with the timing of vaccines but is not caused by vaccines; (3) your personal and professional opinion that vaccines are very safe; and (4) your reminder that vaccine-preventable diseases, which may cause serious complications and even death, remain a threat.

"All those people who say that the MMR vaccine causes autism must be on to something."

"Autism is a burden for many families and people want answers—including me. But well designed and conducted studies that I can share with you show that MMR vaccine is not a cause of autism."

Questions about whether vaccines are more dangerous for infants than the diseases they prevent

Today, parents may not have seen a case of a vaccine-preventable disease firsthand. Therefore, they may wonder if vaccines are really necessary, and they may believe that the risks of vaccinating infants outweigh the benefits of protecting them from infection with vaccine-preventable diseases. Visit <http://www.cdc.gov/vaccines/conversations> for up-to-date information on diseases and the vaccines that prevent them that you can share with parents. You may be able to provide information from your own experience about the seriousness of the diseases, the fact that cases and outbreaks of vaccine-preventable diseases are occurring now in the U.S., and that even when diseases are eliminated in the U.S., they can make a rapid return in children and adults who are not immunized if travelers bring the diseases into the U.S. You also can remind parents about ongoing efforts to ensure the safety of vaccines, including the large-scale reporting system, Vaccine Adverse Event Reporting System (<http://www.vaers.hhs.gov>), used

to alert FDA and CDC to any possible problems with a vaccine so that they can be studied in more detail.

"What are all these vaccines for? Are they really necessary?"

"I know you didn't get all these vaccines when you were a baby. Neither did I. But we were both at risk of serious diseases like Hib and pneumococcal meningitis. Today, we're lucky to be able to protect our babies from 14 serious diseases with vaccines."

Questions about the number of vaccines and vaccine ingredients

Some parents may have a general concern that there are too many vaccines. With respect to timing and spacing of vaccines, the childhood vaccine schedule is designed to provide protection at the earliest possible time against serious diseases that may affect infants early in life. *The Childhood Immunization Schedule* fact sheet (<http://www.cdc.gov/vaccines/conversations>) may be useful for those parents, as well as for parents who have specific questions. Some parents may be able to specify their concerns: whether each vaccine is needed, whether giving several vaccines at one time can cause harm, whether vaccine ingredients are harmful, or how well each vaccine works. For these parents, you can specifically reinforce the seriousness of the diseases prevented by vaccines, and share your knowledge that no evidence suggests that a healthy child's immune system will be damaged or overwhelmed by receiving several vaccines at one time. *Understanding Vaccine Ingredients* (<http://www.cdc.gov/vaccines/conversations>) can help you counter myths that have circulated about vaccine ingredients. You may need to share with some parents that not only should each vaccine series be started on time to protect infants and children as soon as possible, but each multi-dose series must be completed to provide the best protection.

"I'm really not comfortable with my 2-month-old getting so many vaccines at once."

"There's no proven danger in getting all the recommended 2-month vaccines today. Any time you delay a vaccine you leave your baby vulnerable to disease. It's really best to stay on schedule. But if you're very uncomfortable, we can give some vaccines today and schedule you to come back in two weeks for the rest, but this is not recommended."

Questions about known side effects

It is reasonable for parents to be concerned about the possible reactions or side effects listed on the Vaccine Information Statements, especially fever, redness where a shot was given, or fussiness that their child may experience following vaccination. Remind parents to watch for the possible side effects and provide information on how they should treat them and how they can contact you if they observe something they are concerned about. To reinforce how rare serious side effects really are, share your own experience, if any, with seeing a serious side effect from a vaccine.

"I'm worried about the side effects of vaccines. I don't want my child to get any vaccines today."

"I'll worry if your child *doesn't* get vaccines today, because the diseases can be very dangerous—most, including Hib, pertussis, and measles, are still infecting children in the U.S. We can look at the Vaccine Information Statements together and talk about how rare serious vaccine side effects are."

Questions about unknown serious adverse events

Parents who look for information about vaccine safety will likely encounter suggestions about as-yet-unknown serious adverse events from vaccines. It is not unreasonable that parents find this alarming. You can share what the world was like for children before there were vaccines. And you can share that increases in health problems such as autism, asthma, or diabetes don't have a biologic connection to vaccination. We have no evidence to suggest that vaccines threaten a long, healthy life. We know lack of vaccination threatens a long and healthy life.

"You really don't know if vaccines cause any long-term effects."

"We have years of experience with vaccines and no reason to believe that vaccines cause long-term harm. I understand your concern, but I truly believe that the risk of diseases is greater than any risks posed by vaccines. Vaccines will get your baby off to a great start for a long, healthy life."

Communication Strategies—How to Have a Successful Dialogue

A successful discussion about vaccines involves a two-way conversation, with both parties sharing information and asking questions. These communication principles can help you connect with parents by encouraging open, honest, and productive dialogue.

Take advantage of early opportunities such as the prenatal, newborn, 1-week, and 1-month visits to initiate a dialogue about vaccines. These also are good opportunities to provide take-home materials or direct parents to immunization websites that you trust. This gives parents time to read and digest reputable vaccine information before the first and all future immunizations. And when parents have questions, you can build on the reputable information that they already have reviewed. With parents who have many questions, consider an extended visit to discuss vaccinating their child.

Take time to listen.

If parents need to talk about vaccines, give them your full attention. Despite a full schedule, resist the urge to multi-task while a parent talks. Maintain eye contact with parents, restate their concerns to be sure you understand their viewpoint, and pause to thoughtfully prepare your reply. Your willingness to listen will likely play a major role in helping parents with their decisions to choose vaccination.

Solicit and welcome questions.

If parents seem concerned about vaccines but are reluctant to talk, ask them open-ended questions and let them know that you want to hear their questions and concerns.

Put yourself in parents' shoes and acknowledge parents' feelings and emotions, including their fear and desire to protect their children. Remind parents that you know why they are concerned—their infant's health is their top priority. Remind them that it is yours, too.

Keep the conversation going.

If parents come to you with a long list of questions or information from the Web or other sources, don't interpret this as a lack of respect for you. Instead, acknowledge that spending time to research vaccines means that this is an important topic for the parents. If you appear offended by questions, or if you imply that a parent's questions are uncalled for, dialogue may shut down and trust may be eroded.



Science versus anecdote?

Too much science will frustrate some parents. Too little science will frustrate others. For some parents, too much anecdotal information won't hit the mark. For others, a story from your experience about an unprotected child who became ill, or knowing that children in your family have received all of their vaccines, will be exactly on target. Which approach to use will depend on your knowledge of the family. Watch and listen. Be prepared to use the mix of science and personal stories that will be most effective in addressing parents' questions.

Acknowledge benefits and risks.

Always discuss honestly the known side effects caused by vaccines. But don't forget to remind parents of the overwhelming benefit of preventing potentially serious diseases with vaccines. It's honest to say that not vaccinating is a risk that will worry you.

Respect parents' authority.

Many parents today want to work in partnership with their child's physician. Of course, you work in partnership with parents every day, for example, by eliciting reports from them about how their infants are progressing. By talking respectfully with parents about their immunization concerns, you can build on this partnership, build trust, and support parents in the decision to choose vaccination.

Reduce the stress of shots.

Show parents ways they can make the vaccination visit less stressful for the child. It can begin by reinforcing that crying is a normal response for the child and suggesting that they stay calm so that the child does not become aware of their stress. For infants, you can suggest that parents use a favorite blanket or toy to distract the baby from the pain of the shots, and that they touch and soothe the baby, talk softly, and smile and make eye contact during the shots. After shots for infants, mothers may wish to cuddle or breastfeed. For toddlers, there are many more

options to distract from the pain of the shot, including telling a favorite story, singing, or taking deep breaths and blowing out the pain. After the shots, toddlers can be praised for getting through the shots and reassured that everything is okay.

After the Office Visit

Document parents' questions and concerns.

A thorough record of your discussion will be an invaluable reference during the child's future visits.

Follow up.

If parents express extreme worry or doubt, contact them a few days after the visit. A caring call or e-mail will provide comfort and reinforce trust.

What If Parents Refuse to Vaccinate?

Excluding children from your practice when their parents decline immunizations is not recommended. It can put the child at risk of many different health problems—not just vaccine-preventable diseases. Remember, unvaccinated infants did not decide for themselves to remain unvaccinated. They need your care. Make sure that parents are fully informed about clinical presentations of vaccine-preventable diseases, including early symptoms. Diseases like pertussis and measles are highly contagious and may present early as a non-specific respiratory illness. Parents who refuse vaccines should be reminded at every visit to call before bringing the child into the office, clinic, or emergency department when the child is ill so appropriate measures can be taken to protect others. When scheduling an office visit for an ill child who has not received vaccines, take all possible precautions to prevent contact with other patients, especially those too young to be fully vaccinated and those who have weakened immune systems.

If a parent refuses to vaccinate, you can share the fact sheet *If You Choose Not to Vaccinate Your Child, Understand the Risks and Responsibilities* (<http://www.cdc.gov/vaccines/conversations/>), which explains the risks involved with this decision including risks to other members of their community, and the additional responsibilities for parents, including the fact that, when their child is ill, they should always alert health care personnel to their child's vaccination status to prevent the possible spread of vaccine-preventable diseases. You also can tell the parent that you would like to continue the dialogue about vaccines during the next visit, and then make sure to do so. You may wish to have them sign AAP's *Refusal to Vaccinate* form (<http://www.aap.org/immunization/pediatricians/pdf/refusaltovaccinate.pdf>) each time a vaccine is refused so that you have a record of their refusal in their child's medical file.

Remember, not all parents want the same level of medical or scientific information about vaccines. By assessing the level of information that a particular parent wants, you can communicate more effectively and build trust.

For the information resources mentioned in this sheet, and others, look for *Provider Resources for Vaccine Conversations with Parents* at <http://www.cdc.gov/vaccines/conversations> or call **800-CDC-INFO** (800-232-4636). These resources are free to download and ready for color or black and white printing and reproduction.

MMR vaccine does not cause autism

Examine the evidence!

There is no scientific evidence that MMR vaccine causes autism. The question about a possible link between MMR vaccine and autism has been extensively reviewed by independent groups of experts in the U.S. including the National Academy of Sciences' Institute of Medicine. These reviews have concluded that the available epidemiologic evidence does not support a causal link between MMR vaccine and autism.

The suggestion that MMR vaccine might lead to autism had its origins in research by Andrew Wakefield, a gastroenterologist, in the United Kingdom. In 1998, Wakefield and colleagues published an article in *The Lancet* claiming that the measles vaccine virus in MMR caused inflammatory bowel disease, allowing harmful proteins to enter the

bloodstream and damage the brain. The validity of this finding was later called into question when it could not be reproduced by other researchers. In addition, the findings were further discredited when an investigation found that Wakefield did not disclose he was being funded for his research by lawyers seeking evidence to use against vaccine manufacturers. Wakefield was permanently barred from practicing medicine in the United Kingdom (www.neurodiversity.com/wakefield_gmc_ruling.pdf) and *The Lancet* retracted the original article in 2010.

The following list of articles published in peer-reviewed journals is provided so that parents and practitioners can themselves compare the balance of evidence about MMR vaccine and autism.

More than 20 articles refute a connection between MMR vaccine and the development of autism

1. *Vaccines for Measles, Mumps and Rubella in Children*. Demicheli V et al. Cochrane Database Syst Rev. 2012 Feb 15. Literature review of 5 randomized controlled trials, 1 controlled clinical trial, 27 cohort studies, 17 case-control studies, 5 time-series trials, 1 case cross-over trial, 2 ecological studies, 6 and self-controlled case series studies involving in all about 14,700,000 children and assessing effectiveness and safety of MMR vaccine (2004-2011).
Conclusions: Exposure to the MMR vaccine was unlikely to be associated with autism, asthma, leukaemia, hay fever, type 1 diabetes, gait disturbance, Crohn's disease, demyelinating diseases, bacterial or viral infections.
Link: www.ncbi.nlm.nih.gov/pubmed/22336803
2. *Immunization Safety Review: Adverse Effects of Vaccines: Evidence and Causality*. Institute of Medicine. The National Academies Press: 2011. Consensus Report.
Conclusions: Evidence favors rejection of five vaccine-adverse event relationships, including MMR vaccine and autism. Overall, the committee concludes that few health problems are caused by or clearly associated with vaccines.
Link: www.iom.edu/reports/2011/adverse-effects-of-vaccines-evidence-and-causality.aspx
3. *Lack of Association Between Measles-Mumps-Rubella Vaccination and Autism in Children: A Case-Control Study*. Mrozek-Budzyn D et al. *Pediatr Infect Dis J*. 2010;29(5):397-400. The 96 cases with childhood or atypical autism, aged 2 to 15, were included in the study group. Controls consisted of 192 children individually matched to cases by year of birth, sex, and general practitioners.
Conclusions: The study provides evidence against the association of autism with either MMR or a single measles vaccine.
Link: www.ncbi.nlm.nih.gov/pubmed/19952979
4. *Measles Vaccination and Antibody Response in Autism Spectrum Disorders*. Baird G et al. *Arch Dis Child* 2008; 93(10):832-7. Subjects: 98 vaccinated children aged 10-12 years in the UK with autism spectrum disorder (ASD); two control groups of similar age: 52 children with special educational needs but no ASD and 90 children in the typically developing group.

Fully retracted: the single study that purported to show a connection between MMR vaccine and the development of autism

Ileal-Lymphoid-Nodular Hyperplasia, Non-specific Colitis, and Pervasive Developmental Disorder in Children. Wakefield AJ et al. *Lancet* 1998; 351(9251):437-41. Subjects: 12 children with chronic enterocolitis and regressive developmental disorder.

"A Statement by the Editors of the Lancet," *Lancet* 2010; 363(9411):820-1, the editors fully retract this paper from the published record: <http://download.thelancet.com/flatcontentassets/pdfs/S0140673610601754.pdf>

Conclusion: No association between measles vaccination and ASD was shown.

Link: www.ncbi.nlm.nih.gov/pubmed/18252754

5. *Lack of Association between Measles Virus Vaccine and Autism with Enteropathy: A Case-Control Study*. Hornig M et al. *PLoS ONE* 2008; 3(9):e3140. Subjects: 25 children with autism and GI disturbances and 13 children with GI disturbances alone (controls).
Conclusions: This study provides strong evidence against association of autism with persistent MV RNA in the GI tract or MMR exposure.
Link: www.ncbi.nlm.nih.gov/pubmed/18769550
6. *Immunizations and Autism: A Review of the Literature*. Doja A, Roberts W. *Can J Neurol Sci*. 2006; 33(4):341-6. Literature review.
Conclusion: Our literature review found very few studies supporting this theory, with the overwhelming majority showing no causal association between the Measles-Mumps-Rubella vaccine and autism.
Link: www.ncbi.nlm.nih.gov/pubmed/17168158
7. *No Evidence of Persisting Measles Virus in Peripheral Blood Mononuclear Cells from Children with Autism Spectrum Disorder*. D'Souza Y et al. *Pediatrics* 2006; 118(4):1664-75. Subjects: 54 children with autism spectrum disorder and 34 developmentally normal children
Conclusion: There is no evidence of measles virus persistence in the peripheral blood mononuclear cells of children with autism spectrum disorder.
Link: www.ncbi.nlm.nih.gov/pubmed/17015560

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8. *MMR-Vaccine and Regression in Autism Spectrum Disorders: Negative Results Presented from Japan*. Uchiyama T et al. *J Autism Dev Disord* 2007; 37(2):210-7. Subjects: 904 children with autism spectrum disorder. (Note: MMR was used in Japan only between 1989 and 1993.) Conclusions: During the period of MMR usage no significant difference was found in the incidence of regression between MMR-vaccinated children and non-vaccinated children. Among the proportion and incidence of regression across the three MMR-program-related periods (before, during and after MMR usage), no significant difference was found between those who had received MMR and those who had not. Moreover, the incidence of regression did not change significantly across the three periods.
Link: www.ncbi.nlm.nih.gov/pubmed/16865547
9. *Pervasive Developmental Disorders in Montreal, Quebec, Canada: Prevalence and Links with Immunizations*. Fombonne E et al. *Pediatrics*. 2006;118(1):e139-50. Subjects: 27,749 children born from 1987 to 1998 attending 55 schools.
Conclusion: The findings ruled out an association between pervasive developmental disorder and either high levels of ethylmercury exposure comparable with those experienced in the United States in the 1990s or 1- or 2-dose measles-mumps-rubella vaccinations.
Link: www.ncbi.nlm.nih.gov/pubmed/16818529
10. *Is There a 'Regressive Phenotype' of Autism Spectrum Disorder Associated with the Measles-Mumps-Rubella Vaccine? A CPEA Study*. Richler J, Luyster R, Risi S, et al. *J Autism Dev Disord*. 2006 Apr;36(3):299-316. A multi-site study of 351 children with Autism Spectrum Disorders (ASD) and 31 typically developing children used caregiver interviews to describe the children's early acquisition and loss of social-communication milestones.
Conclusion: There was no evidence that onset of autistic symptoms or of regression was related to measles-mumps-rubella vaccination.
Link: www.ncbi.nlm.nih.gov/pubmed/16729252
11. *Relationship between MMR Vaccine and Autism*. Klein KC, Diehl EB. *Ann Pharmacother*. 2004; 38(7-8):1297-300. Literature review of 10 studies.
Conclusion: Based upon the current literature, it appears that there is no relationship between MMR vaccination and the development of autism.
Link: www.ncbi.nlm.nih.gov/pubmed/15173555
12. *Immunization Safety Review: Vaccines and Autism*. Institute of Medicine. The National Academies Press: 2004. Consensus report.
Conclusion: The committee concludes that the body of epidemiological evidence favors rejection of a causal relationship between the MMR vaccine and autism.
Link: www.nap.edu/openbook.php?isbn=030909237X
13. *MMR Vaccination and Pervasive Developmental Disorders: A Case-Control Study*. Smeeth L et al. *Lancet* 2004; 364(9438):963-9. Subjects: 1294 cases and 4469 controls.
Conclusion: Our findings suggest that MMR vaccination is not associated with an increased risk of pervasive developmental disorders.
Link: www.ncbi.nlm.nih.gov/pubmed/15364187
14. *Age at First Measles-Mumps-Rubella Vaccination in Children with Autism and School-Matched Control Subjects: A Population-Based Study in Metropolitan Atlanta*. DeStefano F et al. *Pediatrics* 2004; 113(2): 259-66. Subjects: 624 children with autism and 1,824 controls.
Conclusions: Similar proportions of case and control children were vaccinated by the recommended age or shortly after (ie, before 18 months) and before the age by which atypical development is usually recognized in children with autism (ie, 24 months). Vaccination before 36 months was more common among case children than control children, especially among children 3 to 5 years of age, likely reflecting immunization requirements for enrollment in early intervention programs.
Link: www.ncbi.nlm.nih.gov/pubmed/14754936
15. *Prevalence of Autism and Parentally Reported Triggers in a North East London Population*. Lingam R et al. *Arch Dis Child* 2003; 88(8):666-70. Subjects: 567 children with autistic spectrum disorder.
Conclusions: The prevalence of autism, which was apparently rising from 1979 to 1992, reached a plateau from 1992 to 1996 at a rate of some 2.6 per 1000 live births. This levelling off, together with the reducing age at diagnosis, suggests that the earlier recorded rise in prevalence was not a real increase but was likely due to factors such as increased recognition, a greater willingness on the part of educationalists and families to accept the diagnostic label, and better recording systems. The proportion of parents attributing their child's autism to MMR appears to have increased since August 1997.
Link: www.ncbi.nlm.nih.gov/pubmed/12876158
16. *A Population-Based Study of Measles, Mumps, and Rubella Vaccination and Autism*. Madsen KM et al. *N Engl J Med* 2002; 347(19):1477-82. Subjects: All 537,303 children born 1/91-12/98 in Denmark.
Conclusions: This study provides strong evidence against the hypothesis that MMR vaccination causes autism.
Link: www.ncbi.nlm.nih.gov/pubmed/12421889
17. *Neurologic Disorders after Measles-Mumps-Rubella Vaccination*. Makela A et al. *Pediatrics* 2002; 110:957-63. Subjects: 535,544 children vaccinated between November 1982 and June 1986 in Finland.
Conclusions: We did not identify any association between MMR vaccination and encephalitis, aseptic meningitis, or autism.
Link: www.ncbi.nlm.nih.gov/pubmed/12415036
18. *Relation of Childhood Gastrointestinal Disorders to Autism: Nested Case Control Study Using Data from the UK General Practice Research Database*. Black C et al. *BMJ* 2002; 325:419-21. Subjects: 96 children diagnosed with autism and 449 controls.
Conclusions: No evidence was found that children with autism were more likely than children without autism to have had defined gastrointestinal disorders at any time before their diagnosis of autism.
Link: www.ncbi.nlm.nih.gov/pubmed/12193358
19. *Measles, Mumps, and Rubella Vaccination and Bowel Problems or Developmental Regression in Children with Autism: Population Study*. Taylor B et al. *BMJ* 2002; 324(7334):393-6. Subjects: 278 children with core autism and 195 with atypical autism.
Conclusions: These findings provide no support for an MMR associated "new variant" form of autism with developmental regression and bowel problems, and further evidence against involvement of MMR vaccine in the initiation of autism.
Link: www.ncbi.nlm.nih.gov/pubmed/11850369
20. *No Evidence for a New Variant of Measles-Mumps-Rubella-Induced Autism*. Fombonne E et al. *Pediatrics* 2001;108(4):E58. Subjects: 262 autistic children (pre- and post-MMR samples).
Conclusions: No evidence was found to support a distinct syndrome of MMR-induced autism or of "autistic enterocolitis." These results add to the recent accumulation of large-scale epidemiologic studies that all failed to support an association between MMR and autism at population level. When combined, the current findings do not argue for changes in current immunization programs and recommendations.
Link: www.ncbi.nlm.nih.gov/pubmed/11581466
21. *Time Trends in Autism and in MMR Immunization Coverage in California*. Dales L et al. *JAMA* 2001; 285(9):1183-5. Subjects: Children born in 1980-94 who were enrolled in California kindergartens (survey samples of 600-1,900 children each year).
Conclusions: These data do not suggest an association between MMR immunization among young children and an increase in autism occurrence.
Link: www.ncbi.nlm.nih.gov/pubmed/11231748

22. *Mumps, Measles, and Rubella Vaccine and the Incidence of Autism Recorded by General Practitioners: A Time Trend Analysis.* Kaye JA et al. BMJ 2001; 322:460-63. Subjects: 305 children with autism.

Conclusions: Because the incidence of autism among 2 to 5 year olds increased markedly among boys born in each year separately from 1988 to 1993 while MMR vaccine coverage was over 95% for successive annual birth cohorts, the data provide evidence that no correlation exists between the prevalence of MMR vaccination and the rapid increase in the risk of autism over time. The explanation for the marked increase in

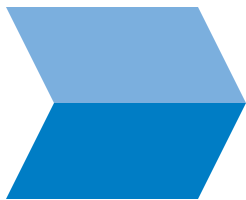
risk of the diagnosis of autism in the past decade remains uncertain.

Link: www.ncbi.nlm.nih.gov/pubmed/11222420

23. *Autism and Measles, Mumps, and Rubella Vaccine: No Epidemiological Evidence for a Causal Association.* Taylor B et al. Lancet 1999;353 (9169):2026-9. Subjects: 498 children with autism.

Conclusion: Our analyses do not support a causal association between MMR vaccine and autism. If such an association occurs, it is so rare that it could not be identified in this large regional sample.

Link: www.ncbi.nlm.nih.gov/pubmed/10376617



4 Vaccine Administration

Introduction

Administering vaccines correctly is a critical part of the health care professional's job. Vaccines are required to be administered in various methods, including intramuscular (IM), subcutaneous (SQ), oral, and nasal. Some vaccines come with a diluent and must be reconstituted, whereas others do not. Needle size and length vary with administration method and size of the patient. Following the most current immunization schedule from the Centers for Disease Control and Prevention (CDC) is another important factor. It is important that health care professionals be knowledgeable and well trained before administering vaccines. If vaccines are given improperly, the patient may not develop immunity.

Learning Objectives

On completion of this unit, the health care professional will be able to

- Describe routes of administering vaccines.
- Demonstrate locations of administering SQ injections to an adult and child.
- Demonstrate locations of administering IM injections to an adult and child.
- List vaccines that require diluents and consequences of not mixing properly.
- Discuss size of needle based on the age and size of a patient.
- Demonstrate holding techniques for administering vaccines to infants and toddlers.
- Explain how to avoid vaccine wastage and consequences of wastage.
- Explain Vaccine Information Statements (VISs) and their required use.

Professional Policies

Registered nurses and medical assistants are the health care professionals most commonly administering vaccines. A few states do not allow medical assistants to administer injections, so it is important to check state statutes. Many medical practices require that medical assistants be certified or registered and have graduated from an accredited medical assisting program to administer vaccines or any type of injections.

Please use this text box to add your practice's specific policies on this topic and any other notes you wish to include in your final document.

About Vaccine Administration

Infection control is very important, and hand washing is the single most important way to prevent the spread of infection. Health care professionals should wash their hands between each patient encounter and before preparing vaccines. Gloves should be worn when administering vaccines if there is a likelihood that the person administering the vaccine might come into contact with body fluids or the person has open sores or cuts on the hands.

Vaccine Information Statements, produced by the CDC, contain information about the benefits and risks of vaccines. By federal law, all vaccine providers must give patients, parents, or legal guardians the appropriate VIS whenever a vaccine is given. These can be obtained on the CDC (www.cdc.gov/vaccines/pubs/vis) and Immunization Action Coalition (IAC) (www.immunize.org) Web sites. Providers may personalize the VIS with their name, address, and phone number as long as the date is not cut off from the bottom of the page and no changes to wording of the VIS are made. For more information on VISs, see Topic 9 of this guide.

Patients who are moderately or severely ill should wait until they recover before getting vaccinated. Some vaccines are made with egg protein, so patients who are severely allergic to eggs should not get these vaccinations.

Syringes can be 1 or 3 mL. It is recommended that safety syringes be used to reduce the incidence of needlesticks and disease transmission. Needle sizes vary on the basis of route, size of the patient, and viscosity of the vaccine. In most cases, a needle gauge of 22 to 25 can be used.

Each vaccine vial should be checked for the expiration date. A vaccine should never be used if it is expired. Some vaccines need to be reconstituted; a specific diluent will be provided by the manufacturer. It is important to follow manufacturer guidelines in reconstituting the vaccine. Once reconstituted, the vaccine must be administered according to the guidelines or discarded. In most cases, if not used within 30 minutes, the vaccine will lose its potency and the patient will not be properly immunized. Measles-mumps-rubella (MMR), varicella, zoster, *Haemophilus influenzae* type b, some meningococcal vaccines, and rotavirus vaccines all require reconstitution.

The CDC does not advise the use of pre-drawn syringes. These are vaccines drawn up and laid out at the beginning of the day or significantly before administration. Prefilled syringes that contain a single dose and are purchased directly from the manufacturer are OK. With pre-drawn syringes, there is a danger of administering the wrong vaccine. Medication guidelines state that the one administering the

injection should be the one who draws up the medication to prevent medication error. If multiple vaccines are to be administered on the same day, once vaccines are drawn up, they should be labeled in some way. Documentation of where each vaccine is administered is important. If syringes are not labeled, this may be difficult. Pre-drawing syringes with vaccine may cause waste of valuable and costly vaccines if they are not used within the manufacturer's time limits.

When administering multiple vaccines, never mix them in the same syringe. If more than one vaccine is being administered to the same limb, injection sites should be 1 to 2 in apart so any reactions can be determined. In most cases, a separate anatomic site should be used for each injection.

Most vaccines are administered IM, but MMR, varicella, zoster, and meningococcal polysaccharide are administered SQ. In administering IM injections, it is important to use a needle with the correct length to reach the muscle mass and not seep into SQ tissue. A chart is provided in the Tools and Resource section that describes doses, route, site, and needle size. This chart is also available on the CDC and IAC Web sites. For newborns, a 5/8-in needle should be used in the vastus lateralis muscle of the upper thigh. For infants up to age 1 year, a 1-in needle should be used in the same location. For toddlers, children, and adults, length varies on the basis of the injection site (vastus lateralis or deltoid) and patient's weight (3/8–1 1/2 in in length). For SQ injections, needle length should be 5/8 in.

When administering IM injections, the needle should be inserted at a 90-degree angle—and quickly. It is not necessary to aspirate after needle insertion. Subcutaneous injections are administered at a 45-degree angle, and the SQ tissue is pinched up to prevent injection into the muscle. It is not necessary to aspirate after needle insertion. Multiple vaccinations should be a minimum of 1 in apart. (See charts on how to administer IM and SQ injections included in Tools and Resource section.)

Another method of immunization is nasal spray, which is available for live attenuated influenza vaccine. Oral polio vaccine has not been used in the United States since 2000 but is still used in other countries. In the United States, inactivated polio vaccine is given and can be administered SQ or IM. Rotavirus vaccine is given orally.

After a vaccine is administered to a preadolescent or an adolescent (ages 11–18), it is recommended that the patient stay for 15 minutes to prevent injury from possible syncope after vaccination.

Key Facts

- Hand washing is critical before preparing or administering vaccines.
- Always check the expiration date before drawing up the vaccine.
- Vaccine Information Statements must be provided to parents or guardians before immunization.
- Reconstitute vaccines according to the manufacturer's guidelines.
- It is important to choose the right vaccine, dose, route, location, and needle size.
- Administer vaccine according to the method indicated (IM, SQ, nasal, or oral) to provide effective immunity to the patient.
- Accurate documentation must be entered in the patient's record; this includes the site, route, name of vaccine, dose, and lot number. Most states now have online registries of vaccines; documentation is required in these registries. This makes access available to any provider who needs to give vaccines to a patient and prevents duplication of immunizations. Two-dimensional bar code scanners may help reduce documentation errors. To learn more, visit www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/immunization/Pages/barcoding.aspx.

Tools and Resources

- For additional learning
 - Centers for Disease Control and Prevention: *One and Only Campaign* "Vaccine Administration Videos" (www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/immunization/Pages/Vaccine-Videos.aspx)
 - Cengage Learning: Lindh WQ, Pooler MS, Tamparo CD, Dahl BM. *Delmar's Comprehensive Medical Assisting: Administrative and Clinical Competencies*. 4th ed. Clifton Park, NY: Delmar, Cengage Learning; 2010
- Documents you may include in your personalized manual (included below)
 - Immunization Action Coalition (Acquired with permission from www.immunize.org on June 15, 2016. We thank the Immunization Action Coalition.)
 - *Administering Vaccines: Dose, Route, Site, and Needle Size* (www.immunize.org/catg.d/p3085.pdf)
 - *How to Administer Intramuscular and Subcutaneous Vaccine Injections* (www.immunize.org/catg.d/p2020.pdf)
 - *How to Administer Intramuscular and Subcutaneous Vaccine Injections to Adults* (www.immunize.org/catg.d/p2020A.pdf)
 - *Vaccines with Diluents: How to Use Them* (www.immunize.org/catg.d/p3040.pdf)

Administering Vaccines:

Dose, Route, Site, and Needle Size

Vaccine	Dose	Route
Diphtheria, Tetanus, Pertussis (DTaP, DT, Tdap, Td)	0.5 mL	IM
Haemophilus influenzae type b (Hib)	0.5 mL	IM
Hepatitis A (HepA)	≤18 yrs: 0.5 mL	IM
	≥19 yrs: 1.0 mL	
Hepatitis B (HepB) <i>Persons 11–15 yrs may be given Recombivax HB (Merck) 1.0 mL adult formulation on a 2-dose schedule.</i>	≤19 yrs: 0.5 mL	IM
	≥20 yrs: 1.0 mL	
Human papillomavirus (HPV)	0.5 mL	IM
Influenza, live attenuated (LAIV)	0.2 mL (0.1 mL in each nostril)	Intranasal spray
Influenza, inactivated (IIV): recombinant (RIV), for ages 18 years and older	6–35 mos: 0.25 mL	IM
	≥3 yrs: 0.5 mL	
Influenza (IIV) Fluzone Intradermal, for ages 18 through 64 years	0.1 mL	ID
Measles, Mumps, Rubella (MMR)	0.5 mL	Subcut
Meningococcal conjugate (MCV4 [MenACWY])	0.5 mL	IM
Meningococcal serogroup B (MenB)	0.5 mL	IM
Meningococcal polysaccharide (MPSV)	0.5 mL	Subcut
Pneumococcal conjugate (PCV)	0.5 mL	IM
Pneumococcal polysaccharide (PPSV)	0.5 mL	IM or Subcut
Polio, inactivated (IPV)	0.5 mL	IM or Subcut
Rotavirus (RV)	Rotarix: 1.0 mL	Oral
	Rotateq: 2.0 mL	
Varicella (Var)	0.5 mL	Subcut
Zoster (Zos)	0.65 mL	Subcut
Combination Vaccines		
DTaP-HepB-IPV (Pediarix) DTaP-IPV/Hib (Pentacel) DTaP-IPV (Kinrix; Quadracel) Hib-HepB (Comvax) Hib-MenCY (MenHibrix)	0.5 mL	IM
MMRV (ProQuad)	≤12 yrs: 0.5 mL	Subcut
HepA-HepB (Twinrix)	≥18 yrs: 1.0 mL	IM

Injection Site and Needle Size		
Subcutaneous (Subcut) injection Use a 23–25 gauge needle. Choose the injection site that is appropriate to the person’s age and body mass.		
AGE	NEEDLE LENGTH	INJECTION SITE
Infants (1–12 mos)	5⁄8"	Fatty tissue over anterolateral thigh muscle
Children 12 mos or older, adolescents, and adults	5⁄8"	Fatty tissue over anterolateral thigh muscle or fatty tissue over triceps
Intramuscular (IM) injection Use a 22–25 gauge needle. Choose the injection site and needle length that is appropriate to the person’s age and body mass.		
AGE	NEEDLE LENGTH	INJECTION SITE
Newborns (1st 28 days)	5⁄8"	Anterolateral thigh muscle
Infants (1–12 mos)	1"	Anterolateral thigh muscle
Toddlers (1–2 years)	1–1¼"	Anterolateral thigh muscle
	5⁄8–1"	Deltoid muscle of arm
Children and teens (3–18 years)	5⁄8–1"*	Deltoid muscle of arm
	1–1¼"	Anterolateral thigh muscle
Adults 19 years or older		
Female or male <130 lbs	5⁄8–1"*	Deltoid muscle of arm
Female or male 130–152 lbs	1"	Deltoid muscle of arm
Female 153–200 lbs Male 130–260 lbs	1–1½"	Deltoid muscle of arm
Female 200+ lbs Male 260+ lbs	1½"	Deltoid muscle of arm

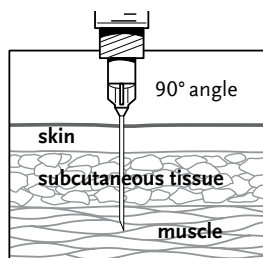
* A 5⁄8" needle may be used for patients weighing less than 130 lbs (<60 kg) for IM injection in the deltoid muscle **only** if the skin stretched tight, the subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle.

NOTE: Always refer to the package insert included with each biologic for complete vaccine administration information. CDC’s Advisory Committee on Immunization Practices (ACIP) recommendations for the particular vaccine should be reviewed as well. Access the ACIP recommendations at www.immunize.org/acip.

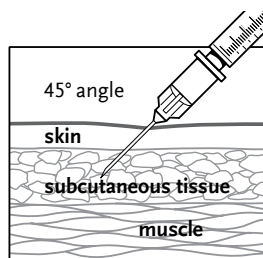
* A 5/8" needle may be used for patients weighing less than 130 lbs (<60 kg) for IM injection in the deltoid muscle **only** if the skin stretched tight, the subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle.

NOTE: Always refer to the package insert included with each biologic for complete vaccine administration information. CDC's Advisory Committee on Immunization Practices (ACIP) recommendations for the particular vaccine should be reviewed as well. Access the ACIP recommendations at www.immunize.org/acip.

Intramuscular (IM) injection



Subcutaneous (Subcut) injection



Intradermal (ID) administration of Fluzone ID vaccine



Intranasal (NAS) administration of Flumist (LAIV) vaccine



Technical content reviewed by the Centers for Disease Control and Prevention

How to Administer Intramuscular and Subcutaneous Vaccine Injections

Administration by the Intramuscular (IM) Route

Administer these vaccines via IM route

- Diphtheria-tetanus-pertussis (DTaP, Tdap)
- Diphtheria-tetanus (DT, Td)
- *Haemophilus influenzae* type b (Hib)
- Hepatitis A (HepA)
- Hepatitis B (HepB)
- Human papillomavirus (HPV)
- Inactivated influenza (IIV)
- Meningococcal serogroup B (MenB)
- Quadrivalent meningococcal conjugate (MenACWY [MCV4])
- Pneumococcal conjugate (PCV13)

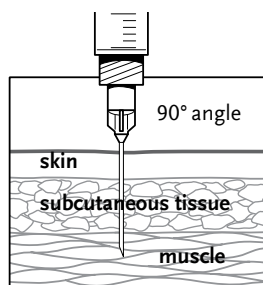
Administer inactivated polio (IPV) and pneumococcal polysaccharide (PPSV23) vaccines either IM or Subcut.

PATIENT AGE	INJECTION SITE	NEEDLE SIZE
Newborn (0–28 days)	Anterolateral thigh muscle	5/8"* (22–25 gauge)
Infant (1–12 months)	Anterolateral thigh muscle	1"* (22–25 gauge)
Toddler (1–2 years)	Anterolateral thigh muscle	1–1 1/4" (22–25 gauge)
	Alternate site: Deltoid muscle of arm if muscle mass is adequate	5/8–1"* (22–25 gauge)
Children (3–18 years)	Deltoid muscle (upper arm)	5/8–1"* (22–25 gauge)
	Alternate site: Anterolateral thigh muscle	1–1 1/4" (22–25 gauge)
Adults 19 years and older	Deltoid muscle (upper arm)	1–1 1/2"*† (22–25 gauge)
	Alternate site: Anterolateral thigh muscle	1–1 1/2" (22–25 gauge)

* A 5/8" needle usually is adequate for neonates (first 28 days of life), preterm infants, and children ages 1 through 18 years if the skin is stretched flat between the thumb and forefinger and the needle is inserted at a 90° angle to the skin.

† A 1 1/2" needle may be used in patients weighing less than 130 lbs (<60 kg) for IM injection in the deltoid muscle only if the skin is stretched tight, the sub-

cutaneous tissue is not bunched, and the injection is made at a 90° angle; a 1" needle is sufficient in patients weighing 130–152 lbs (60–70 kg); a 1 1/2" needle is recommended in women weighing 153–200 lbs (70–90 kg) and men weighing 153–260 lbs (70–118 kg); a 1 1/2" needle is recommended in women weighing more than 200 lbs (91 kg) or men weighing more than 260 lbs (118 kg).



Needle insertion

Use a needle long enough to reach deep into the muscle.

Insert needle at a 90° angle to the skin with a quick thrust.

(Before administering an injection of vaccine, it is not necessary to aspirate, i.e., to pull back on the syringe plunger after needle insertion.†)

Multiple injections given in the same extremity should be separated by a minimum of 1", if possible.

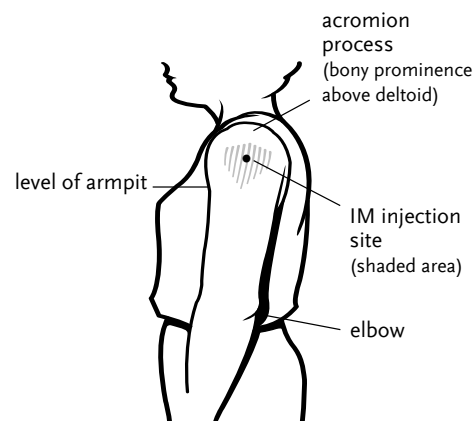
† CDC. "ACIP General Recommendations on Immunization" at www.immunize.org/acip

Intramuscular (IM) injection site for infants and toddlers



Insert needle at a 90° angle into the anterolateral thigh muscle.

Intramuscular (IM) injection site for children and adults



Give in the central and thickest portion of the deltoid muscle – above the level of the armpit and approximately 2–3 fingerbreadths (~2") below the acromion process. See the diagram. To avoid causing an injury, do not inject too high (near the acromion process) or too low.

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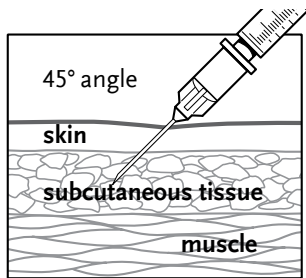
Administration by the Subcutaneous (Subcut) Route

Administer these vaccines via Subcut route

- Measles, mumps, and rubella (MMR)
- Meningococcal polysaccharide (MPSV4)
- Varicella (VAR)
- Zoster (shingles [ZOS])

Administer inactivated polio (IPV) and pneumococcal polysaccharide (PPSV23) vaccines either IM or Subcut.

PATIENT AGE	INJECTION SITE	NEEDLE SIZE
Birth to 12 months	Fatty tissue overlying the anterolateral thigh muscle	5/8" (23–25 gauge)
12 months and older	Fatty tissue overlying the anterolateral thigh muscle or fatty tissue over triceps	5/8" (23–25 gauge)



Needle insertion

Pinch up on subcutaneous tissue to prevent injection into muscle.

Insert needle at 45° angle to the skin.

(Before administering an injection of vaccine, it is not necessary to aspirate, i.e., to pull back on the syringe plunger after needle insertion.*)

Multiple injections given in the same extremity should be separated by a minimum of 1".

* CDC. "ACIP General Recommendations on Immunization" at www.immunize.org/acip

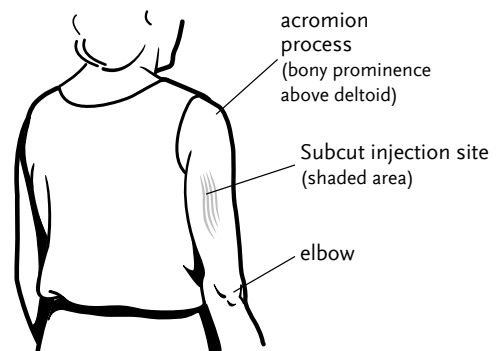
Subcutaneous (Subcut) injection site for infants



Subcut injection site (shaded area)

Insert needle at a 45° angle into fatty tissue of the anterolateral thigh. Make sure you pinch up on subcutaneous tissue to prevent injection into the muscle.

Subcutaneous (Subcut) injection site for children (after the 1st birthday) and adults



Insert needle at a 45° angle into the fatty tissue overlying the triceps muscle. Make sure you pinch up on the subcutaneous tissue to prevent injection into the muscle.

How to Administer Intramuscular and Subcutaneous Vaccine Injections to Adults

Intramuscular (IM) Injections

Administer these vaccines via IM route

- *Haemophilus influenzae* type b (Hib)
- Hepatitis A (HepA)
- Hepatitis B (HepB)
- Human papillomavirus (HPV)
- Influenza vaccine, injectable (IIV)
- Influenza vaccine, recombinant (RIV3)
- Meningococcal conjugate (MCV4)
- Meningococcal serogroup B (MenB)
- Pneumococcal conjugate (PCV13)
- Pneumococcal polysaccharide (PPSV23) – may also be given Subcut
- Polio (IPV) – may also be given Subcut
- Tetanus, diphtheria (Td), or with pertussis (Tdap)

Injection site

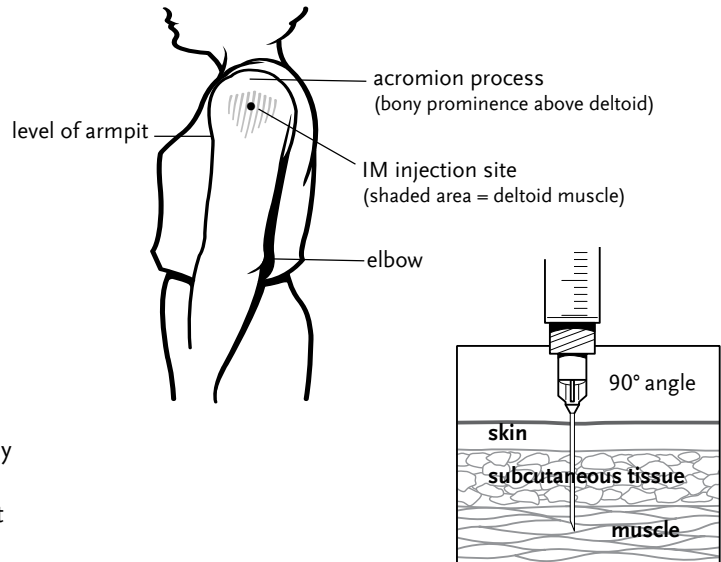
Give in the central and thickest portion of the deltoid muscle – above the level of the armpit and approximately 2–3 fingerbreadths (~2") below the acromion process. *See the diagram.* To avoid causing an injury, do not inject too high (near the acromion process) or too low.

Needle size

22–25 gauge, 1–1½" needle (*see note at right*)

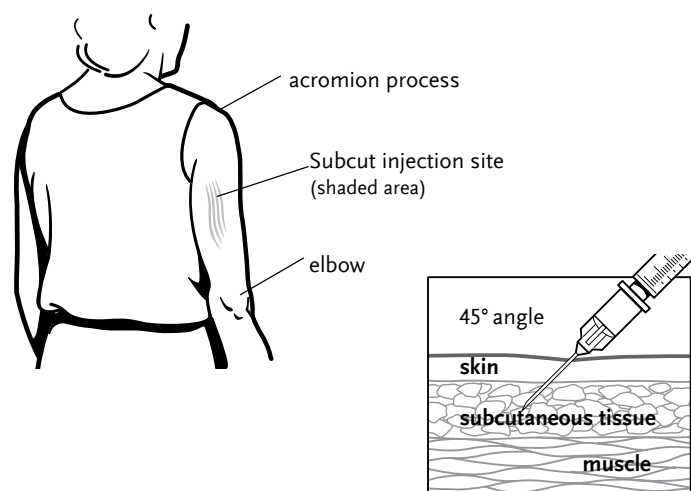
Needle insertion

- Use a needle long enough to reach deep into the muscle.
- Insert the needle at a 90° angle to the skin with a quick thrust.
- Separate two injections given in the same deltoid muscle by a minimum of 1".



Note: A ⅝" needle is sufficient in adults weighing less than 130 lbs (<60 kg) for IM injection in the deltoid muscle **only** if the subcutaneous tissue is not bunched and the injection is made at a 90° angle; a 1" needle is sufficient in adults weighing 130–152 lbs (60–70 kg); a 1–1½" needle is recommended in women weighing 153–200 lbs (70–90 kg) and men weighing 153–260 lbs (70–118 kg); a 1½" needle is recommended in women weighing more than 200 lbs (91 kg) or men weighing more than 260 lbs (more than 118 kg).

Subcutaneous (Subcut) Injections



Administer these vaccines via Subcut route

- Measles, mumps, rubella (MMR)
- Meningococcal polysaccharide (MPSV4)
- Pneumococcal polysaccharide (PPSV23) – may also be given IM
- Polio (IPV) – may also be given IM
- Varicella (Var; chickenpox)
- Zoster (HZV; shingles)

Injection site

Give in fatty tissue over the triceps. *See the diagram.*

Needle size

23–25 gauge, ⅝" needle

Needle insertion

- Pinch up on the tissue to prevent injection into the muscle. Insert the needle at a 45° angle to the skin.
- Separate two injections given in the same area of fatty tissue by a minimum of 1".

Vaccines with Diluents: How to Use Them

Be sure to reconstitute the following vaccines correctly before administering them! Reconstitution means that the lyophilized (freeze-dried) vaccine powder or wafer in one vial must be reconstituted (mixed) with the diluent (liquid) in another.

- Only use the diluent provided by the manufacturer for that vaccine as indicated on the chart.
- ALWAYS check the expiration date on the diluent and vaccine. NEVER use expired diluent or vaccine.

Vaccine product name	Manufacturer	Lyophilized vaccine (powder)	Liquid diluent (may contain vaccine)	Time allowed between reconstitution and use, as stated in package insert*	Diluent storage environment
ActHIB (Hib)	Sanofi Pasteur	Hib	0.4% sodium chloride	24 hrs	Refrigerator
Hiberix (Hib)	GlaxoSmithKline	Hib	0.9% sodium chloride	24 hrs	Refrigerator or room temp
Imovax (RAB _{HDCV})	Sanofi Pasteur	Rabies virus	Sterile water	Immediately†	Refrigerator
M-M-R II (MMR)	Merck	MMR	Sterile water	8 hrs	Refrigerator or room temp
MenHibrix (Hib-MenCY)	GlaxoSmithKline	Hib-MenCY	0.9% sodium chloride	Immediately†	Refrigerator or room temp
Menomune (MPSV4)	Sanofi Pasteur	MPSV4	Distilled water	Single-dose vial: Immediately† Multidose vial: 35 days	Refrigerator
Menveo (MCV4)	Novartis	MenA	MenCWY	8 hrs	Refrigerator
Pentacel (DTaP-IPV/Hib)	Sanofi Pasteur	Hib	DTaP-IPV	Immediately†	Refrigerator
ProQuad (MMRV)	Merck	MMRV	Sterile water	30 min	Refrigerator or room temp
RabAvert (RAB _{PCECV})	Novartis	Rabies virus	Sterile water	Immediately†	Refrigerator
Rotarix (RV1)‡	GlaxoSmithKline	RV1	Sterile water, calcium carbonate, and xanthan	24 hrs	Refrigerator or room temp
Varivax (VAR)	Merck	VAR	Sterile water	30 min	Refrigerator or room temp
YF-VAX (YF)	Sanofi Pasteur	YF	0.9% sodium chloride	60 min	Refrigerator
Zostavax (HZV)	Merck	HZV	Sterile water	30 min	Refrigerator or room temp

Always refer to package inserts for detailed instructions on reconstituting specific vaccines. In general, follow the steps below.

- 1 For single-dose vaccine products (exception is Rotarix[®]), select a syringe and needle of proper length to be used for both reconstitution and administration of the vaccine. Following reconstitution, Menomune in a multidose vial will require a new needle and syringe for each dose of vaccine to be administered. For Rotarix, see the package insert.‡
- 2 Before reconstituting, check labels on both the lyophilized vaccine vial and the diluent to verify that
 - they are the correct two products to mix together,
 - the diluent is the correct volume (especially for Menomune in the multidose vial), and
 - neither the vaccine nor the diluent has expired.

- 3 Reconstitute (i.e., mix) vaccine **just prior to use** by
 - removing the protective caps and wiping each stopper with an alcohol swab,
 - inserting needle of syringe into diluent vial and withdrawing entire contents, and
 - injecting diluent into lyophilized vaccine vial and rotating or agitating to thoroughly dissolve the lyophilized powder.
- 4 Check the appearance of the reconstituted vaccine.
 - Reconstituted vaccine may be used if the color and appearance match the description on the package insert.
 - If there is discoloration, extraneous particulate matter, obvious lack of resuspension, or the

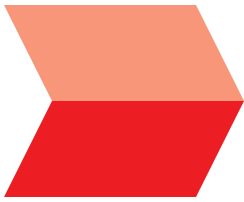
vaccine cannot be thoroughly mixed, mark the vial as “DO NOT USE,” return it to proper storage conditions, and contact your state or local health department immunization program or the vaccine manufacturer.

- 5 If reconstituted vaccine is not used immediately or comes in a multidose vial (i.e., multi-dose Menomune), be sure to
 - clearly mark the vial with the date and time the vaccine was reconstituted,
 - maintain the product at 35°–46°F (2°–8°C); do not freeze, and
 - use only within the time indicated on chart above.

* If the reconstituted vaccine is not used within this time period, it must be discarded.

† For purposes of this guidance, IAC defines “immediately” as within 30 minutes or less.

‡ Rotarix vaccine is administered by mouth using the applicator that contains the diluent. It is not administered as an injection.



5 Immunization Information Systems or Registries

Introduction

In an effort to ensure all pediatric patients receive immunizations at the correct time and only when needed, immunization information systems (IISs), otherwise known as *registries*, have been designed and implemented across the country. All registries offer an opportunity for confidential, secure, centralized, and immediate access to immunization records for authorized users. Some registries also have interoperable capabilities that can communicate with electronic health records (EHR). Other functions of some registries include reminder and recall systems that offices can use to keep their patients up-to-date with vaccinations.

Learning Objectives

On completion of this unit, the health care professional will be able to

- Explain basic components of IISs.
- Verbalize the pros and cons of IISs.
- Identify easily accessible resources concerning IISs.

Please use this text box to add your practice's specific policies on this topic and any other notes you wish to include in your final document.

What Are Immunization Information Systems, and Why Do We Need Them?

Immunization information systems offer health care professionals an opportunity to provide easily accessible, extremely accurate, and completely up-to-date immunization information to patients, parents, and other health care professionals. As described by the Centers for Disease Control and Prevention (CDC), “immunization information systems...are confidential, computerized information systems that attempt to collect vaccination data about all children within a geographic area.... It can provide a single data source for all community immunization partners.” At the population level, IISs provide aggregate data on vaccinations for use in surveillance and program operations, and in guiding public health action with the goals of improving vaccination rates and reducing vaccine-preventable diseases. The American Academy of Pediatrics (AAP) is a strong supporter of IISs to advance immunization coverage, cost-effectiveness, physician payment, quality of care, and integration with EHR systems (see <http://pediatrics.aappublications.org/content/118/3/1293>).

Good research supports the development and refinement of IISs. Every Child by Two states that 21% of children are over-immunized, which means wasted health care costs, and more than 2 million children are under-immunized, leaving themselves and others at risk of vaccine-preventable diseases. Furthermore, as more new immunizations are continually added to recommended schedules and given that parents and patients often overestimate immunization rates, IISs provide an easy means for monitoring immunization status. (For more information, go to the CDC Web site at www.cdc.gov/vaccines/programs/iis/index.html.)

Are There Common Standards for Immunization Information Systems?

The CDC has worked with the American Immunization Registry Association (AIRA) and IIS subject-matter experts to outline functional standards, grouped into 6 goals that an effective IIS should meet. AIRA is a national nonprofit organization whose mission is to “promote the development and implementation of immunization information systems...as an important tool in preventing and controlling vaccine preventable diseases.” Here are the goals and standards. Please visit the AIRA Web site (www.immregistries.org/resources/standards/functional-standards) and the CDC Web site (www.cdc.gov/vaccines/programs/iis/func-stds.html) for more information on functional standards.

1. *Support the delivery of clinical immunization services at the point of immunization administration, regardless of setting.*
 - 1.1 The IIS (immunization information system) provides individual immunization records accessible to authorized users at the point and time where immunization services are being delivered.
 - 1.2 The IIS has an automated function that determines vaccines due, past due, or coming due (“vaccine forecast”) in a manner consistent with current ACIP [Advisory Committee on Immunization Practices] recommendations. Any deficiency is visible to the clinical user each time an individual’s record is viewed.
 - 1.3 The IIS automatically identifies individuals due/past due for immunization(s), to enable the production of reminder/recall notifications from within the IIS itself or from interoperable systems.
 - 1.4 When the IIS receives queries from other health information systems, it can generate an automatic response in accordance with interoperability standards endorsed by CDC (Centers for Disease Control and Prevention) for message content/format and transport.
 - 1.5 The IIS can receive submissions in accordance with interoperability standards endorsed by CDC for message content/format and transport.
2. *Support the activities and requirements for publicly purchased vaccine, including the Vaccines For Children (VFC) and state purchase programs.*
 - 2.1 The IIS has a vaccine inventory function that tracks and decrements inventory at the provider site level according to VFC program requirements.
 - 2.2 The IIS vaccine inventory function is available to direct data entry users and can interoperate with EHR (electronic health record) or other inventory systems.
 - 2.3 The IIS vaccine inventory function automatically decrements as vaccine doses are recorded.
 - 2.4 Eligibility is tracked at the dose level for all doses administered.
 - 2.5 The IIS interfaces with the national vaccine ordering, inventory, and distribution system (currently VTrckS [Vaccine Tracking System]).
 - 2.6 The IIS can provide data and/or produce management reports for VFC and other public vaccine programs.

3. *Maintain data quality (accurate, complete, timely data) on all immunization and demographic information in the IIS.*

- 3.1 The IIS provides consolidated demographic and immunization records for persons of all ages in its geopolitical area, except where prohibited by law, regulation, or policy.
- 3.2 The IIS can regularly evaluate incoming and existing patient records to identify, prevent, and resolve duplicate and fragmented records.
- 3.3 The IIS provides consolidated demographic and immunization records for persons of all ages in its geopolitical area, except where prohibited by law, regulation, or policy.
- 3.4 The IIS can regularly evaluate incoming and existing patient records to identify, prevent, and resolve duplicate and fragmented records.
- 3.5 The IIS can regularly evaluate incoming and existing immunization information to identify, prevent, and resolve duplicate vaccination events.
- 3.6 The IIS can store all IIS Core Data Elements.
- 3.7 The IIS can establish a record in a timely manner from sources such as Vital Records for each newborn child born and residing at the date of birth in its geopolitical area.
- 3.8 The IIS records and makes available all submitted vaccination and/or demographic information in a timely manner.
- 3.9 The IIS documents active/inactive status of individuals at both the provider organization/site and geographic levels.

4. *Preserve the integrity, security, availability, and privacy of all personally identifiable health and demographic data in the IIS.*

- 4.1 The IIS program has written confidentiality and privacy practices and policies based on applicable law or regulation that protect all individuals whose data are contained in the system.
- 4.2 The IIS has user access controls and logging, including distinct credentials for each user, least-privilege access, and routine maintenance of access privileges.
- 4.3 The IIS is operated or hosted on secure hardware and software in accordance with industry standards for protected health information, including standards for security/encryption, uptime, and disaster recovery.

5. *Provide immunization information to all authorized stakeholders.*

- 5.1 The IIS can provide immunization data access to healthcare providers, public health, and other authorized stakeholders (e.g., schools, public programs, payers) according to law, regulation, or policy.
- 5.2 The IIS can generate predefined and/or ad hoc reports (e.g., immunization coverage, vaccine usage, and other important indicators by geographic, demographic, provider, or provider groups) for authorized users without assistance from IIS personnel.
- 5.3 With appropriate levels of authentication, IIS can provide copies of immunization records to individuals or parents/guardians with custodial rights.
- 5.4 The IIS can produce an immunization record acceptable for official purposes (e.g., school, child care, camp).

6. *Promote vaccine safety in public and private provider settings.*

- 6.1 Provide the necessary reports and/or functionality to facilitate vaccine recalls when necessary, including the identification of recipients by vaccine lot, manufacturer, provider, and/or time frame.
- 6.2 Facilitate reporting and/or investigation of adverse events following immunization.

Reproduced from The Centers for Disease Control and Prevention Immunization Information System Functional Standards, 2013-2017. <http://www.cdc.gov/vaccines/programs/iis/func-stds.pdf> Accessed June 6, 2016.

What Information Is Entered Into an Immunization Information System, and How Is It Protected?

In 1995, after initial preparation by the National Center for Immunization and Respiratory Diseases and review by the National Vaccine Advisory Committee (NVAC), a set of core data items to be incorporated in IISs was finalized. Approximately 12 years later, NVAC reviewed those data items and a new set was approved for incorporation.

According to NVAC, the “purpose of the core data element is to facilitate record exchange between IIS[s].” Because of that, a bare minimum set of data must be entered into the system. Other optional information is encouraged but does not have to be entered.

Required core data elements are the patient’s first, middle, and last name; date of birth; sex; race; ethnicity; birth order; birth state and country; and mother’s first, middle, last, and maiden name, as well as vaccine type, vaccine manufacturer, vaccination date, and vaccine lot number.

Examples of optional core data elements include, but are not limited to, the patient's alias, address and phone number, social security number, and father's name, as well as vaccine provider and VFC program eligibility.

Patient confidentiality, information protection, and security are vital to the success of IISs. State laws require that all information entered into an IIS be kept confidential. It is important to remember, however, that immunization records are an exception to the Health Insurance Portability and Accountability Act of 1996 rule because of the public health exception.

Many EHR systems now automatically download immunization data into IISs.

How Do Immunization Information Systems Benefit Patients and Their Families?

The benefits for patients and their families are practical and could potentially be lifesaving. An IIS will

- Provide the most up-to-date immunization records for personal safekeeping, schools, child care, and sports teams.
- Ease parents' minds, knowing that their child is completely and accurately immunized against vaccine-preventable diseases.
- Save time and money by ensuring that patients get only those immunizations that are required at a certain time.

How Do Immunization Information Systems Benefit Health Care Professionals?

The benefits to your practice can be varied and extensive. An IIS will

- Emphasize the medical home concept of pediatrics.
- Save money by maximizing staff time and reducing paperwork.
- Provide easily accessible and extremely reliable information on a patient's immunization status.
- Generate cheap and accurate records for patients, schools, and child care.
- Assist in managing vaccine inventories.
- Assist in immunization recall situations.
- Supply direct information on your practice's immunizations rates, including information required for Healthcare Effectiveness Data and Information Set collection.

Where Can I Find Information About My State's Immunization Information System?

The AAP has a page with information about state registries and Chapter Immunization Representative contact information (www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/immunization/Pages/State-Contacts.aspx).

Furthermore, the CDC has contact information on its "IIS State/Territory/Registry Staff - Main & Technical Contacts" Web page (www.cdc.gov/vaccines/programs/iis/contacts-registry-staff.html).

Specifically, it supplies information concerning IIS legislation throughout the country. Please visit the "Survey of State Immunization Information System Legislation" Web page (www2a.cdc.gov/vaccines/iis/iissurvey/legislation-survey.asp).

Please add information on your state or region's registry and any other notes you wish to include in your final document.

Key Facts

- Immunization information systems or registries assist health care professionals and parents in keeping their patients and children completely and fully immunized by tracking them through a centralized system.
- Immunization information systems or registries are guided by basic principles to protect patients.

Tools and Resources

- Links for additional learning
 - Centers for Disease Control and Prevention (www.cdc.gov)
 - “Immunization Information Systems (IIS)” (www.cdc.gov/vaccines/programs/iis/index.html)
 - *HL7 Version 2.5.1 Implementation Guide for Immunization Messaging* (www.cdc.gov/vaccines/programs/iis/technical-guidance/downloads/hl7guide-1-5-2014-11.pdf)
 - Immunization Information System (IIS) Functional Standards (www.cdc.gov/vaccines/programs/iis/func-stds.html)
 - American Immunization Registry Association (www.immregistries.org/)

6 Provider Prompts and Patient Reminder and Recall Systems

Introduction

Good immunization practices in pediatric offices are important because primary care offices are the most common place for children to receive vaccines. Greater than 70% of children receive their vaccines from pediatricians, and greater than 80% receive vaccines in the private sector. In general, pediatricians are doing a good job delivering routine vaccines, but for many reasons, more than one-fourth of preschool-aged children lack 1 or more routine vaccinations and many adolescents are not completely protected against human papillomavirus (HPV) and meningococcal disease. Systems to remind parents and providers of needed vaccines tend to be effective at increasing coverage.

As you read this section, please keep in mind,

- *Foundational immunization tracking systems.* Both parent reminder and recall systems and provider prompt systems depend on successful immunization tracking systems so patients in need of vaccination can be identified. These range from tickler files to state immunization information systems (IISs), otherwise known as *registries*.
- *All systems are go!* Increasing office immunization rates depends on office personnel's ability to use and fine-tune the systems to meet specific needs of the practice.
- *Assessment.* Pediatricians should assess, "How well am I doing at vaccinating my patients?" Use electronic health record (EHR) system data or contact the local or state health department to request an office assessment of coverage.
- *Information gaps.* Rely on actual immunization records. Parents often do not know their children's vaccination status, and pediatricians sometimes perceive coverage among their patients as higher than it is.
- *Adolescents need extra help.* Reminder and recall and provider prompt systems are especially important for adolescents because compared with babies and toddlers, they are less likely to visit the pediatrician regularly, and adolescent vaccines (eg, HPV, meningococcal) require more than 1 dose.

Learning Objectives

On completion of this unit, the health care professional will be able to

- Formulate a plan for accurately assessing which patients in your office are due or overdue for routinely recommended vaccinations.
- Propose a practical method for reminding clinicians in your setting to order all needed vaccines (provider prompt).
- As applicable, either create a sustainable method for letting parents know their child is due or overdue for routine vaccinations or manage (ie, appraise, improve) the current reminder and recall systems at his or her practice.

Please use this text box to add your practice's specific policies on this topic and any other notes you wish to include in your final document.

Provider Prompt Systems

Provider prompt systems remind clinicians to order needed vaccines. Prompts range from a pop-up message embedded in EHR systems, to a colorful sticker or reminder note in a paper record, to a member of the nursing staff nudging the provider to order all vaccines that are due. Provider prompts may relate only to vaccination or be as comprehensive as a checklist of preventive services, including vaccinations. Provider prompts may decrease the proportion of patients being seen in the office who leave incompletely vaccinated. Here are a few tips on provider prompt systems.

- Reminders to providers should be prominently displayed on the EHR system screen or paper chart.
- Reminders that require some type of acknowledgment (eg, checkmark) are more effective than those that can be ignored without action.
- Providers experiencing “prompt fatigue” may click through the immunization prompt, so only turn on essential EHR system prompts.

Patient Reminder and Recall Systems

Reminder and recall systems identify children and adolescents in need of vaccination and let their parents know to bring them to the physician's office. Reminder systems track appointments needed in the future, whereas recall systems track missed appointments during which vaccines would have been given. Combining reminder and recall systems is a powerful way to ensure optimal vaccination rates. Using reminder and recall systems within a medical home has been shown to improve use of other important clinical services such as lead and vision screening. This makes sense because children and adolescents who are behind on immunizations are at greater risk of being behind on other preventive services. Unfortunately, studies suggest that fewer than 1 in 5 pediatric or multispecialty group practices are using reminder and recall systems.

How to Implement a Patient Reminder and Recall System

For many reminder and recall methods described next, staff must pull a list containing names and relevant contact information of patients who are due or overdue for immunizations. Many state IISs and EHR systems can run such reports easily if immunization records and family contact information are updated at every visit. Building those updates into patient flow is key. In an office that is not computerized, a 3 x 5—in card file system can be used to track dates vaccines were given and due dates for future vaccines. Office personnel can review these cards to determine missed appointments and follow up with parents. The key is to create a system that allows personnel to identify children in need of vaccinations.

Offices use varied reminder systems, detailed below. For examples of how pediatricians can implement reminder and recall systems, refer to the “Immunization: Reminder & Recall Systems” Web page (www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/immunization/Pages/reminder-recall-systems.aspx)

Phone Calls by Office Staff

Staff phone parents (or patients themselves if ≥18 years of age), let them know a vaccination is due, and offer them the opportunity to schedule an appointment. Calls placed by office staff tend to be more effective than autodialer calls, but often cost more.

Autodialers

Autodialers automatically dial phone numbers and either play a recorded message or connect the call to a live person. Such systems can also be used for appointment reminders.

Mail Reminder Cards or Letters (Snail Mail)

Staff send a postcard or letter to the parent or patient reminding him or her that a vaccination is due and offer to schedule an appointment. Your IIS or EHR system may help print these for you. Another approach is to have family fill out the reminder card for the next visit when in your office (eg, fill out a reminder for HPV vaccine dose #2 during the dose #1 visit).

Electronic Reminders (E-mail or Text Message)

Sending reminders via e-mail or text message could be a good way to reach your patients' parents (or adult patients). An automated system could save office staff a lot of time, but even sending one e-mail to a list of blind-copied patients who are due for vaccines would also be a time-saver. These methods have been shown to be effective at increasing immunization coverage in adolescents.

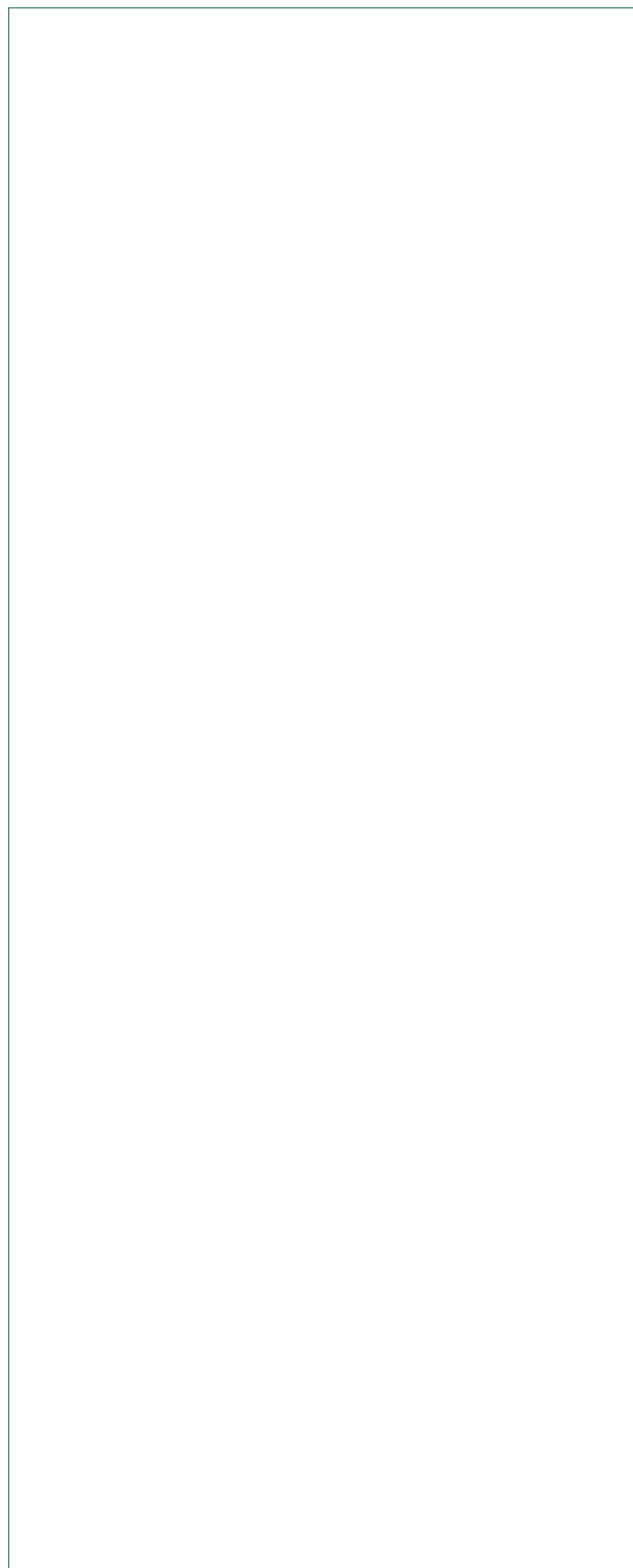
Patient Portals

Many EHR systems come with a patient portal option. Practices can use this feature to send e-mails to patients or parents, prompting them to check their patient portal, which will remind them of vaccinations that are due.

Tiered Approach

The tiered approach to patient reminders has some of the best evidence for effectiveness. Tiered approaches include using multiple approaches and continued attempts to bring the patient into the office. For example, patients who are overdue for a vaccine may receive a letter asking them to visit the office and a call to follow up a few days later. With a tiered approach, this would be repeated about a month later if there were no response.

Please use this text box to add an additional method your practice currently uses or may want to implement or add an image of systems you use or wish to use.



Key Facts

- Provider prompt systems, which remind clinicians to order needed vaccines, range from an EHR system pop-up message, to a message in a paper record, to an in-person nudge to the clinician to order all vaccines that are due.
- Provider prompts may decrease the proportion of patients being seen in the office who leave incompletely vaccinated.
- Reminder and recall systems identify children and adolescents in need of vaccination and let their parents know to bring them to the physician's office.
- Using reminder and recall systems within a medical home has been shown to improve rates of immunization as well as other preventive measures (eg, lead and vision screening).
- Office staff can play a vital role in ensuring that children are vaccinated on time by implementing provider prompts and patient reminder and recall systems.

Tools and Resources

- Links for additional learning
 - American Academy of Pediatrics
 - "Immunization: Reminder & Recall Systems" (www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/immunization/Pages/reminder-recall-systems.aspx)
 - "Office Strategies for Improving Immunization Rates" (www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/immunization/Pages/office-strategies.aspx)
 - The Community Guide Branch; Epidemiology Analysis Program Office; Office of Surveillance, Epidemiology, and Laboratory Services; Centers for Disease Control and Prevention: "Increasing Appropriate Vaccination: Client Reminder and Recall Systems" (www.thecommunityguide.org/vaccines/clientreminder.html)
 - Washington State Department of Health: sample reminder card (<http://here.doh.wa.gov/materials/immunization-reminder-recall-card/?searchterm=reminder%20recall%20card>)
 - Academic Pediatric Association: Szilagyi PG, Serwint JR, Humiston SG, et al. Effect of provider prompts on adolescent immunization rates: a randomized trial. *Acad Pediatr*. 2015;15(2):149-157. [http://www.academicpediatricsjournal.net/article/S1876-2859\(14\)00388-X/abstract](http://www.academicpediatricsjournal.net/article/S1876-2859(14)00388-X/abstract). Accessed May 11, 2016

7 Standards for Child and Adolescent Immunization Practices

Introduction

The American Academy of Pediatrics (AAP) endorses the **Standards for Child and Adolescent Immunization Practices** of the National Vaccine Advisory Committee (NVAC). The standards describe optimal immunization practices (eg, proper storage and administration of vaccines, documentation of vaccinations, implementation of strategies to improve vaccination coverage, effective communication about vaccine benefits and risks) as well as a few health care system goals (eg, immunization services available free or for a minimal fee). The most recent standards are summarized in Box 7-1. In endorsing these standards, the AAP points out these are goals for pediatric practices to work toward. A few of the standards follow, with examples of ways they can be adopted in practice.

Box 7-1. The Standards for Child and Adolescent Immunization Practices

Availability of vaccines

1. Vaccination services are readily available.
2. Vaccinations are coordinated with other health care services and provided in a medical home when possible.
3. Barriers to vaccination are identified and minimized.
4. Patient costs are minimized.

Assessment of vaccination status

5. Health care professionals review the vaccination and health status of patients at every encounter to determine which vaccines are indicated.
6. Health care professionals assess for and follow only medically accepted contraindications.

Effective communication about vaccine benefits and risks

7. Parents/guardians and patients are educated about the benefits and risks of vaccination in a culturally appropriate manner and in easy-to-understand language.

Proper storage and administration of vaccines and documentation of vaccinations

8. Health care professionals follow appropriate procedures for vaccine storage and handling.
9. Up-to-date, written vaccination protocols are accessible at all locations where vaccines are administered.

10. People who administer vaccines and staff who manage or support vaccine administration are knowledgeable and receive ongoing education.
11. Health care professionals simultaneously administer as many indicated vaccine doses as possible.
12. Vaccination records for patients are accurate, complete, and easily accessible.
13. Health care professionals report adverse events after vaccination promptly and accurately to the Vaccine Adverse Events Reporting System (VAERS) and are aware of a separate program, the Vaccine Injury Compensation Program (VICP).
14. All personnel who have contact with patients are appropriately vaccinated.

Implementation of strategies to improve vaccination coverage

15. Systems are used to remind parents/guardians, patients, and health care professionals when vaccinations are due and to recall those who are overdue.
16. Office- or clinic-based patient record reviews and vaccination coverage assessments are performed annually.
17. Health care professionals practice community-based approaches.

Reproduced with permission from National Vaccine Advisory Committee. Standards for Child and Adolescent Immunization Practices. *Pediatrics*. 2003;112(4):958–963.

Learning Objectives

On completion of this unit, the health care professional will be able to

- Appraise his or her practice in light of the standards. (Does the practice adhere to each of the standards?)
- Identify an opportunity for practice improvement and construct a plan for improvement with respect to any of the standards.
- Set 1 or more goals for practice system improvement that are SMART (specific, measurable, achievable, realistic, and time bound).

Professional Policies

Medical practices will set and maintain office procedures and policies that follow and uphold the Standards for Child and Adolescent Immunization Practices.

Please use this text box to add your practice's specific policies on this topic and any other notes you wish to include in your final document.

Implementing the Standards: A Few Examples

Below are a few of the NVAC standards, each with a short vignette illustrating how they can be met in a pediatric practice.

Standard #4: Patient Costs Are Minimized

Dr Kennedy, recently hired to manage Frederick Douglass Pediatrics, finds there is a strict "2 vaccines per visit, maximum" policy for patients of all ages. This has led to delays in protection, but most patients eventually get caught up. Parents must make additional visits, which are associated with additional parent costs for transportation and time off from work. Dr Kennedy discusses the issue with the lead nurse who then gathers information on multiple vaccines and the immune system (www.cdc.gov/vaccinesafety/concerns/multiple-vaccines-immunity.html). She holds nursing staff in-services on the topic and distributes the *Immunization Site Map* (<http://eziz.org/assets/docs/IMM-718.pdf>). Once each staff member is signed off on the competency sheet, she or he starts giving all needed vaccines at a single visit. At the start of each day, problems from the day before are discussed in nursing huddles, but soon the concerns are replaced with relief about the new "one and done" visit approach because patients coming in at 4 and 6 months of age are ready for the next vaccines in the series. (Note that the office's new policy is also concordant with standard #11: health care professionals simultaneously administer as many indicated vaccine doses as possible.)

Standard #5: Health Care Professionals Review the Vaccination and Health Status of Patients at Every Encounter to Determine Which Vaccines Are Indicated

Dr Brayer is doing the immunization module in Education in Quality Improvement for Pediatric Practice for Maintenance of Certification Part 4 credit. She finds that her office has low rates of some adolescent vaccinations. The office manager says that in the last 2 years, greater than 50% of adolescent patients have come in for health maintenance visits, but the team never gives vaccines at other types of visits (eg, acute care, chronic care). Dr Brayer brings the issue to the practice leadership team and they decide to give vaccines at all visit types when indicated. To implement this, the physicians discuss potential barriers and how to address the barriers; mini-teams are tasked with activities designed to prevent snags. Collaboratively, the nursing staff brainstorm potential barriers from their perspective and implement solutions. (Soon after these changes are made to utilize every encounter, the practice leadership decides to use the practice electronic health record system to send recall messages to parents of adolescents behind on vaccinations, which increases adolescent participation in health maintenance visits.)

Standard #7: Parents/Guardians and Patients Are Educated About the Benefits and Risks of Vaccination in a Culturally Appropriate Manner and in Easy-to-Understand Language

Because Dr Chin cares for many patients from minority populations or who have low socioeconomic status, she has become interested in identifying patients' specific health literacy levels and making simple communication adjustments to improve her communication. After reading some introductory material about health literacy (see www.hrsa.gov/publichealth/healthliteracy), Dr Chin decides to focus initially on a few simple techniques.

- Using simple language and short sentences
- Defining technical terms
- Supplementing instruction with appropriate materials (eg, videos, models, pictures)
- Asking patients to explain her instructions (teach back method)
- Asking questions that begin with how and what, rather than closed-ended yes or no questions
- Organizing information so the most important points stand out and repeating this information
- Reflecting the age, cultural, ethnic, and racial diversity of patients
- For patients with limited English proficiency, providing information in their primary language

Dr Chin notes some immediate improvements in the proportion of parents who accept human papillomavirus (HPV) vaccination. She tells her colleagues, *"I used to give parents a long dissertation on HPV, but now I hit the key point: 'I want to give your child HPV vaccine because it prevents cancer!' I make sure my families understand that HPV is not HIV! I never use the term oropharyngeal cancer anymore—no one understands that. I just say, 'HPV vaccine can prevent infection with most HPV types that cause throat and certain other cancers in men.' I have infographics at hand and even a model so girls can see where the cervix is!"*

Standard #10: People Who Administer Vaccines and Staff Who Manage or Support Vaccine Administration Are Knowledgeable and Receive Ongoing Education

During the influenza vaccination season, Mayville Pediatrics does not have enough regular appointments available for all patients who need to be vaccinated. The group provides influenza vaccine-only clinics during daytime hours, in the evening, and on Saturday mornings. The physicians establish standing orders using templates from the Immunization Action Coalition (see www.immunize.org/standing-orders) in accordance with their state laws. To be sure everyone in the office is knowledgeable enough to deliver a quality service and handle parents' questions, all staff members take the AAP PediaLink course on influenza. This course, free to members and nonmembers, can be found by using https://pedialink.aap.org/ped/cme/cme_finder.

Additionally, to prepare for influenza vaccination season, the head nurse

- Gathers attestations from all team members that they themselves are vaccinated against influenza in accordance with the office policy. (See standard 14.)
- Sets up regular reviews of immunization techniques (www.immunize.org/catg.d/p2024.pdf).
- Posts a list of true contraindications (www.immunize.org/catg.d/p3072a.pdf).
- Distributes written screening tools to assess patients' eligibility for the vaccine (www.immunize.org/catg.d/p4066.pdf) and (www.immunize.org/catg.d/p4067.pdf).

Standard #11: Health Care Professionals Simultaneously Administer as Many Indicated Vaccine Doses as Possible

Evan is a 4-year-old boy whose parents have brought him in for a well-child examination for preschool entry. Both parents have come because they remember how hard it was for Evan's 6-year-old brother to have the shots.

- The parents know he is due for diphtheria and tetanus toxoids and acellular pertussis, inactivated polio virus, measles-mumps-rubella, varicella, and influenza vaccines.
- At check-in they learn that Evan needs *Haemophilus influenzae* type b vaccine dose because he did not receive it when he was due as a result of a now-resolved shortage.
- For children aged 14 through 59 months who, like Evan, received an age-appropriate series of 7-valent pneumococcal conjugate vaccine (PCV), a single supplemental dose of 13-valent PCV is now recommended.

Evan's parents ask if it is safe to give so many vaccines at one visit. They are reassured that the immune system will not be used up or overstimulated by these vaccines. Each infant probably has the capacity to respond to about 10,000 vaccines at any one time. See www.chop.edu/centers-programs/vaccine-education-center/vaccine-safety/immune-system-and-health#VvG6GRlrJ3k. The parents are also given a sheet on how to make Evan comfortable after vaccination (www.immunize.org/catg.d/p4015.pdf).

Standard #15: Systems Are Used to Remind Parents/Guardians, Patients, and Health Care Professionals When Vaccinations Are Due and to Recall Those Who Are Overdue

Olivia is a 12-year-old girl. She has not seen her pediatrician for a well-child visit since age 7 years. She has not received any of her adolescent vaccines (tetanus and diphtheria toxoids and acellular pertussis, HPV, quadrivalent meningococcal conjugate, and influenza). Using an established protocol, your office

1. Sends her parents a letter requesting they bring her in for a well-child care check and the recommended vaccinations.
2. No appointment is scheduled, so 2 weeks later a phone call is placed to her home, and a message is left for her parents.

3. One month after the initial letter is sent, a second letter is sent to Olivia's parents with the same request.
4. A week later, your staff are preparing to make a second phone call to Olivia's parents when the mother calls in to schedule an appointment.

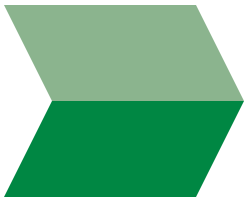
Please use this text box to add your practice's specific policies on this topic and any other notes you wish to include in your final document.

Key Facts

- The NVAC Standards for Child and Adolescent Immunization Practice are goals that physicians and other health care professionals can work to meet.
- The standards describe goals to optimize availability of vaccines, iteratively assess vaccination status, effectively communicate about vaccine benefits and risks, properly store and administer vaccines, accurately and thoroughly document vaccinations, and implement strategies to improve vaccination coverage.

Tools and Resources

- Links for additional learning
 - National Vaccine Advisory Committee. Standards for Child and Adolescent Immunization Practices. *Pediatrics*. 2003;112(4):958–963. <http://pediatrics.aappublications.org/content/112/4/958.full.pdf>. Accessed May 11, 2016 (Log-in required.)



8 Tracking Adverse Events

Post-licensure: Vaccine Adverse Event Reporting System and Vaccine Safety Datalink

Introduction

Two key components of the US federal government efforts to track vaccine adverse events post-licensure are the **Vaccine Adverse Event Reporting System (VAERS)** and **Vaccine Safety Datalink (VSD)**. Cosponsored by the Centers for Disease Control and Prevention (CDC) and US Food and Drug Administration (FDA), “VAERS is a post-marketing safety surveillance program, collecting information about adverse events (possible side effects) that occur after the administration of vaccines licensed for use in the United States.” The VSD is a collaborative effort between the CDC Immunization Safety Office and 9 health care organizations. The VSD team has published many studies to address vaccination-related safety topics such as vaccine preservatives, febrile seizures, and human papillomavirus vaccine. Although quite different, both VAERS and the VSD play an important role in our understanding of vaccine safety.

Learning Objectives

On completion of this unit, the health care professional will be able to

- Discuss the primary objectives of VAERS.
- Describe how to report an adverse event to VAERS.

Please use this text box to add your practice’s specific policies on this topic and any other notes you wish to include in your final document.

The Vaccine Adverse Event Reporting System

Even after an extensive and exhaustive pre-licensure process of verifying that a vaccine is effective and safe, the safety of that vaccine is scrutinized and tracked for years after licensure through VAERS (<http://vaers.hhs.gov>) According to the VAERS Web site (<https://vaers.hhs.gov/about/index>), VAERS primary objectives include

1. Detect new, unusual, or rare vaccine adverse events.
2. Monitor increases in known adverse events.
3. Identify potential patient risk factors for particular types of adverse events.
4. Identify vaccine lots with increased numbers or types of reported adverse events.
5. Assess the safety of newly licensed vaccines.

Who, what, how? Anyone (eg, patient, doctor, vaccine manufacturer, health department personnel) can report an adverse event to VAERS. Any medical event that occurs after vaccine administration should be reported, even if the reporter cannot be sure the vaccine caused the event. The job of VAERS is to assist the medical community in evaluating causation; therefore, the more reports given to the system, the more accurate the results. There are 3 ways to report to VAERS: online, by fax, or by mail. For details, see <https://vaers.hhs.gov/esub/index> Information identifying the person who filed the report and person who received the vaccine are not made public.

Vaccine Adverse Event Reporting System limitations. There are limitations to VAERS. The most common are overreporting and underreporting. For example, shortly after a new vaccine begins to be widely used, VAERS reports for that vaccine are at their highest. Once people become familiar and comfortable with the vaccine, perceptions of adverse events—and consequent VAERS reports—diminish. Similarly, media reports of a specific adverse event after vaccination are often followed by a spike in similar reports; on the basis of VAERS data alone, it is not possible to know if a media report leads to fear-induced overreporting or more thorough and accurate reporting. It is vital to remember that there is no control group with VAERS. That means there is no comparison group when studying the numbers, so special care must be taken when evaluating the meaningfulness of VAERS statistics. As a hypothetical example, imagine that 100 reports came in that children's shoe size enlarged within 6 months of vaccination with a new vaccine. The VAERS data alone do not reflect on the shoe size of unvaccinated children, so VAERS can only generate a hypothesis about vaccination and shoe size.

Vaccine Adverse Event Reporting System value. The VAERS serves us well to generate vaccine safety hypotheses. No practical pre-licensure vaccine safety assessment could be expected to reveal extremely rare adverse events; VAERS increases the likelihood that such issues will be discovered. For example, a VAERS signal about the first-generation

rotavirus vaccine (Rotashield) led to an investigation that revealed the vaccine imposed a small, but increased, risk of intussusception. Consequently, Rotashield was pulled from the market, protecting the public.

The Vaccine Safety Datalink

The VSD project began in 1990 to monitor vaccine safety and address gaps in scientific knowledge about rare and serious adverse events after immunization. The VSD project uses information from 9 health care organizations that includes

- Patients' demographics (eg, date of birth)
- Vaccination details (eg, type of vaccine, simultaneous vaccinations, date of vaccination)
- Medical outcomes (eg, health care use, test results)

This project allows for planned vaccine safety studies as well as timely investigations of hypotheses that develop from review of medical literature, reports to VAERS, changes in immunization schedules, or introduction of new vaccines. The VSD has evolved to provide near real-time post-marketing surveillance and—through data sharing and external input—is increasing vaccine safety transparency.

Key Facts

- In the United States, both VAERS and the VSD are used to track vaccine adverse events post-licensure.
- Anyone with a concern about an adverse event following a vaccination can report to VAERS (see <https://vaers.hhs.gov/esub/index>).
- The VAERS does not define causality between the vaccine and adverse event.
- Patterns in reports to VAERS can be studied and investigated through the VSD.

Tools and Resources

- Links for additional learning
 - Centers for Disease Control and Prevention and US FDA: VAERS (<http://vaers.hhs.gov>)
 - US FDA: "Vaccine Adverse Events" (www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ReportProblem/VaccineAdverseEvents/default.htm)
 - Centers for Disease Control and Prevention: "Vaccine Adverse Event Reporting System (VAERS)" (www.cdc.gov/vaccinesafety/Activities/vaers.html)
 - American Academy of Pediatrics (for more on VSD): Baggs J, Gee J, Lewis E, et al. The Vaccine Safety Datalink: a model for monitoring immunization safety. *Pediatrics*. 2011;127(Suppl 1):S45–S53. http://pediatrics.aappublications.org/content/127/Supplement_1/S45.

9 Vaccine Information Statements

Introduction

Vaccine Information Statements (VISs) are produced by the Centers for Disease Control and Prevention (CDC) as 1-page information sheets. They are designed to inform vaccine recipients and their parents or guardians about the benefits and risks of vaccines. Health care professionals are required by law to hand VISs out before each vaccination.

Learning Objectives

On completion of this unit, the health care professional will be able to

- Explain federal requirements for distributing VISs.
- Develop or maintain policy addressing distribution of VISs.
- Develop or maintain policy addressing updating of VISs in the office.

Professional Policies

It is important your practice have policies addressing distribution of VISs. The responsibilities listed previously may help shape your office policy. Other suggestions include

- Give patients or parents a copy of the VIS to read during the immunization visit and allow them to take it home.
- Give patients or parents the opportunity to ask questions.
- Give patients or parents a copy of the VIS at the visit before the immunization visit, or instruct them to download the VIS so they can read it ahead of time (in this case, you may still want to provide a VIS at the time of the immunization visit).
- Allow patients or parents to view a permanent copy of the VIS during the visit (eg, laminated, electronic copy on an examination room computer).
- Always encourage patients or parents to take a copy of the VIS with them and keep them so they can recognize and report an adverse event.
- Supplement VISs with additional information whenever possible.
- Always include distribution of VISs in the patient record. Include
 - Edition date of the VIS (found on the back in either lower corner)
 - Date the VIS was provided
 - Name, address, and title of health care professional who administered the vaccine
 - Date the vaccine is administered
 - Vaccine manufacturer and lot number

Please use this text box to add your practice's specific policies on this topic and any other notes you wish to include in your final document.

About Vaccine Information Statements

The law stating that health care professionals must hand out VISs is from the National Childhood Vaccine Injury Act of 1986. Regardless of whether a vaccine being administered was bought privately or through the Vaccines for Children program, a VIS must be given out in all circumstances.

The CDC lists the following provider responsibilities with regard to VIS distribution:

- Providers must give the appropriate VIS to the recipient or recipient's parent or legal representative with each dose of vaccine.
- Providers must give it before administration of the vaccine.
- Providers must give it each time vaccine is given (not just with the first dose).
- Providers must record certain information in the patient's permanent medical record.

Altering Vaccine Information Statements

Providers may add a practice name, address, or phone number to an existing VIS. They should also add the date if it is cut off during downloading. Providers should never change a VIS or create their own. The law requires providers to use those developed by the CDC.

Some states may require the addition of information about inclusion in the state's registry to the VIS form. Check with your local American Academy of Pediatrics chapter for more details.

Key Facts

- Always provide a VIS when a vaccination is administered; it is required by law.
- Never change or create your own VIS.

Tools and Resources

- Links for additional learning
 - Centers for Disease Control and Prevention (www.cdc.gov)
 - Fact sheet for Vaccine Information Statements (www.cdc.gov/vaccines/pubs/vis/vis-facts.htm)
 - "Vaccine Information Statements (VIS)" (www.cdc.gov/vaccines/pubs/vis/default.htm)
 - Immunization Action Coalition (www.immunize.org) "Vaccine Information Statements" (www.immunize.org/vis)
- Document you may include in your personalized manual (included below. Acquired with permission from <http://www.immunize.org/catg.d/p2027.pdf> on June 16, 2016. We thank the Immunization Action Coalition.)
- Immunization Action Coalition: *It's Federal Law!* (www.immunize.org/catg.d/p2027.pdf)

It's Federal Law! You must give your patients current Vaccine Information Statements (VISs)

What are Vaccine Information Statements (VISs)?

Vaccine Information Statements (VISs) are documents produced by the Centers for Disease Control and Prevention (CDC), in consultation with panels of experts and parents, to properly inform vaccinees (or their parents/legal representatives) about the risks and benefits of each vaccine. VISs are not meant to replace interactions with health care providers, who should address any questions or concerns that the vaccinee (or parent/legal representative) may have.

Using VISs is legally required!

Federal law (under the National Childhood Vaccine Injury Act) requires a health care provider to give a copy of the current VIS to an adult patient or to a child's parent/legal representative before vaccinating an adult or child with a dose of the following vaccines: diphtheria, tetanus, pertussis, measles, mumps, rubella, polio, hepatitis A, hepatitis B, *Haemophilus influenzae* type b (Hib), influenza, pneumococcal conjugate, meningococcal, rotavirus, human papillomavirus (HPV), or varicella (chickenpox only).

Where to get VISs

All available VISs can be downloaded from the websites of the Immunization Action Coalition at www.immunize.org/vis or CDC at www.cdc.gov/vaccines/hcp/vis/index.html. Ready-to-copy versions may also be available from your state or local health department.

Translations: You can find VISs in more than 30 languages on the Immunization Action Coalition website at www.immunize.org/vis.

To obtain translations of VIS in languages other than English, go to www.immunize.org/vis.

According to CDC, the appropriate VIS must be given:

- Prior to the vaccination (and prior to each dose of a multi-dose series);
- Regardless of the age of the vaccinee;
- Regardless of whether the vaccine is given in a public or private health care setting.

Top 10 Facts About VISs

FACT 1 It's federal law! You must give current VISs to all your patients before vaccinating them.

Federal law requires that VISs must be used for patients of **ALL** ages when administering these vaccines:

- DTaP (includes DT)
- Td and Tdap
- Hib
- hepatitis A
- hepatitis B
- HPV
- influenza (inactivated and live, intranasal vaccines)
- MMR and MMRV
- meningococcal
- pneumococcal conjugate
- polio
- rotavirus
- varicella (chickenpox)

For the vaccines not covered under the National Childhood Vaccine Injury Act (i.e., adenovirus, anthrax, Japanese encephalitis, pneumococcal polysaccharide, rabies, shingles, typhoid, and yellow fever), providers are not required by federal law to use VISs unless they have been purchased under CDC contract. However, CDC recommends that VISs be used whenever these vaccines are given.

FACT 2 VISs can be given to patients in a variety of ways.

In most medical settings, VISs are provided to patients (or their parents/legal representatives) in paper form. However, VISs also may be provided using electronic media. Regardless of the format used, the goal is to provide a current VIS just prior to vaccination.

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Most current versions of VISs (table)

As of April 18, 2016, the most recent versions of the VISs are as follows:

Adenovirus	6/11/14	MMR	4/20/12
Anthrax	3/10/10	MMRV	5/21/10
Chickenpox	3/13/08	Multi-vaccine	11/5/15
DTaP	5/17/07	PCV13	11/5/15
Hib	4/2/15	PPSV	4/24/15
Hepatitis A	10/25/11	Polio	11/8/11
Hepatitis B	2/2/12	Rabies	10/6/09
HPV-Cervarix	5/3/11	Rotavirus	4/15/15
HPV-Gardasil	5/17/13	Shingles	10/6/09
HPV-Gardasil 9	3/31/16	Td	2/24/15
Influenza	8/7/15	Tdap	2/24/15
Japanese enceph	1/24/14	Typhoid	5/29/12
MCV4/MPSV4	3/31/16	Yellow fever	3/30/11
MenB	8/14/15		

A handy list of current VIS dates is also available at www.immunize.org/catg.d/p2029.pdf.

(For information on special circumstances involving vaccination of a child when a parent/legal representative is not available at the time of vaccination, see CDC's *Frequently Asked Questions* at www.cdc.gov/vaccines/hcp/vis/about/vis-faqs.html.)

Prior to vaccination, VIS may be:

- Provided as a paper copy
- Offered on a permanent, laminated office copy
- Downloaded by the vaccinee (parent/legal representative) to a smartphone or other electronic device (VISs have been specially formatted for this purpose)
- Made available to be read before the office visit, e.g., by giving the patient or parent a copy to take home during a prior visit, or telling them how to download or view a copy from the Internet. These patients must still be offered a copy in one of the formats described previously to read during the immunization visit, as a reminder.

Regardless of the way the patient is given the VIS to read, providers must still offer a copy (which can be an electronic copy) of each appropriate VIS to take home following the vaccination. However, the vaccinee may decline.

FACT 3 VISs are required in both public and private sector health care settings.

Federal law requires the use of VISs in both public and private sector settings, regardless of the source of payment for the vaccine.

FACT 4 You must provide a current VIS *before* a vaccine is administered to the patient.

A VIS provides information about the disease and the vaccine and must be given to the patient **before** a vaccine is administered. It is also acceptable to hand out the VIS well before administering vaccines (e.g., at a prenatal visit or at birth for vaccines an infant will receive during infancy), as long as you still provide a current VIS right before administering vaccines.

FACT 5 You must provide a current VIS for *each* dose of vaccine you administer.

The most current VIS must be provided before **each dose** of vaccine is given, including vaccines given as a series of doses. For example, if 5 doses of a single vaccine are required (e.g., DTaP), the patient (parent/legal representative) must have the opportunity to read the information on the VIS before each dose is given.

FACT 6 You must provide VISs whenever you administer combination vaccines.

If you administer a combination vaccine that does not have a stand-alone VIS (e.g., Kinrix, Quadracel, Pediarix, Pentacel, Twinrix) you should provide the patient with individual VISs for the component vaccines, or use the Multi-Vaccine VIS (see below).

The Multi-Vaccine VIS may be used in place of the individual VISs for DTaP, Hib, hepatitis B, polio, and pneumococcal when two or more of these vaccines are administered during the same visit. It may be used for infants as well as children through 6 years of age. The Multi-Vaccine VIS should not be used for adolescents or adults.

FACT 7 VISs should be given in a language/format that the recipient can understand, whenever possible.

For patients who don't read or speak English, the law requires that providers ensure all patients (parent/legal representatives) receive a VIS, regardless of their ability to read English. To obtain VISs in more than 30 languages, visit the Immunization Action Coalition website at www.immunize.org/vis. Providers can supplement VISs with visual presentations or oral explanations as needed.

FACT 8 Federal law does not require signed consent in order for a person to be vaccinated.

Signed consent is not required by federal law for vaccination (although some states may require it).

FACT 9 To verify that a VIS was given, providers must record in the patient's medical record (or permanent office log or file) the following information:

- The edition date of the VIS (found on the back at the right bottom corner)
- The date the VIS is provided (i.e., the date of the visit when the vaccine is administered)

In addition, providers must record:

- The office address and name and title of the person who administers the vaccine
- The date the vaccine is administered
- The vaccine manufacturer and lot number

FACT 10 VISs should not be altered before giving them to patients, but you can add some information.

Providers should not change a VIS or write their own VISs. However, it is permissible to add a practice's name, address, and contact information to an existing VIS.

Additional resources on VISs and their use are available from the following organizations:

Immunization Action Coalition

- VIS general information and translations in more than 30 languages: www.immunize.org/vis
- Current Dates of Vaccine Information Statements: www.immunize.org/catg.d/p2029.pdf

Centers for Disease Control and Prevention

- VIS website: www.cdc.gov/vaccines/hcp/vis
- VIS Facts: www.cdc.gov/vaccines/hcp/vis/about/facts-vis.html
- VIS FAQs: www.cdc.gov/vaccines/hcp/vis/about/vis-faqs.html