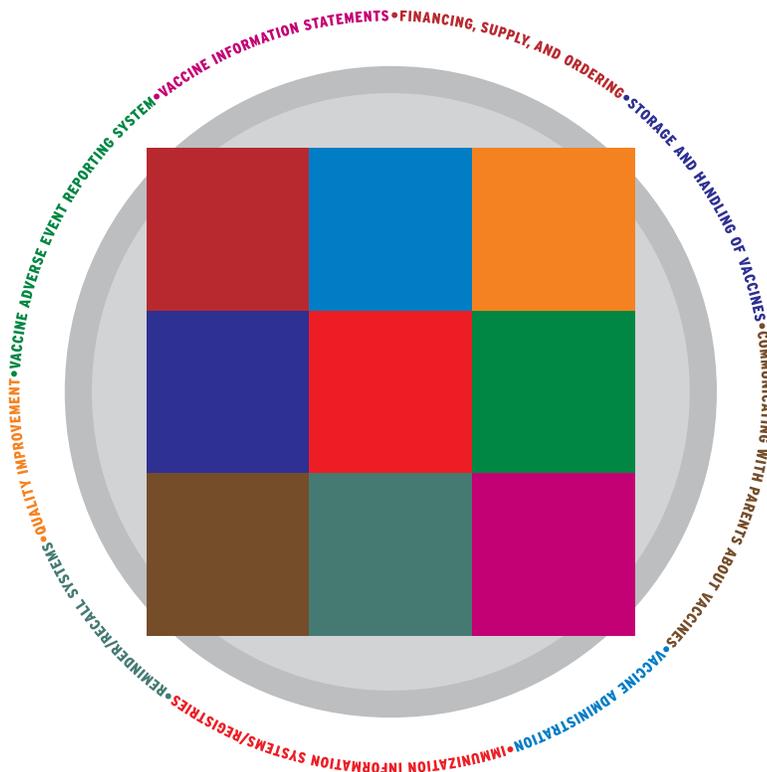


Immunization Training Guide & Practice Procedure Manual

For Pediatricians, Physicians, Nurse Practitioners,
Physician Assistants, Nurses, Medical Assistants,
and Office Managers



American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN™



Immunization Training Guide & Practice Procedure Manual

For Pediatricians, Physicians, Nurse Practitioners, Physician Assistants, 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. These notes will be included when the guide is printed. Any resources or sections of content that you wish to exclude from your customizable practice procedure manual can be deleted once the guide has been printed.

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Topics

-  **Financing, Supply, and Ordering**
-  **Storage and Handling of Vaccines**
-  **Communicating With Parents About Vaccines**
-  **Vaccine Administration**
-  **Immunization Information Systems/Registries**
-  **Reminder/Recall Systems**
-  **Quality Improvement**
-  **Vaccine Adverse Event Reporting System**
-  **Vaccine Information Statements**

Index of Acronyms and Terms

Acronyms

AIRA: American Immunization Registry Association
 ASP: average sales price
 AWP: average wholesale price
 CDC: Centers for Disease Control and Prevention
 FDA: Food and Drug Administration
 GPO: group purchasing organization
 HIPAA: Health Insurance Portability and Accountability Act of 1996
 IIS: immunization information system
 NVAC: National Vaccine Advisory Committee
 PBG: physician buying group
 VAERS: Vaccine Adverse Event Reporting System
 VFC: Vaccines for Children
 VICP: National Vaccine Injury Compensation Program
 VIS: Vaccine Information Statement
 VSD: Vaccine Safety Datalink

Vaccines

- DT, Td: diphtheria/tetanus, pediatric, or tetanus/diphtheria toxoid, adult
- DTaP, Tdap: diphtheria, tetanus, acellular pertussis combinations
- Hep A, Hep B, Hep A-Hep B: 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
- TIV: trivalent inactivated influenza vaccine
- 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 (IM): 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 before receiving payment for them. During this time money is tied up and unavailable for other purchases or investment.

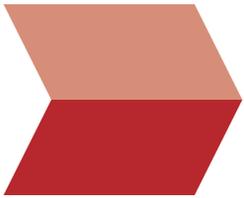
Subcutaneous (SQ): needle inserted just under the skin. Vaccine can then be delivered into subcutaneous tissues.

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 that 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 (HPV).
- Use reminder/recall systems. Immunization reminder/recall systems are cost-effective methods to identify and notify families whose children are due soon for immunizations (reminder) or are already behind (recall). Reminder/recall systems are powerful ways to ensure optimal vaccination 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.



Financing, Supply, and Ordering

Introduction

Administering vaccines in pediatric practices is about providing a critical service to patients while making a reasonable contribution to your office overhead. Many practice administrators are forced to decide between staying in business and asking their patients to obtain vaccine protection elsewhere or giving vaccinations at a loss and risk going out of business. Fortunately, it does not have to be this way. With a basic understanding of the financial aspects of immunizations, including supply maintenance and ordering, practices can protect their patients, sustain appropriate profits, and continue their practice mission of helping children stay healthy.

Learning Objectives

On completion of this unit, the health 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, vaccine administration, and vaccine refusal.
- Begin to determine the immunization supply needs of their practice and order according to those needs.

Professional Policies

- American Academy of Pediatrics (AAP) Task Force on Immunization: "Immunization Financing: Where is the Breaking Point?" (www.aap.org/immunization/pediatricians/pdf/TaskForceWhitePaper.pdf)

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 avenues to ordering vaccines for your practice. It is vital to understand the pros and cons of each to maximize cost benefits to your practice.

1. *Standard programs.* Direct purchasing access is offered by all major vaccine manufacturers. Although these programs offer easy access, there can be large fluctuations in pricing depending on market competitiveness. Some specific benefits of participating in standard programs are prompt pay discounts (if payment is received in a certain amount of time, usually 60 to 90 days), Web site ordering discounts, and promotional sales.
2. *Physician buying groups (PBGs).* These offer group access to 1 or 2 major vaccine manufacturers. Competing vaccine companies will not be in a PBG together. For example, because Sanofi Pasteur and GlaxoSmithKline produce similar vaccines and are in direct competition with each other, they will not be paired in the same PBG. This will directly limit your ability to buy certain vaccines. Furthermore, if you do purchase vaccines outside of the PBG, a practice may be removed from that specific PBG. A major benefit of the PBG model is discounts—the purchaser may receive up-front discounts based on contractual language or quarterly rebates based on utilization.
3. *Group purchasing organizations (GPOs).* These are typically operated by hospital-affiliated purchasing groups. Although pricing models are not as favorable as in PBGs, purchasers are not limited to certain vaccine manufacturers or products. For more information on GPOs, please visit the AAP Practice Support pages (<http://practice.aap.org>).

No matter what model a purchaser uses to order vaccines, it is vital that the purchaser ask appropriate questions of the practice itself and the ordering group. Those questions should include the following:

- Which manufacturer(s) are included in the program? Under what circumstances can I purchase outside the plan? What are the purchasing compliance requirements?
 - Based on this contract, how will my usual vaccine regimen be affected? Would I need to start administering different vaccines? How will this affect office education or nurses' time?
 - If I have to change an order, is the change worth it? Is there another option with similar pricing that would allow me to order what I currently use?
- Is there a cost to participate? What is the length of my contract commitment? Does this plan provide rebates to its participants?
- Is pricing tied to volume? Do all participants have the same terms?
 - How do these discounts compare with my current pricing?
 - Does placing large- or small-volume orders allow me to receive the optimal discount?

- How frequently am I allowed to order? What is the process to order vaccines? Is a code needed to order online? Is there an administrator to call?
- Can the practice order whenever it wants? Is there a limit to how many orders can be placed in a given time? What is the process for ordering (eg, phone, online)?
- Can I take advantage of additional manufacturer discounts through this program?
- Can I reduce my practice's time and resources spent on ordering vaccines so that maximum discounts are still achieved? Does 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 supply assistance? How long has the plan been in business, and how many doctors does it work with? (You can also ask your manufacturer representatives for their views of the program.)
- Are there geographic limitations to participation?
- What value-added services (eg, payment support) does the plan provide?

Borrowed and adapted from American Academy of Pediatrics PediaLink course, Immunizations: Best Business Practices

Vaccine Pricing

Most organizations base their purchase price of a vaccine on 1 of 2 models: average sales price (ASP) or average wholesale price (AWP).

AWP is the national average price assigned to a vaccine or drug by its manufacturer and is compiled by various vendors, such as Thomson Reuters' Red Book (which is different from the AAP Red Book®), First Databank, and Medi-Span, for use by carriers. In general, AWP is the cost of the vaccine plus (depending on the vendor) a 20% to 25% markup and excise tax. Carriers will purchase AWP calculations from one of these vendors. Following is a chart showing AWP calculations by vendor:

| Vendor | Average Wholesale Price Calculation |
|---------------------------------|-------------------------------------|
| Thomson Reuters <i>Red Book</i> | List price x 1.20 plus excise tax |
| First DataBank | List price x 1.25 plus excise tax |
| Medi-Span | List price x 1.25 plus excise tax |

The AWP for a particular vaccine can be obtained by contacting the vaccine manufacturer. In reviewing carrier vaccine payments, identify how the carrier determines AWP (ie, which vendor is used and how frequently AWP is updated).

ASP is based on quarterly sales reports by manufacturers to the Centers for Medicare & Medicaid Services (CMS) on the sale prices of vaccines sold for that period. For Medicare, vaccine payments are made at 106% of the ASP. In general, ASP is usually less than AWP because it reflects all sales of the vaccine, including volume discounts. Many pediatric vaccines

do not have an ASP determined; therefore, any insurance companies that use ASP for determining payments for vaccines must have another method to calculate how much to pay for vaccines pediatricians administer.

ASP data are updated quarterly. Depending on the vendor, AWP data are updated monthly or quarterly. In addition, there is a time lag (ranging from 1 to 3 months) for carriers to update their claims systems, and not all carriers update their systems quarterly.

Because of vendor licensing agreements, there are restrictions on how AWP data can be exchanged (eg, posting lists of AWP on Web sites). Unlike ASP, which is collected by the federal government through the CMS, AWP is proprietary data of vendors. In lieu of purchasing AWP listings from vendors, vaccine manufacturers have established payment support programs that physician practices can call to obtain AWP information.

- Sanofi Pasteur: 800/822-2463
- GlaxoSmithKline: 866/475-8222
- Merck: 800/734-6282
- MedImmune: 800/949-3789
- Pfizer: 800/666-7248

To obtain current ASP data, log onto www.cms.gov/McrPartBDrugAvgSalesPrice/01_overview.asp.

For new vaccines on the market that have not yet had AWP or ASP calculated, pediatricians need to check with their carrier(s) to see how vaccine payments will be calculated. Some carriers may base payment on a percentage of billed charges. The AAP has developed "Vaccine Addendum to Payer Contracts" to address this situation and provide guidance when negotiating for vaccine payments. This document is available on the AAP Practice Support site at <http://www.aap.org/en-us/my-aap/Documents/VaccineAddendumtoPayerContracts.pdf> (login required).

More and more, however, the trend is to encourage payers and pediatricians to use the Centers for Disease Control and Prevention (CDC) Price List to gauge immunization costs. This list is nationally representative and does not include average costs. Bottom line, it is the most accurate assessment of immunization price. More information can be found at <http://www.cdc.gov/vaccines/programs/vfc/awardees/vaccine-management/price-list/index.html>.

Overhead Costs When Providing Immunizations

When calculating the total cost of providing a vaccine to a patient, one must factor in multiple facets. Those facets include purchasing, storing, and administering the vaccine. Following is a detailed explanation of the various types of overhead affecting a practice:

Every vaccine has a list price advertised by the manufacturer. But it is common to pay significantly above or even below this price for vaccines.

Excise tax is determined by the federal government and is set at \$0.75 per vaccine component. Thus, a single-component vaccine, such as hepatitis B, has a tax of \$0.75, whereas a multicomponent vaccine, such as measles, mumps, rubella, has a tax of $\$0.75 \times 3$, or \$2.25. You have no control over this cost. The purpose of this tax is to fund the National Vaccine Injury Compensation Program (VICP), which plays a critical role in protecting vaccine manufacturers and, to a lesser extent, protecting your practice from litigation related to alleged injuries from vaccines.

Sales tax is determined by local government and is not a cost that can be controlled.

Staff time for

- **Ordering vaccines and managing inventory**
The major component of this cost is personnel. Choose the lowest-paid employee qualified to perform these tasks. Train selected personnel to correctly manage inventory. Having too much inventory on hand can increase opportunity cost, create cash flow problems, and increase inventory insurance costs. Stock too little inventory and you may run out of a vaccine, thus creating the administrative hassles of return visits by patients, inconveniencing patients, and adversely affecting the image of the office.
- **Negotiating prices**
Minimal time is needed for this cost component, but staff time will be used when researching physician buying groups or group purchasing organizations and while periodically reviewing the marketplace for better deals.
- **Billing and collections activity**
Again, personnel choice is very important. Having an effective billing department 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. Initially, this may mean spending more time on billing, but the time investment often translates into large increases in revenue. An in-depth discussion of this topic is beyond the scope of this module, but it is important to note that costs associated with staff time remain one of the biggest contributors to vaccine administration overhead.

Storage (eg, purchase of refrigerator, freezer, generator)

Quality and reliability are important when it comes to storing vaccines (one of your highest-priced hard assets). Buy quality equipment; remember that equipment costs will be allocated among thousands of vaccine doses and will minimally affect per-dose overhead.

Insurance on Vaccine Inventory

Purchasing insurance for your vaccine inventory is critical and prudent. If an office refrigerator malfunctions, your practice could suffer without insurance coverage. The insurance is not very expensive and 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 purchased before you administer them and before you receive payment for them. During this time your money is tied up and unavailable for other purchases or investment.

There are many ways to mitigate opportunity cost. There are 3 periods over which you have some control: the time between ordering vaccines and administration, the time between ordering vaccines and paying for them, and the time between administering vaccines and receiving payment.

- Period 1: Control inventory by minimizing the time you have to hold vaccines before administration. Time spent assessing inventory needs will help optimize the finances of this period. Balance the risk of supply shortfall with quantity pricing.
- Period 2: Delay paying for vaccines after ordering. One obvious way is to charge the purchase to a credit card; the charge account balance won't be due for 20 to 30 days. If you have a rebate or miles card, you can receive cash back or rewards. Another way to delay payment is to negotiate billing dates with vaccine manufacturers. Make sure you do not lose any prompt-payment discounts in the process, because these can be substantial.
- Period 3: The time between vaccine administration and payment receipt is probably the most difficult to control but remains important. Your accountant can provide you with the average number of days you wait before receiving payment on a claim. If it is more than 50 days, you are not receiving payment in a timely manner. Your goal should be to receive payment within 30 to 45 days (or fewer). A detailed discussion of decreasing accounts receivable days is beyond the scope of this module, but note that prompt electronic submittal of claims that have been carefully review 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 doctors 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 that 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.

Borrowed and adapted from American Academy of Pediatrics PediaLink module, Immunizations: Best Business Practices

Practices must pay special attention to wastage. Although many people think that this is not a huge factor in overhead, it is. That false thinking 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, your practice decides to purchase and administer it. To be sure you receive appropriate payment, you charge \$300. 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 in actuality, you 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 \div 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 ever lose money administering immunizations to patients.

Proper coding is the key to correct payment. Each vaccine has an individual *International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-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 (<http://www2.aap.org/immunization/pediatricians/pdf/VaccineCodingTable.pdf>) for a list of all *ICD-9-CM* and *Current Procedural Terminology (CPT®)* codes required for administering vaccines.

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 <http://www2.aap.org/immunization/pediatricians/pdf/AAPPositionPaper99211.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.

Insert your practice's specific immunization schedule 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.

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

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:
 - CDC: Current Vaccine Shortages & Delays
(www.cdc.gov/vaccines/vac-gen/shortages/default.htm)
 - Pediatric/VFC Vaccine Price List
(<http://www.cdc.gov/vaccines/programs/vfc/awardees/vaccine-management/price-list/index.html>)
 - Vaccine Purchasing Groups
(<https://www2.aap.org/immunization/pediatricians/GPO.html>)
- Documents you may include in your personalized manual (included below):
 - AAP Position Paper 99211
(<http://www2.aap.org/immunization/pediatricians/pdf/AAPPositionPaper99211.pdf>).
 - *Red Book*® Online Vaccine Status Table
(<http://aapredbook.aappublications.org/site/news/vaccstatus.pdf>)
 - Commonly Administered Pediatric Vaccines table
(<http://www2.aap.org/immunization/pediatricians/pdf/VaccineCodingTable.pdf>)

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This document was originally prepared for American Academy of Pediatrics (AAP) members on the AAP Member Center web site (<http://www.aap.org/moc>).

When Is it Appropriate to Report 99211 During Immunization Administration?

American Academy of Pediatrics Committee on Coding and Nomenclature

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**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.  
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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?

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 | 2011 Medicare Non-Facility Payment |
|---------------|-----------|------------------------------------|------------------|-------------------------|------------------------------------|
| 90460‡ | 0.17 | 0.50 | 0.01 | 0.68 | \$17.35* |
| 90461‡ | 0.15 | 0.18 | 0.01 | 0.34 | \$8.68 |
| 90471 | 0.17 | 0.50 | 0.01 | 0.68 | \$17.35 |
| 90472 | 0.15 | 0.18 | 0.01 | 0.34 | \$8.68 |
| 90473 | 0.17 | 0.50 | 0.01 | 0.68 | \$17.35 |
| 90474 | 0.15 | 0.18 | 0.01 | 0.34 | \$8.68 |

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 2011 conversion factor = \$25.5217

0.68 RVUs x \$25.5217 = \$17.35

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 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, Ninth Revision, Clinical Modification (ICD-9-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.”

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-9-CM

786.2 (cough)

V04.81 (need for prophylactic vaccination and inoculation against certain viral diseases; influenza)

V04.81 (need for prophylactic vaccination and inoculation against certain viral diseases; influenza)

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 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-9-CM

V06.4 (*need for prophylactic vaccination and inoculation against combinations of diseases; measles-mumps-rubella [MMR]*)

V06.4 (*need for prophylactic vaccination and inoculation against combinations of diseases; measles-mumps-rubella [MMR]*)

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-9-CM

V67.59 (*follow-up examination; following other treatment; other*)

V05.3 (*need for other prophylactic vaccination and inoculation against single diseases; viral hepatitis*)

V05.3 (*need for other prophylactic vaccination and inoculation against single diseases; viral hepatitis*)

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 “V” ICD-9-CM code. Neither CPT nor ICD-9-CM guidelines* prohibit such reporting when the ICD-9-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 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 “V” ICD-9-CM codes with anything other than Preventive Medicine Services CPT codes are inconsistent with CPT and ICD-9-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 “V” codes or any other ICD-9-CM codes that most appropriately reflect the reason for the encounter with the Office or Other Outpatient Services codes.

*International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) *Official Guidelines For Coding and Reporting*

C. Chapter-Specific Coding Guidelines

C18. Classification of Factors Influencing Health Status and Contact with Health Service

A. ICD-9-CM provides codes to deal with encounters for circumstances other than a disease or injury. The Supplementary Classification of Factors Influencing Health Status and Contact with Health Services (V01.0 - V83.89) is provided to deal with occasions when circumstances other than a disease or injury (codes 001-999) are recorded as a diagnosis or problem. There are four primary circumstances for the use of V codes, including:

- 1. When a person who is not currently sick encounters the health services for some specific reason, such as to act as an organ donor, to receive prophylactic care, such as inoculations or health screenings, or to receive counseling on health related issue.*

D. Categories of V Codes

- 2. Inoculations and vaccinations: Categories V03-V06 are for encounters for inoculations and vaccinations. They indicate that a patient is being seen to receive a prophylactic inoculation against a disease. The injection itself must be represented by the appropriate procedure code. A code from V03-V06 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.

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/rr6002a1.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*** |
|---|---------------------|---------------|--|---|--|
| Herpes zoster vaccine (ZOSTAVAX®) | Merck | Spring 2005 | Greater than or equal to 60 years of age | May 2006 | CDC: cdc.gov/mmwr/preview/mmwrhtml/rr57e0515a1.htm |
| | | sBLA Mar 2011 | 50 through 59 years of age | Mar 2011 | Pending review |
| Influenza vaccines | several | Varies | See Influenza Vaccine Table | varies | AAP: pediatrics.aappublications.org/content/130/4/780.full CDC 2013-14: cdc.gov/mmwr/preview/mmwrhtml/mm6218a3.htm CDC Seasonal: cdc.gov/flu <i>Red Book Online</i> Influenza Resource Page: aapredbook.org/site/flu |
| Japanese Encephalitis (IXIARO®) | Novartis | Dec 2007 | Greater than or equal to 17 years of age | Mar 2009 | CDC: cdc.gov/mmwr/preview/mmwrhtml/rr5901a1.htm May 2011 Update: cdc.gov/mmwr/preview/mmwrhtml/mm6020a6.htm |
| | | | Booster dose | Sep 2011 | CDC: cdc.gov/mmwr/preview/mmwrhtml/mm6020a5.htm |
| | | Jul 2012 | 1 through 16 years of age | To be reviewed | Pending review |
| MCV4 (Menactra®) | Sanofi Pasteur | Dec 2003 | Routine: 11 through 21 years of age | Jan 2005 | AAP: pediatrics.aappublications.org/content/128/6/1213.full CDC: cdc.gov/mmwr/preview/mmwrhtml/rr6202a1.htm |
| | | | High Risk: 2 through 10 years of age | Oct 2007 | |
| | | | High Risk: 9 months through 55 years of age | Apr 2011 | |
| MCV4 (Menveo®) | Novartis | Apr 2010 | Routine: 11 through 21 years of age | Feb 2010 | Pending review |
| | | | High Risk: 2 through 10 years of age | Jan 2011 | |
| | | | 2, 4, 6, 12 through 16 months of age | To be reviewed | |
| Hib-MenCY (MenHibrix®) | GSK | Aug 2009 | High Risk: 2, 4, 6 and 12 months of age | Jun 2012 | CDC: cdc.gov/mmwr/preview/mmwrhtml/rr6202a1.htm |
| MMR (M-M-R-II) | Merck | 1971 | <ul style="list-style-type: none"> - Healthcare personnel - presumptive evidence of immunity - Measles post-exposure prophylaxis with IG - HIV-infected people | Updates | CDC: (MMWR at press) |
| PCV13 (Prevnar 13®) | Pfizer | Mar 2009 | Routine: 2 months through 71 months of age | Feb 2010 | CDC: cdc.gov/mmwr/preview/mmwrhtml/rr5911a1.htm |
| | | | 6 through 18 years of age with high risk conditions | Feb 2010 | CDC: cdc.gov/mmwr/preview/mmwrhtml/mm5909a2.htm |
| | | | 19 years of age and older with immunocompromising conditions | Feb 2010 | CDC: cdc.gov/mmwr/preview/mmwrhtml/mm6140a4.htm |
| | | | Routine: Greater than or equal to 50 years of age | Dec 2011 | CDC: cdc.gov/mmwr/preview/mmwrhtml/mm5934a3.htm |
| PPSV23 (Pneumovax 23®) | Merck | | All adults aged 65 years and older and those adults aged 19--64 years with underlying medical conditions that put them at greater risk for serious pneumococcal infection. | Sep 2010 | CDC: cdc.gov/mmwr/preview/mmwrhtml/mm5934a3.htm |
| Tdap (ADACEL®) | Sanofi Pasteur | Aug 2004 | | | AAP: pediatrics.aappublications.org/cgi/content/full/128/4/809 CDC Pregnancy: cdc.gov/mmwr/preview/mmwrhtml/mm6041a4.htm CDC: (MMWR at press) |
| Tdap (BOOSTRIX®) | GSK | Jul 2004 | <ul style="list-style-type: none"> - Pregnancy - Repeat dose in pregnancy - Health care personnel (HCP) - Expanded age indications (adults ≥ 65) | Off Label Off Label Licensed (11/2011) Off Label (10/2012) | CDC HCP: cdc.gov/mmwr/preview/mmwrhtml/rr5517a1.htm ; cdc.gov/mmwr/preview/mmwrhtml/rr6007a1.htm CDC Age: cdc.gov/mmwr/preview/mmwrhtml/mm6037a3.htm |
| VariZIG | Cangene Corporation | n/a | Post-exposure prophylaxis of varicella | Dec 2012 | CDC: cdc.gov/mmwr/preview/mmwrhtml/mm6112a4.htm |

Table Updated: 5/15/13

Table available on Red Book Online: www.aapredbook.org/site/news/vaccstatus.xhtml
Current 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, HPV = human papillomavirus vaccine, IPV = Inactivated Poliovirus Vaccine, LAIV-T = Live attenuated influenza vaccine-trivalent, MCV4 = Meningococcal conjugate vaccine, MMRV = 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 approved by the CDC Director and Department of HHS and publication in MMWR



Table 2: Influenza Vaccines
General Recommendations on Immunization from ACIP - cdc.gov/mmwr/preview/mmwrhtml/rr6002a1.htm

| Vaccine | Manufacturer | Comments | BLA age indications** | FDA licensure | Status of AAP/CDC recommendations*** |
|--|-------------------------------|---|--|---|---|
| Influenza vaccines | several | n/a | See recommendations below | varies | AAP: pediatrics.aappublications.org/content/130/4/780.full CDC: cdc.gov/mmwr/preview/mmwrhtml/mm6218a3.htm CDC Seasonal: cdc.gov/flu Red Book Online Influenza Resource Page: aapredbook.org/flu |
| Vaccine – Inactive Trivalent | Manufacturer | Comments | BLA age indications** | FDA licensure | Status of AAP/CDC recommendations*** |
| Influenza – IIV3 (Agriflu®) | Novartis | IM | Greater than or equal to 18 years of age | 2009 | CDC: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6132a3.htm |
| Influenza – IIV3 (Afluria®) | CSL Biotherapies | IM | Greater than or equal to 5 years of age | Aug 2010 | CDC: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6132a3.htm |
| Influenza – IIV3 (Fluarix®) | GlaxoSmithKline (GSK) | IM | Greater than or equal to 3 years of age | Aug 2005 (≥18 yr) Oct 2009 (3-17 yr) | CDC: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6132a3.htm |
| Influenza – IIV3 (FluBlok®) | Protein Sciences Corporation | IM, Novel recombinant expression vector (baculovirus) | 18 through 49 years of age | Jan 2013 | CDC: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6132a3.htm |
| Influenza – IIV3 (Flucelvax®) | Novartis | IM, Cell culture derived | Greater than or equal to 18 years of age | Nov 2012 | CDC: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6132a3.htm |
| Influenza – IIV3 (FluLaval®) | ID Biomedical Corp. of Québec | IM | Greater than or equal to 18 years of age | Oct 2006 | CDC: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6132a3.htm |
| Influenza – IIV3 (Fluvirin®) | Novartis | IM | Greater than or equal to 4 years of age | 2012 | CDC: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6132a3.htm |
| Influenza – IIV3 (Fluzone®) | Sanofi Pasteur | IM | 6 months of age and older | 1980 | CDC: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6132a3.htm |
| Influenza – IIV3 (Fluzone® High-Dose) | Sanofi Pasteur | IM, High dose | 65 years of age and older | Dec 2009 | CDC: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6132a3.htm |
| Influenza – IIV3 (Fluzone® Intradermal) | Sanofi Pasteur | Intradermal | 18 through 64 years of age | May 2011 | CDC: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6132a3.htm |
| Vaccine – Inactive Quadrivalent (IM) | Manufacturer | Comments | BLA age indications** | FDA licensure | Status of AAP/CDC recommendations*** |
| Influenza – IIV4 (Fluarix®) | GlaxoSmithKline (GSK) | IM, QIV; includes 2 B strains | Greater than or equal to 3 years of age | Dec 2012 | CDC: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6132a3.htm |
| Influenza – IIV4 (FluLaval®) | ID Biomedical Corp. of Québec | IM, QIV; includes 2 B strains | Greater than or equal to 18 years of age | To be reviewed | Pending licensure |
| Influenza – IIV4 (Fluzone®) | Sanofi Pasteur | IM, QIV; includes 2 B strains | 6 months of age and older | To be reviewed | Pending licensure |
| Vaccine – Live Attenuated (Nasal) | Manufacturer | Comments | BLA age indications** | FDA licensure | Status of AAP/CDC recommendations*** |
| Influenza – LAIV-Trivalent (FluMist®) | MedImmune | Nasal, 2012-2013 season only | 24 months through 49 years of age | 2003 | CDC 2012-13: cdc.gov/mmwr/preview/mmwrhtml/mm6132a3.htm |
| Influenza – LAIV-Quadrivalent (FluMist® Quadrivalent) | MedImmune | Nasal, 2013-2014 season; includes 2 B strains | 24 months through 49 years of age | Feb 2012 | |

Table Updated: 5/15/13

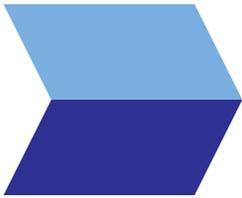
Commonly Administered Pediatric Vaccines

| Vaccine | <i>Separately report the administration with codes 90460-90461 or 90471-90474 [Please see table below]</i> | Manufacturer | Brand | ICD-9-CM† | Number of Vaccine Components |
|---------|--|---|--|-----------|------------------------------|
| 90633 | Hepatitis A vaccine, pediatric/adolescent dosage, 2 dose, for intramuscular use | GlaxoSmithKline Merck | HAVRIX® VAQTA® | V05.3 | 1 |
| 90634 | Hepatitis A vaccine, pediatric/adolescent dosage, 3 dose, for intramuscular use | GlaxoSmithKline | HAVRIX® | V05.3 | 1 |
| 90644 | Meningococcal conjugate vaccine, serogroups C & Y and Hemophilus influenza B vaccine (MenCY-Hib), 4-dose schedule, when administered to children 2-15 months of age, for intramuscular use | GlaxoSmithKline | MenHibrix™ | V06.8 | 2 |
| 90647 | Hemophilus influenza B vaccine (Hib), PRP-OMP conjugate, 3 dose, for intramuscular use | Merck | PedvaxHIB® | V03.81 | 1 |
| 90648 | Hemophilus influenza B vaccine (Hib), PRP-T conjugate, 4 dose, for intramuscular use | sanofi pasteur GlaxoSmithKline | ActHIB® HIBERIX® | V03.81 | 1 |
| 90649 | Human Papilloma virus (HPV) vaccine, types 6, 11, 16, 18 (quadrivalent), 3 dose schedule, for intramuscular use | Merck | GARDASIL® | V04.89 | 1 |
| 90650 | Human Papilloma virus (HPV) vaccine, types 16 and 18, bivalent, 3 dose schedule, for intramuscular use | GlaxoSmithKline | CERVARIX™ | V04.89 | 1 |
| 90655 | Influenza virus vaccine, split virus, preservative free, for children 6-35 months of age, for intramuscular use | Merck sanofi pasteur | Afluria® Fluzone No Preservative Pediatric® | V04.81 | 1 |
| 90656 | Influenza virus vaccine, split virus, preservative free, when administered to 3 years of age and above, for intramuscular use | Merck sanofi pasteur Novatis GlaxoSmithKline | Afluria® Fluzone No Preservative® Fluvirin® FLUARIX™ | V04.81 | 1 |
| 90657 | Influenza virus vaccine, split virus, 6-35 months dosage, for intramuscular use | Merck sanofi pasteur | Afluria® Fluzone® | V04.81 | 1 |
| 90658 | Influenza virus vaccine, split virus, 3 years and older dosage, for intramuscular use | Merck sanofi pasteur Novartis | Afluria® Fluzone® Fluvirin® | V04.81 | 1 |
| 90660 | Influenza virus vaccine, live, intranasal use | MedImmune | FluMist® | V04.81 | 1 |
| 90670 | Pneumococcal conjugate vaccine, 13 valent, for intramuscular use | Pfizer | PREVNAR 13™ | V03.82 | 1 |
| 90680 | Rotavirus vaccine, pentavalent, 3 dose schedule, live, for oral use | Merck | RotaTeq® | V04.89 | 1 |
| 90681 | Rotavirus vaccine, human, attenuated, 2 dose schedule, live, for oral use | GlaxoSmithKline | ROTARIX® | V04.89 | 1 |
| 90696 | Diphtheria, tetanus toxoids, and acellular pertussis vaccine and poliovirus vaccine, inactivated (DTaP-IPV), when administered to children 4 years through 6 years of age, for intramuscular use | GlaxoSmithKline | KINRIX™ | V06.3 | 4 |
| 90698 | Diphtheria, tetanus toxoids, acellular pertussis vaccine, haemophilus influenza Type B, and poliovirus vaccine, inactivated (DTaP-Hib-IPV), for intramuscular use | sanofi pasteur | Pentacel® | V06.8 | 5 |
| 90700 | Diphtheria, tetanus toxoids, and acellular pertussis vaccine (DTaP), when administered to younger than seven years, for intramuscular use | sanofi pasteur sanofi pasteur GlaxoSmithKline | DAPTACEL® Tripedia® INFANRIX® | V06.1 | 3 |
| 90702 | Diphtheria and tetanus toxoids (DT), adsorbed when administered to younger than seven years, for intramuscular use | sanofi pasteur | Diphtheria and Tetanus Toxoids Adsorbed | V06.5 | 2 |
| 90707 | Measles, mumps, and rubella virus vaccine (MMR), live, for subcutaneous use | Merck | M-M-R II® | V06.4 | 3 |
| 90710 | Measles, mumps, rubella, and varicella vaccine (MMRV), live, for subcutaneous use | Merck | ProQuad® | V06.8 | 4 |
| 90713 | Poliovirus vaccine (IPV), inactivated, for subcutaneous or intramuscular use | sanofi pasteur | IPOL® | V04.0 | 1 |
| 90714 | Tetanus and diphtheria toxoids (Td) adsorbed, preservative free, when administered to seven years or older, for intramuscular use | sanofi pasteur | DECAVAC® | V06.5 | 2 |

| Vaccine | Separately report the administration with codes 90460-90461 or 90471-90474 [Please see table below] | Manufacturer | Brand | ICD-9-CM† | Number of Vaccine Components |
|--|---|---|---|------------|------------------------------|
| 90715 | Tetanus, diphtheria toxoids and acellular pertussis vaccine (Tdap), when administered to 7 years or older, for intramuscular use | sanofi pasteur GlaxoSmithKline | ADACEL® BOOSTRIX® | V06.1 | 3 |
| 90716 | Varicella virus vaccine, live, for subcutaneous use | Merck | VARIVAX® | V05.4 | 1 |
| 90718 | Tetanus and diphtheria toxoids (Td) adsorbed when administered to 7 years or older, for intramuscular use | sanofi pasteur | Tetanus and Diphtheria Toxoids Adsorbed for Adult Use | V06.5 | 2 |
| 90721 | Diphtheria, tetanus toxoids, and acellular pertussis vaccine and Hemophilus influenza B vaccine (DTaP-Hib) | sanofi pasteur | TriHIBit® | V06.8 | 4 |
| 90723 | Diphtheria, tetanus toxoids, acellular pertussis vaccine, Hepatitis B, and poliovirus vaccine (DTaP-Hep B-IPV), for intramuscular use | GlaxoSmithKline | PEDIARIX® | V06.8 | 5 |
| 90732 | Pneumococcal polysaccharide vaccine, 23-valent, adult or immunosuppressed patient dosage, when administered to 2 years or older, for subcutaneous or intramuscular use | Merck | PNEUMOVAX 23® | V03.82 | 1 |
| 90733 | Meningococcal polysaccharide vaccine, for subcutaneous use | sanofi pasteur | Menomune® | V03.89 | 1 |
| 90734 | Meningococcal conjugate vaccine, serogroups A, C, Y and W-135 (tetravalent), for intramuscular use | sanofi pasteur Novartis | Menactra® Menveo® | V03.89 | 1 |
| 90740 | Hepatitis B vaccine, dialysis or immunosuppressed patient dosage, 3 dose, for intramuscular use | Merck | RECOMBIVAX HB® | V05.3 | 1 |
| 90743 | Hepatitis B vaccine, adolescent, 2 dose, for intramuscular use | Merck | RECOMBIVAX HB® | V05.3 | 1 |
| 90744 | Hepatitis B, pediatric/adolescent dosage, 3 dose, for intramuscular use | Merck GlaxoSmithKline | RECOMBIVAX HB® ENERGIX-B® | V05.3 | 1 |
| 90746 | Hepatitis B vaccine, adult dosage, for intramuscular use | Merck GlaxoSmithKline | RECOMBIVAX HB® ENERGIX-B® | V05.3 | 1 |
| 90747 | Hepatitis B vaccine, dialysis or immunosuppressed patient dosage, 4 dose, for intramuscular use | GlaxoSmithKline | ENERGIX-B® | V05.3 | 1 |
| 90748 | Hepatitis B and Hib (Hep B-Hib), for intramuscular use | Merck | COMVAX® | V06.8 | 2 |
| 90749 | Unlisted vaccine or toxoid | Please | See | ICD | Manual |
| Immunization Administration Codes | | | | | |
| Immunization Administration Through Age 18 With Counseling^ | | | | | |
| 90460 | Immunization administration 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 | ^CPT 2012 manual has defined an “other qualified healthcare professional” as one who is qualified by education and training, licensure/regulation, and facility privileging who performs a professional service within his/her scope of practice and independently reports that service. These professionals are distinct from “clinical staff.” A clinical staff member is a person who works under the supervision of a physician or other qualified healthcare professional and who is allowed by law, regulation and facility policy to perform or assist in the performance of a specified professional service, but who does not individually report that professional service. Therefore based on these new restrictions, if clinical staff alone performs vaccine counseling, you must defer to codes 90471-90474 . | | | |
| 90461 | Immunization administration 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 | Immunization administration, one vaccine | | | | |
| 90472 | Immunization administration, each additional vaccine | | | | |
| 90473 | Immunization administration by intranasal/oral route; one vaccine | | | | |
| 90474 | Immunization administration by intranasal/oral route; each additional vaccine | | | | |

† ICD-9-CM guidelines indicate that immunizations administered as part of a routine well baby or child check should be reported with code V20.2. The codes listed above can be reported in addition to the V20.2 code if specific payers request them. Immunizations administered in encounters **other than those for a routine well baby or child check** should be reported only with the codes listed above.

^ Vaccine pending FDA approval [<http://www.ama-assn.org/ama/pub/category/10902.html>]
Developed and maintained by the American Academy of Pediatrics. For reporting purposes only.



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 OIG report found that 76% of sampled Vaccines for Children (VFC) providers had vaccines that were exposed to temperatures outside of recommended ranges for more than 5 hours over a 2-week period. In October 2012, in response to this report, the Centers for Disease Control and Prevention (CDC) published Interim Vaccine Storage and Handling Guidance, which included many new recommendations for safe storage and handling practices. The guidance will be finalized when additional data become available.

Learning Objectives

On completion of this unit, the health 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. There should be a minimum of 2 designated health care professionals in an office 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 recommended storage, then contact the manufacturer's quality control office or state VFC coordinator for guidance.

STORAGE AND HANDLING OF VACCINES

| Vaccine | Where to store vaccine | Acceptable temperature range | Where to store diluent | Diluent temperature ranges | Special instructions |
|--|--|------------------------------|---|----------------------------|--|
| DTaP DTaP-Hep B-IPV (Pediatrix), DTaP-IPV (KINRIX) | Refrigerator | 2°C–8°C | No diluent | | |
| DTaP-IPV/Hib (Pentacel) | Refrigerator (Hib-lyophilized vaccine) | 2°C–8°C | Refrigerator with vaccine (DTaP-IPV diluent) | 2°C–8°C | |
| PedvaxHIB and Comvax vaccines | Refrigerator | 2°C–8°C | No diluent | | |
| ActHIB vaccine | Refrigerator | 2°C–8°C | Refrigerator with vaccine | 2°C–8°C | |
| Hiberix vaccine | Refrigerator | 2°C–8°C | May be stored with vaccine in the refrigerator or alone at room temperature | 2°C–8°C or 20°C–25°C | |
| Hep A: Havrix, VAQTA Hep B: Engerix-B, Recombivax HB Hep A-Hep B: Twinrix | Refrigerator Do not freeze or expose to freezing temperatures | 2°C–8°C | No diluent | | |
| HPV2: Cervarix HPV4: Gardasil | Refrigerator Do not freeze or expose to freezing temperatures | 2°C–8°C | No diluent | | For Gardasil: Protect vaccine from light at all times by storing in the original box |
| LAIV: FluMist | Refrigerator Do not freeze or expose to freezing temperatures | 2°C–8°C | No diluent | | |
| TIV: Afluria, Fluarix, FluLaval, Fluvirin, Fluzone, Fluzone High-Dose, Fluzone Intradermal | Refrigerator Do not freeze or expose to freezing temperatures | 2°C–8°C | | | Afluria, Fluarix, FluLaval, and Fluvirin: Protect vaccine from light at all times by storing in the original box. |
| MMR: M-M-RII | Refrigerator or Freezer | -50°C to +8°C | Refrigerator or room temperature Do not freeze or expose to freezing temperatures | 2°C–8°C or 20°C–25°C | Protect vaccine from light at all times by storing in the original box. Use of dry ice is not recommended, even for temporary storage. Dry ice may subject MMR vaccine to temperatures colder than -50°C. |
| MCV4: Menactra | Refrigerator Do not freeze or expose to freezing temperatures | 2°C–8°C | | | |
| MCV4: Menveo | Refrigerator Do not freeze or expose to freezing temperatures | 2°C–8°C | Refrigerator Store with vaccine | 2°C–8°C | Protect Menveo from light at all times by storing in the original box. |

STORAGE AND HANDLING OF VACCINES

| Vaccine | Where to store vaccine | Acceptable temperature range | Where to store diluent | Diluent temperature ranges | Special instructions |
|--|--|------------------------------|---|--|---|
| MPSV4: Menomune | Refrigerator Do not freeze or expose to freezing temperatures | 2°C–8°C | Refrigerator Store with vaccine | 2°C–8°C | |
| PCV13: Prevnar 13 PPSV23: Pneumovax 23 | Refrigerator Do not freeze or expose to freezing temperatures | 2°C–8°C | | | |
| IPV: IPOL | Refrigerator Do not freeze or expose to freezing temperatures | 2°C–8°C | | | |
| RV1: ROTARIX | Refrigerator Do not freeze or expose to freezing temperatures | 2°C–8°C | Store diluent separately at room temperature | 20°C–25°C | Protect vaccine from light at all times by storing in the original box. |
| RV5: RotaTeq | Refrigerator Do not freeze or expose to freezing temperatures | 2°C–8°C | | | Protect vaccine from light at all times by storing in the original box. |
| Td: DECAVAC DT: Diphtheria and Tetanus Toxoid | Refrigerator Do not freeze or expose to freezing temperatures | 2°C–8°C | | | |
| Tdap: Adacel, Boostrix | Refrigerator Do not freeze or expose to freezing temperatures | 2°C–8°C | | | |
| VAR: Varivax (chickenpox) zoster/shingles) | Freezer Vaccine should be stored only in freezers or refrigerator/freezer units with separate compartments and exterior doors | -50°C to -15°C | Refrigerator or room temperature Store separately from vaccine. | 2°C–8°C or 20°C–25°C Do not freeze diluent or expose to freezing temperatures. | Protect vaccine from light at all times by storing in the original box. |
| MMRV: ProQuad | Freezer Vaccine should be stored only in freezers or refrigerator/freezer units with separate compartments and exterior doors | -50°C to -15°C | Refrigerator or room temperature Store separately from vaccine. | 2°C–8°C or 20°C–25°C Do not freeze diluent or expose to freezing temperatures. | Protect vaccine from light at all times by storing in the original box. |
| Zostavax (herpes zoster/shingles) | Freezer Vaccine should be stored only in freezers or refrigerator/freezer units with separate compartments and exterior doors | -50° to -15°C | Refrigerator or room temperature Store separately from vaccine. | 2°C–8°C or 20°C–25°C Do not freeze diluent or expose to freezing temperatures. | Protect vaccine from light at all times by storing in the original box. |

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 unless contaminated.

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. Meningococcal polysaccharide multidose vials may be refrigerated and used up to 35 days after reconstitution.
3. 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.
4. Rotarix (rotavirus) oral applicator should be administered within 24 hours of reconstitution.
5. Varicella vaccine must be discarded if reconstituted vaccine is not used within 30 minutes. Do not freeze reconstituted vaccine.
6. Zoster 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 of the requirements, label them "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.

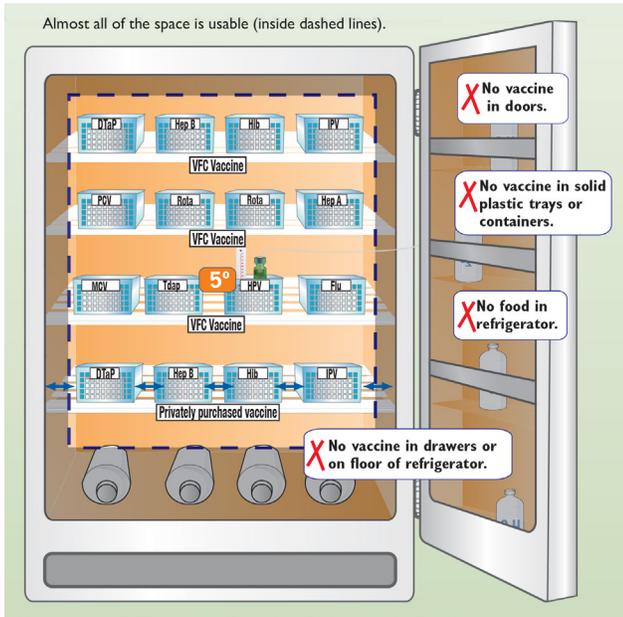
Inventory should be rotated so that vaccines are used before they expire. Electronic systems can be used to monitor vaccine inventory.

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/Notes

- No food or drinks can be stored in the vaccine freezer or refrigerator.
- Use a stand-alone refrigerator and a stand-alone freezer suitable for vaccine storage rather than a combination unit (refrigerator + freezer) or other units not designed for storing fragile biologics, such as vaccines.
- Dormitory-type refrigerators are no longer allowed, even for short-term/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
 - 2 to 3 inches from the sides and back of refrigerator and other plastic containers
 - Not in the door of the vaccine storage unit

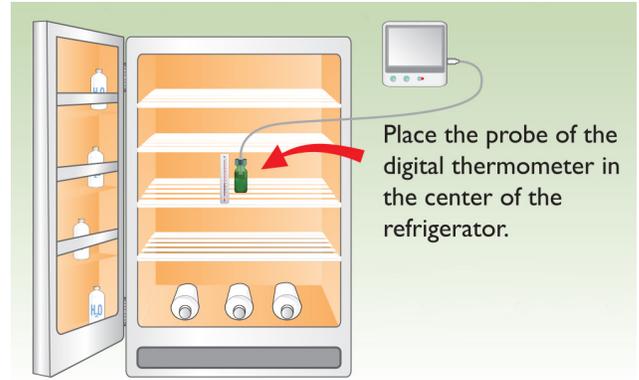
Refrigerator Only Unit



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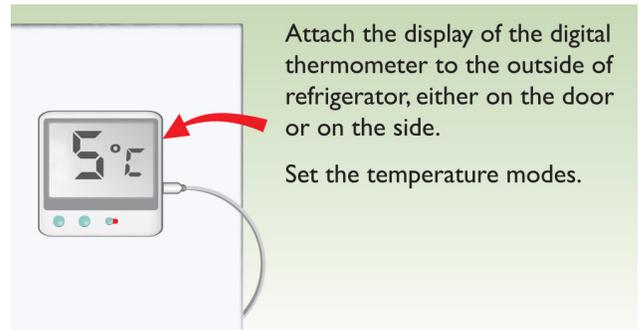
- Post a sign on the door to indicate which vaccines are to be stored in the refrigerator and which should be stored in the freezer.

- A certified calibrated glycol-encased thermometer probe should always be kept in the refrigerator and freezer.



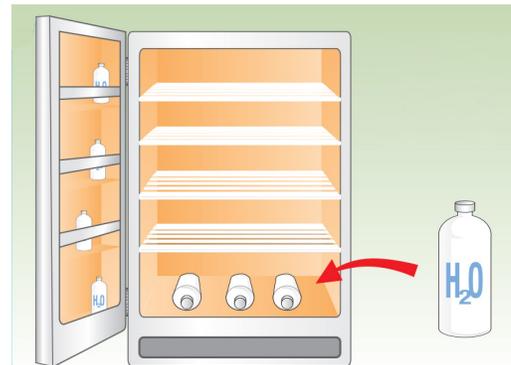
Reproduced with permission from the California Department of Public Health, Immunization Branch

- Use digital data loggers with detachable probes that record and store temperature information at frequent programmable intervals for 24-hour temperature monitoring rather than noncontinuous temperature monitoring.



Reproduced with permission from the California Department of Public Health, Immunization Branch

- Water bottles should line the back, top, bottom, and doors of the refrigerator to help maintain temperatures and prevent vaccines from freezing in the refrigerator.



Reproduced with permission from the California Department of Public Health, Immunization Branch

- Store vaccines away from refrigerator vents.
- Ice packs should be stored in the freezer to help maintain cold temperatures.

STORAGE AND HANDLING OF VACCINES

- A “Do Not Unplug” sign must be posted by the outlet to the freezer and refrigerator.



Reproduced with permission from the California Department of Public Health, Immunization Branch

- The state immunization program should be contacted for instructions on how to dispose of expired VFC vaccines. For private purchased vaccines, always contact the manufacturer, who may offer a refund.
- Varicella and zoster vaccines will lose potency if stored in a temperature warmer than -15°C .
- Vaccines meant to be stored in the refrigerator will lose potency if stored in a temperature colder than 2°C .
- A backup plan should be developed in case of power outages or equipment failure.

Key Facts

- Refrigerator should measure between 2°C and 8°C .
- Freezer should measure -15°C or lower.
- Vaccines meant to be stored in the refrigerator should never be frozen.
- Temperatures of the refrigerator and freezer should be checked at least twice each day and documented on a temperature log. The maximum and minimum temperatures reached each day should also be recorded on this log.

Tools and Resources

• Links for additional learning:

- American Academy of Pediatrics Vaccine Storage and Handling (<http://www2.aap.org/immunization/pediatricians/storageandhandling.html>)
- Immunization Action Coalition (www.immunize.org)
- Centers for Disease Control and Prevention (www.cdc.gov/vaccines)
 - Interim Vaccine Storage and Handling Guidance (<http://www.cdc.gov/vaccines/recs/storage/interim.htm>)
 - Vaccine Storage and Handling Toolkit (<http://www.cdc.gov/vaccines/recs/storage/toolkit/default.htm>)

• Documents you may include in your personalized manual (included below):

- American Academy of Pediatrics
 - Refrigerators, Freezers, and Vaccine Storage (<http://www2.aap.org/immunization/pediatricians/pdf/VaccineStorageRF.pdf>)
 - Data Loggers and Vaccine Monitoring (<http://www2.aap.org/immunization/pediatricians/pdf/DataLoggers.pdf>)
 - Storage and Handling Checklist (<http://www2.aap.org/immunization/pediatricians/pdf/S&HChecklist.pdf>)
 - Disaster Planning (<http://www2.aap.org/immunization/pediatricians/pdf/DisasterPlanning.pdf>)
 - Safe Vaccine Transport (<http://www2.aap.org/immunization/pediatricians/pdf/SafeTransport.pdf>)
- Immunizations Action Coalition
 - Temperature Logs for Vaccines
 - Fahrenheit: <http://www.immunize.org/catg.d/p3039f.pdf>
 - Celsius: <http://www.immunize.org/catg.d/p3039c.pdf>
 - Don't Be Guilty of These Errors in Vaccine Storage and Handling (<http://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)
- 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>



AAP Immunization Resources

Storage and Handling Series

Refrigerators, Freezers, and Vaccine Storage

The Centers for Disease Control and Prevention (CDC) has developed interim guidance on proper storage and handling of vaccines. Their guidance provides recommendations on storage units for vaccines. To see the guidance issued by the CDC, visit: <http://www.cdc.gov/vaccines/recs/storage/interim.htm>.

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 briefly 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, visit: <http://www.cdc.gov/vaccines/recs/storage/toolkit/storage-handling-toolkit.pdf> (pages 29, 31, 34, 56, and 57) and <http://eziz.org/assets/docs/IMM-962.pdf>.

Key Points:

- Stand-alone vaccine storage units are safest for storing vaccines.
- There are different types of stand-alone refrigerators and freezers. Evaluate which type is best for your practice.
- Vaccine storage units have optional features (such as wire shelves and more) that can make storage of vaccines even safer.

CDC recommends stand-alone refrigerators and freezers:

CDC strongly recommends the use of stand-alone refrigerator and freezer units, meaning a self-contained unit that only refrigerates or only freezes and is suitable for vaccine storage. These units can vary in size, from a compact, under-the-counter style to a large, stand-alone, pharmaceutical-grade storage unit. The transitional use of standard domestic combination refrigerator/freezer units is appropriate only for the refrigerator portion, but its continued use is discouraged. The use of dormitory or bar-style refrigerator/freezers (small refrigerator units with interior freezer sections) is no longer allowed at any time for Vaccines for Children (VFC) program providers.

The characteristics of an appropriate storage unit include:

- ability to maintain required vaccine storage temperatures year-round
 - refrigerator: 2-8°C
 - freezer: -15 to -50°C
- enough room to store the year's largest inventory without crowding;
- sufficient room to store water bottles in the refrigerator and frozen coolant packs in the freezer to add thermal mass and stabilize the temperature; and
- a working, calibrated thermometer accurate to +/- 0.5°C with Certificate of Traceability and Calibration (also known as Report of Calibration) placed in a central area inside each storage compartment.



AAP Immunization Resources

Storage and Handling Series

Refrigerators, Freezers, and Vaccine Storage

CDC recommends stand-alone refrigerators and freezers (continued):

The characteristics of an appropriate storage unit include:

- ability to maintain required vaccine storage temperatures year-round
 - refrigerator: 2-8°C
 - freezer: -15 to -50°C
- enough room to store the year's largest inventory without crowding;
- sufficient room to store water bottles in the refrigerator and frozen coolant packs in the freezer to add thermal mass and stabilize the temperature; and
- a working, calibrated thermometer accurate to +/- 0.5°C with Certificate of Traceability and Calibration (also known as Report of Calibration) placed in a central area inside each storage compartment.

If the refrigerator portion of a combination unit must be used, avoid using the top shelf, the doors, the bottom bins (if present), and leave a gap between the vaccine and walls. These restrictions greatly reduce the usefulness of domestic combination units. Replacement is strongly advised.

Experience has shown that separate units greatly decrease the risk of freezing refrigerated vaccine. Dual units with separate, independent evaporator coils for the freezer and refrigerator portions also minimize the risk and are acceptable.

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 "gold-standard" vaccine units 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. Manufacturers in this category offer a range of sizes and options to fit any clinic's needs. Size options include one and two door bulk storage units, under-counter units, glass doors to help with inventory, and small point of service units to replace the disallowed dorm units. Keep in mind, biologic-grade units often require over a month to deliver.

Biologic-grade Freezers and Domestic Freezers

Freezers are easier to construct since they do not need a precise range – they just need to be colder than -15°C. Freezers can be much smaller than is normally used in a home. Although frost-free freezers are recommended, that feature is generally found only in freezers much larger than what is needed for most practices. The frost-free feature can also mean the freezer is routinely warmer than the specified -15°C during the frost-free cycle. Be careful not to purchase more freezer than you need – vaccines containing Varivax are the only pediatric vaccines that require frozen storage. Adequate freezers for 2 pediatricians can be as small as 1.5 cubic feet and cost as little as \$200. When ordering, keep in mind that biologic-grade units often require over a month to deliver. 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.



AAP Immunization Resources

Storage and Handling Series

Refrigerators, Freezers, and Vaccine Storage

Standard Refrigerators and Freezers

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, and are not “biologic-grade”. Generally you should consider the refrigerator-only or freezer-only units. One exception is a domestic refrigerator + freezer unit that advertises “twin cooling”. This dual unit has a separate evaporator coil for the freezer and a separate coil for the refrigerator, with the two sections completely isolated from each other and each controlled by an electronic thermostat. While not ideal for vaccine storage (nearly equal in cost to a biologic-grade refrigerator, no interior fan, glass shelves, much wasted space in the doors), it may be an “only option” with instant availability to replace an unexpected refrigerator failure.

If you choose a standard domestic refrigerator-only unit, some essential features to look for are:

- minimal space wasted in door storage;
- no icemaker in the refrigerator-only units;
- fully adjustable wire shelves (better air circulation than glass shelves);
- ample room to store all vaccine product without touching the walls; and
- ability to consistently maintain required temperature ranges.

Some *recommended* features include:

- locks on the outside of the doors;
- digital thermostat controls;
- forced air circulation;
- alarm on door to detect door ajar; and
- port for entry of external temperature probe wire.

Glass doors may be a desired feature for quicker inventory control, but they also lose their temperature more quickly in a power outage. Practices that purchase refrigerators with glass doors should alter their emergency plans accordingly.

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 cispimmunize@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 | http://www.fishersci.com/ |
| Follett | http://www.follettice.com |
| Helmer | http://www.helmerinc.com/ |
| Lab Research Products | http://www.labresprod.com/ |
| Living Direct | http://www.livingdirect.com/on/demandware.store/Sites-LD-Site/default/Search-Show?q=american%20biotech%20supply |
| Migali Scientific Refrigeration | http://migaliscientific.com/ |
| Sanyo Biomedical | http://us.sanyo.com/biomedical |
| Sun Frost | http://www.sunfrost.com/ |
| Thermo Scientific | http://www.thermo.com/ |



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

Refrigerator:

Add the number of doses *on hand* (current inventory) from your last order form.

| | |
|---|----------------|
| VFC vaccine | + _____ |
| VFC flu vaccine (if off-season, include average number of doses you order) | + _____ |
| Private vaccine | + _____ |
| Private flu vaccine (if off-season, include average number of doses you order) | + _____ |
| Total doses | = _____ |

Freezer:

Add the number of doses *on hand* (current inventory) from your last order form.

| | |
|----------------------------------|----------------|
| VFC MMRV & Varicella vaccine | + _____ |
| Private MMRV & Varicella vaccine | + _____ |
| Total doses | = _____ |
| | |
| Multiply (max inventory) | x 1.25 |
| Maximum doses | = _____ |

| Doses Per Year | Equipment Size |
|--|---|
| Very high volume (10,000+ doses/year) | Biologic-grade stand-alone units. |
| High volume (2,000-10,000 doses/year) | 16.7 cubic-foot minimum refrigerator + stand-alone freezer units. |
| Medium volume (500-2,000) doses/year | 16.7 cubic-foot minimum refrigerator + stand-alone freezer units or Biologic-grade under the counter units. |
| Low volume (fewer than 500 doses/year) | |

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!

AAP Immunization Resources

Storage and Handling Series

Refrigerators, Freezers, and Vaccine Storage

The vaccine storage units 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. 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. As mentioned it may be difficult to find frost-free freezers.

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.

If you are a manufacturer of equipment and wish to add or edit information below, please contact cispimmunize@aap.org.

Refrigerators:

| Max Doses: | Min Cubic Feet: | Examples: |
|-------------|----------------------|--------------------------------|
| 2,000+ | May require 1+ units | See below |
| 1,000-2,000 | 40 | Revco REL-4504A; REL-4504D |
| | | Sanyo SRR-49GD-MED |
| 901-1,000 | 36 | Sanyo MPR-1013; MPR-1013R |
| | | Turbo Air GST-40DR |
| 801-900 | 21-23 | Aegis Scientific 1-R-25 |
| | | Sanyo SRR-23FD; SRR-23GD |
| 701-800 | 17-19.5 | Aegis Scientific 3-CR-17 |
| | | Frigidaire FCRS201RFB |
| 400-700 | 16.7 | Nor-Lake LR161WWW/0 |
| | | Kenmore 60722 |
| | | Frigidaire FRU17B2J; FRU17B2JW |
| 100-399 | 4.9-6.7 | Sanyo SR-L4110W; SF-L6111W |
| | | Nor-Lake NSLR051WMW/0 |
| | | Revco REL-404A |

Freezers:

| Max Doses: | Min Cubic Feet | Examples: |
|------------|----------------|------------------------------------|
| 501-6,000 | 7-14.8 | Whirlpool EH151FXRQ |
| | | Frigidaire AFFC1466DW |
| 201-500 | 5-5.6 | Revco ULT-430A |
| | | Frigidaire FFC0522DW |
| 0-200 | 3.5-4.9 | Nor-Lake LF041WWW/OM |
| | | Barnstead International Model 3752 |
| | | Revco ULT-430A |



AAP Immunization Resources

Storage and Handling Series

Data Loggers and Vaccine Monitoring

The Centers for Disease Control and Prevention (CDC) has developed interim guidance on proper storage and handling of vaccines. Their guidance suggests that all practices use a data logger connected to a thermometer probe in vaccine storage units (refrigerators and freezers). To see the guidance issued by the CDC, visit: <http://www.cdc.gov/vaccines/recs/storage/interim.htm>.

Key Points:

- You may be required to purchase a data logger to record temperatures in the storage unit containing your Vaccines For Children (VFC) vaccines.
- Data loggers have many different features. CDC recommendations are below, but call your VFC coordinator to learn what is required of your practice.
- Always download data each week and clear the logger.
- Consider an alarm-dialer to reach you when the office is closed.

The CDC now recommends the use of digital thermometers with a glycol-encased (or similar temperature buffer) probe that is able to provide and store data. Such a device is referred to as a data logger.

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 minimum and maximum temperatures (visible from outside of the vaccine storage unit);
- Reset button for the maximum and minimum temperatures recorded in period;
- Low battery indicator;
- Accuracy of $\pm 0.5^{\circ}\text{C}$ as certified by a current Certificate of Traceability and Calibration;
- Memory storage with at least two weeks recording time at a sample interval of 5 minutes (approx 4,000 readings or more).
- Data recording loops when memory is full.* (Remember to download data weekly and always clear/reset the data logger to preserve adequate memory);
- Detachable temperature buffered probe, or one that allows the probe to remain in the unit undisturbed while the temperature is displayed and data is recorded via computer;
- User programmable logging interval (or sampling rate) of 10 minutes or less.

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 recorded by office staff twice daily, along with the maximum and minimum temperatures. 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 raw 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. Occasionally the data logger reader – the device which displays the current temperature to the user – is also sold separately.

*Please note this differs from CDC guidance.



What else do I need to consider?

- **Contact your Vaccines for Children (VFC) State 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 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 the event so the situation can be corrected 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.
 - Equipment failure, door left open: This is by far the most common and easiest 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. You may want to look for a unit that will allow you to program or specify a 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. These dialers can continue calling until an acknowledgement code is entered or texted back to the dialer.
 - 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 copper phone, “land line,” tied directly to the dialer (does not go through an office phone system) is the most reliable. 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 (modems, routers, switches, servers all need to be working) or in the immediate area, thus rendering these methods less dependable.
 - Regional power failure (natural disasters, floods, hurricane, snow storm, large-scale grid failure) is more difficult since the notification infrastructure can be compromised. Usually responsible staff can be aware of such events and should physically go to the site to inspect. Having a phone-dialer that can answer a temperature query is very helpful and may save a trip. Your office should have a plan in place for vaccine storage and transport during emergencies. Please see the [AAP Disaster Planning tip sheet](#).



What else do I need to consider (continued)?

- **A unit with a continuous-tracking feature**
 - Continuous-tracking thermometers are devices attached to a refrigeration unit that continuously, directly record the unit's temperature onto a circular piece of graph paper. These have been totally replaced by electronic data loggers and should not be used. (**Please note: use of continuous tracking does not preclude you from recording the temperature twice daily; this should still be done**).
- **Vaccine Insurance**
 - When private-purchase vaccine expires or is destroyed by temperature excursions, the manufacturer may take back non-flu vaccine and exchange for new vaccine. Replacement is not an option if the vaccine is physically destroyed (fire) or in case of theft. Returning vaccine is not 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. Contact your local VFC program to determine your financial risk when handling VFC vaccine.
 - 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 your old glass thermometers in your employee or break-room refrigerator and maintain/monitor that refrigerator at 2°C-8°C just like you would a vaccine refrigerator. That way if you have an unexpected failure of a refrigerator, you can remove all food and have a safe and readily available refrigerator that you know is capable of receiving the vaccine.
 - Have coolers capable of safely transporting your vaccine to an alternate refrigerator in case of power failure stored in your building. Frozen water bottles make excellent cooling for transport and should be on hand at all times.* Studies are underway related to use of water bottles; the CDC still recommends frozen gel packs for transport. The AAP has concerns the gel packs could inadvertently lead to freezing vaccine. (See [AAP Vaccine Transport Tip Sheet](#)).
- **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 fail. If the power returns in a few moments, the device will remain "off" and so will the refrigerator! Propane or natural gas emergency generators with automatic start and professionally installed by an electrician are appropriate in areas at risk for power outages. Gasoline and diesel fuel age quickly and are not appropriate fuels for emergency refrigerators. Refrigerators generally exceed 8°C after 4 hours of no power at room temperature.

What else do I need to consider (continued)?

- **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, which is demonstrated on the NIST Vaccine Web site: <http://www.nist.gov/pml/div685/grp01/vaccines.cfm>
 - An easy method is to purchase a soup thermos, fill with more ice than water, and place the probe into the water while in the refrigerator. If, after 10 minutes, the thermometer reads within 0.5°C of zero, the thermometer passes and is now known to be accurate. If it fails, it should be calibrated or replaced.
 - Refrigerators can die slowly, where the thermostat must be turned colder and colder to maintain 5°C. If you notice that pattern, you should replace the refrigerator quickly.
- **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 wall of the unit designed to allow a probe to enter.
 - Domestic refrigerators must have the probe enter through the door opening. The wire should enter the refrigerator/freezer on the hinge side high in the 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 and using clay or putty to smooth and taper the edges for a good seal.
 - Place the probe in the center of the refrigerator with extra wire. That will allow you to move it throughout the vaccine storage area to verify that the entire refrigerator is safe for vaccine.



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.

Data logger manufacturers and distributors:

| | |
|--------------------------|---|
| Accsense | http://www.accsense.com/p_p_a102.html |
| Dickson | http://www.dicksondata.com/products/find/data-logger |
| Lascar Electronics | http://www.lascarelectronics.com/data-logger/ |
| Onset (Hobo) | http://www.onsetcomp.com/ |
| T&D Corporation | http://www.tandd.com/#fragment-1 |
| Temperature Guard | http://temperatureguard.com/ |
| Temperature@lert | http://www.temperaturealert.com/Temperature-Alarm.aspx |
| Control Solutions Inc. | www.vfcdataloggers.com |
| Tip Temperature Products | www.tiptemp.com |

Alarm phone-dialer manufacturers

| | |
|--------------------------|---|
| Dickson | http://www.dicksondata.com/ |
| 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 |



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 +/- 0.5°C and come with a Certificate of Traceability and Calibration?
- Can it record at least 2 weeks of readings at a 5 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?
 - 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 Can an Ice Melting Point (IMP) Verification be done by user? | Other features |
|-------------------------------|-------|-------------|--------------------------------|--|---|----------|-----------------------------|--|-------------------------------------|--|--|---|
| Dickson FH635 | \$529 | Yes | Yes | Yes, logger can be cleared | Yes (indicates when A/C power is removed) | ±0.45C | 32,000 (16,000 per channel) | Y Various intervals available | Yes | Yes, remote probe. | Annually \$99-\$269 Not specified | Relay (function for external alarm hook-up); UBS/flash card |
| | | | | | | | | | | | | |
| | | | | | | | | | | | | |
| | | | | | | | | | | | | |
| | | | | | | | | | | | | |



The CDC has developed interim guidance on proper storage and handling of vaccines. Their guidance suggests activities at regular intervals to maintain proper vaccine storage and handling. To see the guidance issued by the CDC, visit: <http://www.cdc.gov/vaccines/recs/storage/interim.htm>.

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 **digital thermometer** with a **glycol-encased probe** or a similar temperature-buffered probe.
- Maintain a digital data logger connected to the digital thermometer to continuously record temperature readings and to alert you when temperatures are out of range.
- 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 doors are closed.

The following should be done **WEEKLY**:

- Download and review stored temperature data to ensure timely review and appropriate response to issues. Appropriate responses include:
 - If temperature monitoring equipment shows an out of range temperature, determine the cause and correct it. This may include closing the refrigerator door completely, adjusting the thermostat, 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 for refrigerated-vaccines, ≤-15°C for frozen vaccine).
 - 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.
- Delete the data upon downloading it. 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 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.





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.
- Clean refrigerator and freezer units every month to discourage bacterial and fungal growth.
 - Remove vaccines from the unit and store them in another functioning unit or temporarily store vaccines in appropriately packed coolers. For help, see [AAP Safe Vaccine Transport Tip Sheet](#).
 - Unplug the unit or turn off the power.
 - Wash all inside surfaces and shelves with warm, slightly soapy water.
 - Dry thoroughly.
 - Plug in the unit and/or turn the thermostat back to an appropriately cold setting.
 - When the unit has reached the proper temperature, restock vaccine.
- 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](#).
- Ensure that the vaccine champions of the office receive continuing education on vaccine management.
- Verify thermometer accuracy.
 - This can be done by sending it for verification or calibration to a laboratory with accreditation from an International Laboratory Accreditation Cooperation Mutual Recognition Arrangement signatory body.
 - Follow links for listings of accredited laboratories:
 - The American Association for Laboratory Accreditation (A2LA)
<http://www.a2la.org/dirsearchnew/newsearch.cfm>
 - Laboratory Accreditation Bureau (L-A-B)
<http://www.l-a-b.com/content/directory-accredited-labs>
 - ANSI-ASQ National Accreditation Board (ACLASS)
<http://www.aiclasscorp.com/search-accredited-companies.aspx>
 - International Accreditation Service (IAS)
http://www.iasonline.org/Calibration_Laboratories/CL.html
 - Perry Johnson Laboratory Accreditation, Inc.(PJLA)
<http://www.pjlabs.com/search-accredited-labs>
 - A listing of signatory bodies outside of the U.S. can be found on the ILAC website:
https://www.ilac.org/members_contact_details.html
 - Consider an ice melting point (IMP) 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.
 - To view a video demonstrating an IMP, visit:
<http://www.youtube.com/watch?v=KYOJayWqB3g&noredirect=1>

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. To access this tool visit:

<http://www.cdc.gov/vaccines/recs/storage/toolkit/default.htm>.

The 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.

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

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;
 - ensure the appropriate handling of vaccine during a disaster or power outage;
 - ensure 24-hour access to the building and vaccine storage unit(s).
- Ensure backup energy source (generator).
 - Ensure that sufficient fuel is on hand 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, preferable near the vaccine storage units.
- Ensure access to up-to-date phone numbers for vaccine distributors, vaccine manufacturers, and VFC Coordinators.
- Ensure all staff 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.

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, vehicles, and drivers for transporting vaccines to and from the alternate vaccine storage facility.
- 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 [AAP Storage and Handling Tip Sheet: Safe Vaccine Transport](#).
 - Communicate to staff where everything is kept.
 - Include written directions for packing vaccines and diluents for transport.
 - A calibrated thermometer or 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 within 4 hours of a power outage. If it is likely for the power to be off for more than 4 hours, plan on moving the vaccine to a safer location.
- Always carefully follow proper transport protocols (see AAP Transport Tip Sheet).
- Continue to monitor temperatures. If possible, do so without opening the door.
- Do not discard vaccine that has been warm. Most vaccine is very heat tolerant. Immediately segregate all compromised vaccine in a container or bag and place refrigerated-vaccine at 2°C to 8°C and frozen vaccine at ≤15°C.
- Call vaccine distributors and VFC Coordinators to cancel any upcoming vaccine deliveries.



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.

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.
- 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.
- 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 Tip Sheet: Safe Vaccine Transport
<http://www2.aap.org/immunization/pediatricians/pdf/SafeTransport.pdf>
- CDC Vaccine Storage and Handling Toolkit
<http://www.cdc.gov/vaccines/recs/storage/toolkit/default.htm>
- CDC Vaccine Storage and Handling Guide
<http://www.cdc.gov/vaccines/recs/storage/guide/default.htm>
- Immunization Action Coalition Emergency Response Worksheet
<http://www.immunize.org/catg.d/p3051.pdf>



AAP Immunization Resources

Storage and Handling Series

Safe Vaccine Transport

While it is best to never transport vaccine, on occasion moving vaccine is necessary. The tips below are available to help vaccine providers transport their vaccine in the safest way possible. The CDC Vaccine Storage and Handling Toolkit also includes guidance on how to transport vaccine. To view the CDC guidance visit: <http://www.cdc.gov/vaccines/recs/storage/toolkit/>.

Key Points:

- Do not transport vaccines unless necessary.
- Use gel packs or conditioned frozen water bottles for safe transport of refrigerated-vaccines.
- Never transport opened multi-dose vials.
- Protect refrigerated-vaccine from freezing during transport.
- Immediately place vaccines in an appropriate storage unit at the recommended temperature ranges upon arrival at the alternative facility.
- Keep a calibrated thermometer(s) in the storage unit(s) with the vaccines.

When is it appropriate to transport vaccine?

- During an emergency or power outage expected to last over 4 hours – if there is a safe place with proper storage units to receive the vaccine.
- When your vaccine storage equipment is not functioning.
- When you need to redistribute vaccine among different clinics. This should not happen regularly. All attempts should be made to order correctly for each clinic.

When is transport of vaccine prohibited?

- Never transport multi-dose vials of vaccine that have been opened. That is against FDA regulations. All opened vials must be used in the facility that opened them.

General rules for transporting vaccines:

- Transport refrigerated-vaccine in a separate container than frozen vaccine (those containing Varivax).
- Always hand-carry by a trusted & trained employee. Do not delegate to a commercial service.
 - Do not place in the trunk of the vehicle – carry in the passenger cabin.
 - Deliver directly to the alternative facility.
 - Promptly unpack and place into appropriate storage units upon arrival
- Never use dry ice, not even for frozen vaccine.



Materials for Transporting Vaccine

- Coolers:
 - Polystyrene coolers
 - These are the coolers that manufacturers use to ship vaccine.
 - These are ideal vaccine transport if coolers with a tighter fitting lid are not available.
 - Hard-sided insulated coolers with at least 2-inch walls
 - If polystyrene coolers are not available, consider using collapsible coolers:
 - Store these in a refrigerator so they are already chilled.
 - They can then be placed in a larger hard-sided insulated cooler with at least 2-inch walls with additional coolant for longer transportation.
- Calibrated thermometer (preferably with a glycol-encased thermometer probe) for each cooler
- Insulation:
 - cardboard,
 - table paper,
 - Styrofoam beads, or
 - bubble wrap.

Materials for refrigerated-vaccine

- Portable refrigerators are ideal.
- Use either appropriately conditioned, frozen gel packs or conditioned frozen water bottles (CFWBs) as the coolant for refrigerated-vaccine, taking care not to freeze vaccine.
 - CFWBs are clear plastic drinking water bottles (available by the case at grocery stores) that have been hard frozen and then “conditioned.”
 - Conditioning means warming them until a small amount of liquid water is visible on the inside of the bottle where the solid ice has begun to melt. Water bottles or gel packs that are not “conditioned” may be colder than 0°C and can freeze vaccine. Freezing refrigerated-vaccine can render them impotent. Take precautions to never freeze these vaccines!
- Additional studies are under way to determine the most appropriate materials for transporting refrigerated-vaccine.

Materials for frozen vaccine (Varicella-containing vaccine)

- Portable freezer unit that maintains the temperature between -50°C and -15°C.
 - These may be available to rent in some places.
- Frozen gel packs.



Packing for Vaccine Transport

Procedures for refrigerated-vaccine transport

- If available, place vaccine and diluents in a portable refrigerator.
- If a portable refrigerator is not available, layer the following in one of the types of coolers described above:
 - a row of CFWBs on the bottom,
 - insulation (this will protect the vaccine from condensation),
 - the refrigerated vaccine & corresponding diluent,
 - more insulation,
 - another layer of CFWBs on top.
- If the cooler is not big enough for two layers of bottles, at least put one layer on top of the vaccines (with a layer of insulation in between).
- Place a calibrated thermometer (preferably with a glycol-encased thermometer probe) in the cooler, as close to the vaccines as possible.

Procedures for Varicella-containing vaccine transport (if a portable freezer is not available)

- Use the same procedures as refrigerated-vaccine, but use frozen gel packs instead of CFWBs (they should not be conditioned).
- Keep frozen vaccine and frozen gel packs in a separate cooler than the refrigerated-vaccine.
- If vaccine cannot be kept frozen, please do as follows:
 - Using a calibrated thermometer (preferably with a glycol-encased thermometer probe) in the container used for transport as close as possible to the vaccines. Record:
 - the time the vaccines are removed from the storage unit and placed in the container;
 - the temperature during transport;
 - the time and temperature at the beginning and end of transport.
 - According to the vaccine manufacturer, immediately upon arrival at the alternate storage facility:
 - Place the vaccines in the freezer between -50°C and -15°C and label "DO NOT USE." Any stand-alone freezer that reliably maintains a temperature between -50°C and -15°C is acceptable for storage of varicella-containing vaccines.
 - Document the time the vaccines are removed from the container and placed in the alternate storage unit.
 - Note that this is considered a temperature excursion, so contact the manufacturer (Merck) at 1-800-637-2590 for further guidance.
- Do not discard vaccines without contacting the manufacturer and/or your immunization program for guidance, as Varicella-containing vaccine may still be potent after up to 72 hours if stored at refrigerated-vaccine temperatures (2°C - 8°C).

What else should I know about transporting vaccines?

- Transport diluents with corresponding vaccines, never freeze diluents.
- Always continue to monitor temperature of vaccines when transporting, and when stored at a temporary location.
- Only remove vaccine that will be administered immediately from its temporary storage location.
- Keep temporary storage containers closed as much as possible.

Resources:

AAP Vaccine Storage and Handling Web page:

<http://www2.aap.org/immunization/pediatricians/storageandhandling.html>

AAP Storage and Handling Tip Sheet: Disaster Planning

<http://www2.aap.org/immunization/pediatricians/pdf/DisasterPlanning.pdf>

CDC Vaccine Storage and Handling Toolkit

<http://www.cdc.gov/vaccines/recs/storage/toolkit/default.htm>

CDC Vaccine Storage and Handling Guide

<http://www.cdc.gov/vaccines/recs/storage/guide/default.htm>

Immunization Action Coalition Emergency Response Worksheet

<http://www.immunize.org/catg.d/p3051.pdf>



Temperature Log for Refrigerator and Freezer — Fahrenheit

Month/Year: _____ Days 1–15

Completing this temperature log: Check the temperatures in both the freezer and the refrigerator compartments of your vaccine storage units at least twice each working day. Place an “X” in the box that corresponds with the temperature and record the ambient (room) temperature, the time of the temperature readings, and your initials. Once the month has ended, save each month’s completed form for 3 years, unless state or local jurisdictions require a longer time period.

If the recorded temperature is in the shaded zone: This represents an unacceptable

temperature range. Follow these steps:

1. **Store the vaccine** under proper conditions as quickly as possible.
2. **Temporarily mark exposed vaccine “do not use”** until you have verified whether or not the vaccine may be used.
3. **Call the immunization program** at your state or local health department and/or the vaccine manufacturer to determine whether the vaccine is still usable: (____) _____.
4. **Document the action taken** on the reverse side of this log.

| Day of Month | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 |
|--------------------------|-------|--|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| Staff Initials | | | | | | | | | | | | | | | |
| Room Temp. | | | | | | | | | | | | | | | |
| Exact Time | | | | | | | | | | | | | | | |
| °F Temp | 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 |
| Refrigerator temperature | ≥49° | Take immediate corrective action if temperature is in shaded section* | | | | | | | | | | | | | |
| | 48° | | | | | | | | | | | | | | |
| | 47° | | | | | | | | | | | | | | |
| | 46° | | | | | | | | | | | | | | |
| | 45° | | | | | | | | | | | | | | |
| | 44° | | | | | | | | | | | | | | |
| | 43° | | | | | | | | | | | | | | |
| | 42° | | | | | | | | | | | | | | |
| | 41° | | | | | | | | | | | | | | |
| | 40° | | | | | | | | | | | | | | |
| 39° | | | | | | | | | | | | | | | |
| 38° | | | | | | | | | | | | | | | |
| 37° | | | | | | | | | | | | | | | |
| 36° | | | | | | | | | | | | | | | |
| 35° | | | | | | | | | | | | | | | |
| Too cold* | 34° | Take immediate corrective action if temperature is in shaded section* | | | | | | | | | | | | | |
| | 33° | | | | | | | | | | | | | | |
| | ≤32° | | | | | | | | | | | | | | |
| Freezer temp | ≥8° | Take immediate corrective action if temperature is in shaded section* | | | | | | | | | | | | | |
| | 7° | | | | | | | | | | | | | | |
| | 6° | | | | | | | | | | | | | | |
| | 5° | | | | | | | | | | | | | | |
| | 4° | | | | | | | | | | | | | | |
| | ≤3°† | | | | | | | | | | | | | | |

Aim for 40°

*Some frozen vaccines must not be stored colder than -58°F. Check the Prescribing Information on the vaccine manufacturer’s website for specific storage temperature instructions.

Adapted by the Immunization Action Coalition courtesy of the Michigan Department of Community Health and the California Department of Health Services.

Vaccine Storage Troubleshooting Record

Use this page to record the details of the vaccine storage incident, including the date and time of the last known temperature within the appropriate vaccine storage range.

| Date | Time | Storage Unit Temp | Room Temp | Incident | Action Taken | Results | Initials |
|------|------|-------------------|-----------|----------|--------------|---------|----------|
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Temperature Log for Refrigerator and Freezer — Fahrenheit

Month/Year: _____ Days 16–31

Completing this temperature log: Check the temperatures in both the freezer and the refrigerator compartments of your vaccine storage units at least twice each working day. Place an “X” in the box that corresponds with the temperature and record the ambient (room) temperature, the time of the temperature readings, and your initials. Once the month has ended, save each month’s completed form for 3 years, unless state or local jurisdictions require a longer time period.

If the recorded temperature is in the shaded zone: This represents an unacceptable

temperature range. Follow these steps:

1. **Store the vaccine** under proper conditions as quickly as possible.
2. **Temporarily mark exposed vaccine “do not use”** until you have verified whether or not the vaccine may be used.
3. **Call the immunization program** at your state or local health department and/or the vaccine manufacturer to determine whether the vaccine is still usable: (____) _____.
4. **Document the action taken** on the reverse side of this log.

| Day of Month | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 | 29 | 30 | 31 |
|--------------------------|-------|--|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| Staff Initials | | | | | | | | | | | | | | | | |
| Room Temp. | | | | | | | | | | | | | | | | |
| Exact Time | | | | | | | | | | | | | | | | |
| °F Temp | 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 |
| Too warm* | ≥49° | | | | | | | | | | | | | | | |
| | 48° | Take immediate corrective action if temperature is in shaded section* | | | | | | | | | | | | | | |
| | 47° | | | | | | | | | | | | | | | |
| Refrigerator temperature | 46° | | | | | | | | | | | | | | | |
| | 45° | | | | | | | | | | | | | | | |
| | 44° | | | | | | | | | | | | | | | |
| | 43° | | | | | | | | | | | | | | | |
| | 42° | | | | | | | | | | | | | | | |
| | 41° | | | | | | | | | | | | | | | |
| | 40° | | | | | | | | | | | | | | | |
| | 39° | | | | | | | | | | | | | | | |
| | 38° | | | | | | | | | | | | | | | |
| | 37° | | | | | | | | | | | | | | | |
| 36° | | | | | | | | | | | | | | | | |
| 35° | | | | | | | | | | | | | | | | |
| Too cold* | 34° | | | | | | | | | | | | | | | |
| | 33° | Take immediate corrective action if temperature is in shaded section* | | | | | | | | | | | | | | |
| | ≤32° | | | | | | | | | | | | | | | |



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|-----------|--------------|------|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Too warm* | Freezer temp | ≥8° | | | | | | | | | | | | | | |
| | | 7° | Take immediate corrective action if temperature is in shaded section* | | | | | | | | | | | | | |
| | | 6° | | | | | | | | | | | | | | |
| | | 5° | | | | | | | | | | | | | | |
| | | 4° | | | | | | | | | | | | | | |
| | | ≤3°† | | | | | | | | | | | | | | |

†Some frozen vaccines must not be stored colder than -58°F. Check the Prescribing Information on the vaccine manufacturer’s website for specific storage temperature instructions.

Adapted by the Immunization Action Coalition courtesy of the Michigan Department of Community Health and the California Department of Health Services.

Vaccine Storage Troubleshooting Record

Use this page to record the details of the vaccine storage incident, including the date and time of the last known temperature within the appropriate vaccine storage range.

| Date | Time | Storage Unit Temp | Room Temp | Incident | Action Taken | Results | Initials |
|------|------|-------------------|-----------|----------|--------------|---------|----------|
| | | | | | | | |
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Temperature Log for Refrigerator and Freezer — Celsius

Month/Year: _____ Days 1–15

Completing this temperature log: Check the temperatures in both the freezer and the refrigerator compartments of your vaccine storage units at least twice each working day. Place an “X” in the box that corresponds with the temperature and record the ambient (room) temperature, the time of the temperature readings, and your initials. Once the month has ended, save each month’s completed form for 3 years, unless state or local jurisdictions require a longer time period.

If the recorded temperature is in the shaded zone: This represents an unacceptable

temperature range. Follow these steps:

1. **Store the vaccine** under proper conditions as quickly as possible.
2. **Temporarily mark exposed vaccine “do not use”** until you have verified whether or not the vaccine may be used.
3. **Call the immunization program** at your state or local health department and/or the vaccine manufacturer to determine whether the vaccine is still usable: (____) _____.
4. **Document the action taken** on the reverse side of this log.

| Day of Month | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | |
|---|------|--|----|----|----|----|----|----|----|----|----|----|----|----|----|----|
| Staff Initials | | | | | | | | | | | | | | | | |
| Room Temp. | | | | | | | | | | | | | | | | |
| Exact Time | | | | | | | | | | | | | | | | |
| °C Temp | am | pm | am | pm | am | pm | am | pm | am | pm | am | pm | am | pm | am | pm |
| <div style="writing-mode: vertical-rl; transform: rotate(180deg);"> Too warm* Refrigerator temperature Too cold* </div> | ≥11° | Take immediate corrective action if temperature is in shaded section* | | | | | | | | | | | | | | |
| | 10° | | | | | | | | | | | | | | | |
| | 9° | | | | | | | | | | | | | | | |
| | 8° | | | | | | | | | | | | | | | |
| | 7° | | | | | | | | | | | | | | | |
| | 6° | | | | | | | | | | | | | | | |
| | 5° | | | | | | | | | | | | | | | |
| | 4° | | | | | | | | | | | | | | | |
| | 3° | | | | | | | | | | | | | | | |
| | 2° | | | | | | | | | | | | | | | |
| | 1° | Take immediate corrective action if temperature is in shaded section* | | | | | | | | | | | | | | |
| 0° | | | | | | | | | | | | | | | | |
| ≤-1° | | | | | | | | | | | | | | | | |



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|---|--------|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| <div style="writing-mode: vertical-rl; transform: rotate(180deg);"> Too warm* Freezer temp </div> | ≥-12° | Take immediate corrective action if temperature is in shaded section* | | | | | | | | | | | | | |
| | -13° | | | | | | | | | | | | | | |
| | -14° | | | | | | | | | | | | | | |
| | -15° | | | | | | | | | | | | | | |
| | -16° | | | | | | | | | | | | | | |
| | ≤-17°† | | | | | | | | | | | | | | |

†Some frozen vaccines must not be stored colder than -50°C. Check the Prescribing Information on the vaccine manufacturer’s website for specific storage temperature instructions.

Adapted by the Immunization Action Coalition courtesy of the Michigan Department of Community Health and the California Department of Health Services.

Vaccine Storage Troubleshooting Record

Use this page to record the details of the vaccine storage incident, including the date and time of the last known temperature within the appropriate vaccine storage range.

| Date | Time | Storage Unit Temp | Room Temp | Incident | Action Taken | Results | Initials |
|------|------|-------------------|-----------|----------|--------------|---------|----------|
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Temperature Log for Refrigerator and Freezer — Celsius

Month/Year: _____ Days 16–31

Completing this temperature log: Check the temperatures in both the freezer and the refrigerator compartments of your vaccine storage units at least twice each working day. Place an “X” in the box that corresponds with the temperature and record the ambient (room) temperature, the time of the temperature readings, and your initials. Once the month has ended, save each month’s completed form for 3 years, unless state or local jurisdictions require a longer time period.

If the recorded temperature is in the shaded zone: This represents an unacceptable

temperature range. Follow these steps:

1. **Store the vaccine** under proper conditions as quickly as possible.
2. **Temporarily mark exposed vaccine “do not use”** until you have verified whether or not the vaccine may be used.
3. **Call the immunization program** at your state or local health department and/or the vaccine manufacturer to determine whether the vaccine is still usable: (____) _____.
4. **Document the action taken** on the reverse side of this log.

| Day of Month | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 | 29 | 30 | 31 |
|----------------|--|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| Staff Initials | | | | | | | | | | | | | | | | |
| Room Temp. | | | | | | | | | | | | | | | | |
| Exact Time | | | | | | | | | | | | | | | | |
| °C Temp | 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 |
| ≥11° | Take immediate corrective action if temperature is in shaded section* | | | | | | | | | | | | | | | |
| 10° | | | | | | | | | | | | | | | | |
| 9° | | | | | | | | | | | | | | | | |
| 8° | | | | | | | | | | | | | | | | |
| 7° | | | | | | | | | | | | | | | | |
| 6° | | | | | | | | | | | | | | | | |
| 5° | | | | | | | | | | | | | | | | |
| 4° | Take immediate corrective action if temperature is in shaded section* | | | | | | | | | | | | | | | |
| 3° | | | | | | | | | | | | | | | | |
| 2° | | | | | | | | | | | | | | | | |
| 1° | | | | | | | | | | | | | | | | |
| ≤-1° | Take immediate corrective action if temperature is in shaded section* | | | | | | | | | | | | | | | |
| 0° | | | | | | | | | | | | | | | | |
| 1° | | | | | | | | | | | | | | | | |
| 2° | | | | | | | | | | | | | | | | |
| 3° | | | | | | | | | | | | | | | | |

Aim for 5°

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|--------|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| ≥-12° | Take immediate corrective action if temperature is in shaded section* | | | | | | | | | | | | | | | |
| -13° | | | | | | | | | | | | | | | | |
| -14° | | | | | | | | | | | | | | | | |
| -15° | | | | | | | | | | | | | | | | |
| -16° | | | | | | | | | | | | | | | | |
| ≤-17°† | Take immediate corrective action if temperature is in shaded section* | | | | | | | | | | | | | | | |
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†Some frozen vaccines must not be stored colder than -50°C. Check the Prescribing Information on the vaccine manufacturer’s website for specific storage temperature instructions.

Adapted by the Immunization Action Coalition courtesy of the Michigan Department of Community Health and the California Department of Health Services.

Vaccine Storage Troubleshooting Record

Use this page to record the details of the vaccine storage incident, including the date and time of the last known temperature within the appropriate vaccine storage range.

| Date | Time | Storage Unit Temp | Room Temp | Incident | Action Taken | Results | Initials |
|------|------|-------------------|-----------|----------|--------------|---------|----------|
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Don't Be Guilty of These Errors in Vaccine Storage and Handling

The following are frequently reported errors in vaccine storage and handling. Some of these errors are much more serious than others, but none of them should occur. Be sure your clinic or practice is not making errors such as these.

Error #1: Designating only one person, rather than at least two, to be responsible for storage and handling of vaccines

Since vaccines are both expensive and fragile, 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. It's very important to train at least one back-up person in all aspects of proper storage and handling of vaccines. 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, how to properly record refrigerator and freezer temperatures, and should be prepared to lead the response to an equipment problem or power outage.

Error #2: Refrigerating vaccine in a manner that could jeopardize its quality

The temperature in the vegetable bins, on the floor, next to the walls, in the door, and near the cold air outlet from the freezer may differ significantly from the temperature in the body of the refrigerator: do not store your vaccines or place thermometers in these locations. Always store vaccines in their original packaging in the body of the refrigerator away from these locations, and place your thermometer with the vaccines. Place vaccine packages in such a way that air can circulate around the compartment. Never overpack a refrigerator compartment.

Error #3: 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.

Error #4: Inadvertently leaving the refrigerator or freezer door open or having inadequate seals

Remind staff to close the unit doors tightly each time they open them. Also, check the seals on the doors on a regular schedule, and if there is any indication the door seal may be cracked or not sealing properly, have it replaced. Replacing a seal is much less costly than replacing a box of pneumococcal conjugate or varicella vaccine.

Error #5: Storing vaccine in a dorm-style refrigerator

All vaccines should be stored in a refrigerator and/or freezer unit that is designed specifically for the storage of biologics or, alternatively, in a separate free-standing unit. A dorm-style combination refrigerator-freezer unit with just one exterior door has been shown to be unacceptable no matter where the vaccine was placed inside the unit. Small stand-alone refrigerator or freezer units are best for short-term storage needs.

Error #6: Recording temperatures only once per day

Temperatures fluctuate throughout the day. Temperatures in the refrigerator and freezer should be checked at the beginning and end of the day to determine if the unit is getting too cold or too warm. Ideally, you should have continuous thermometers that record temperatures all day and all night; those with alarms can alert you when temperatures go out of range. A less expensive alternative is to purchase maximum/minimum thermometers. Only thermometers with a Current Certificate of Traceability and Calibration* should be used for vaccine storage. It's also a good idea to record the room temperature on your temperature log in case there is a problem with the storage unit. This information may

*A calibrated thermometer with a Certificate of Traceability and Calibration with calibration measurements traceable to a testing laboratory accredited by the International Organization of Standardization, to the Standards of the National Institute of Standards and Technology, or to another internationally recognized standards agency.

be helpful to the vaccine manufacturer and/or state immunization program in determining whether your vaccine is still usable.

Error #7: Recording temperatures for only the refrigerator or freezer, rather than both

It is essential to monitor and record temperatures in all refrigerators and freezers used to store vaccine. At all times you should have calibrated thermometers in the refrigerators as well as the freezers. Assure that your storage temperature monitoring is accurate by purchasing thermometers that have a Certificate of Traceability and Calibration* and recalibrate them according to the manufacturer's instructions. Your state immunization program may be able to provide more information on calibrated thermometers.

Error #8: Documenting out-of-range temperatures on vaccine temperature logs but not taking action

Documenting temperatures is not enough. Acting on the information is essential! So, what should you do? Notify your supervisor whenever you have an out-of-range temperature. Sometimes the solution is as simple as shutting a door left ajar or re-checking a freezer temperature that is slightly elevated as it goes through a normal, brief defrost cycle. Check the condition of the unit for problems. Are the seals on the door tight? Is there excessive lint or dust on the coils? After you have made any adjustment, document the date, time, temperature, the nature of the problem, the action you took, and the results of your action. Recheck the temperature every two hours. Call maintenance or a repair person if the temperature is still out of range. If the solution is not quick and easy, you will need to safeguard your vaccines by moving them to another storage unit that is functioning at the proper temperature. Label the affected vaccines "Do not use" and contact your state immunization program or vaccine manufacturer to find out if the affected vaccine is still usable. Be sure to notify your state's VFC Program Coordinator if VFC vaccine was involved.

Error #9: Discarding temperature logs at the end of every month

It's important that you keep your temperature logs for at least three years. As your refrigerator or freezer ages, you can track recurring problems. If out-of-range temperatures have been documented, you can determine how long and how often this has been happening and take appropriate action. It's also a great way to demonstrate why you need a new refrigerator or freezer.

Error #10: Discarding multi-dose vials 30 days after they are opened

Don't discard your multi-dose vials of vaccines prematurely. Almost all multi-dose vaccine vials 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 temperatures. However, you must discard multi-dose vials of reconstituted vaccine (e.g., meningococcal polysaccharide, yellow fever) if they are not used within a defined period after reconstitution. Refer to the vaccine package inserts for detailed information.

Error #11: Not having emergency plans for a power outage or natural disaster

Every clinic should have a written Emergency Response Plan that identifies a refrigerator and freezer in another location (ideally, a storage unit with a back-up generator) in which to store vaccine in the event of a power outage or natural disaster. Consider arranging in advance for a local hospital or similar facility to be your back-up location if you should need it. Be sure back-up location staff understand vaccine storage and will allow you to supervise placement and verify storage temperatures so vaccine is not damaged.

Emergency Response Worksheet

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

Follow these procedures:

1. Close the door tightly and/or plug in the refrigerator/freezer.
2. Ensure the vaccine is kept at appropriate temperatures. Make sure the refrigerator/freezer is working properly or move the vaccines to a unit that is. Do not discard the affected vaccines. Mark the vaccines so that the potentially compromised vaccines can be easily identified.
3. Notify the local or state health department or call the manufacturer (see manufacturers' phone numbers below).
4. Record action taken.

Record this information*:

1. Temperature of refrigerator: current _____ max. _____ min. _____
2. Temperature of freezer: current _____ max. _____ min. _____
3. Air temperature of room where refrigerator is located: _____
4. Estimated amount of time the unit's temperature was outside normal range:
refrigerator _____ freezer _____
5. Vaccines in the refrigerator/freezer during the event (use the table below)

* Using a recording thermometer is the most effective method of tracking the refrigerator and freezer temperatures over time. Visually checking thermometers twice a day is an effective method to identify inconsistent or fluctuating temperatures in a refrigerator and freezer.

Vaccines Stored in Refrigerator

| Vaccine, manufacturer, and lot # | Expiration date | # of doses | # of affected vials | Action taken |
|----------------------------------|-----------------|------------|---------------------|--------------|
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Vaccines Stored in Freezer

| Vaccine, manufacturer, and lot # | Expiration date | # of doses | # of affected vials | Action taken |
|----------------------------------|-----------------|------------|---------------------|--------------|
| | | | | |
| | | | | |
| | | | | |

Other Conditions

1. Prior to this event, was the vaccine exposed to temperatures outside the recommended range? Y N
2. Were water bottles in the refrigerator and ice packs in the freezer at the time of this event? Y N
3. Other: _____

Manufacturers

- Crucell Vaccines Inc. (800) 533-5899
- CSL Biotherapies, Inc. (888) 435-8633
- GlaxoSmithKline (888) 825-5249
- MedImmune, Inc. (877) 633-4411
- Merck & Co., Inc. (800) 672-6372
- Novartis Vaccines (800) 244-7668
- Pfizer Inc. (800) 438-1985
- sanofi pasteur (800) 822-2463

Other Resources

Local health department phone number _____ State health department phone number _____

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, October 2010.

www.immunize.org/catg.d/p3051.pdf • Item #P3051 (10/10)

Checklist for Safe Vaccine Storage and Handling

Here are the most important things you can do to safeguard your vaccine supply. Are you doing them all? Review this list to see where you might make improvements in your vaccine management practices. Fill in each box with either YES or NO.

Establish Storage and Handling Policies

- YES NO 1. We have designated a primary vaccine coordinator and at least one back-up coordinator to be in charge of vaccine storage and handling at our facility.
- YES NO 2. Both the primary and back-up vaccine coordinator(s) have completely reviewed either CDC's online vaccine storage and handling guidance or equivalent training materials offered by our state 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 and handling guidance 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 refrigerator and freezer units designed specifically for storing biologics, including vaccines. Alternatively, we keep frozen and refrigerated vaccines in separate, free-standing freezer and refrigerator units. At a minimum, we use a household-style unit with a separate exterior door for the freezer and separate thermostats for the freezer and refrigerator. We do NOT use a dormitory-style unit (a small combination freezer-refrigerator unit with a freezer compartment inside the refrigerator).
- YES NO 7. We use only calibrated thermometers with a Certificate of Traceability and Calibration* that are recalibrated as recommended by the manufacturer.
- YES NO 8. We have planned back-up storage unit(s) in the event of a power failure or other unforeseen event. We perform regular maintenance to assure optimal functioning.

Ensure Optimal Operation of Storage Units

- YES NO 9. We have a "Do Not Unplug" sign next to the electrical outlets for the refrigerator and freezer and a "Do Not Stop Power" warning label by the circuit breaker for the electrical outlets. Both include emergency contact information.
- YES NO 10. We keep the storage unit clean, dusting the coils and cleaning beneath it every 3–6 months.

Maintain Correct Temperatures

- YES NO 11. We always keep at least one accurate calibrated thermometer (+/-1°C [+/-2°F]) with the vaccines in the refrigerator; ideally, we have a continuous-temperature logger and/or temperature-sensitive alarm system.
- YES NO 12. We maintain the refrigerator temperature at 35–46°F (2–8°C), and we aim for 40°F (5°C).

(Maintain Correct Temperatures continued on page 2)

*Certificate of Traceability and Calibration with calibration measurements traceable to a testing laboratory accredited by the International Organization of Standardization, to the standards of the National Institute of Standards and Technology, or to another internationally recognized standards agency.

(Maintain Correct Temperatures continued from page 1)

- YES NO 13. We keep extra containers of water in the refrigerator (e.g., in the door, on the floor of the unit where the vegetable bins were located) to help maintain cool temperatures.
- YES NO 14. We always keep at least one accurate calibrated thermometer (+/-1°C [+/-2°F]) with vaccines in the freezer.
- YES NO 15. We maintain the average temperature in the freezer at +5°F (-15°C), preferably colder but no colder than -58°F (-50°C).
- YES NO 16. We keep ice packs or ice-filled containers in the freezer to help maintain cold temperatures.

Store Vaccines Correctly

- YES NO 17. We post signs 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 18. We do NOT store any food or drink in any vaccine storage unit.
- YES NO 19. We store vaccines in the middle of the refrigerator or freezer (never in the doors), with room for air to circulate.
- YES NO 20. We have removed all vegetable and deli bins from the storage unit.
- YES NO 21. If we are using a combination refrigerator-freezer unit, we do not store vaccines in front of the cold air outlet that leads from the freezer to the refrigerator (often near the top shelf).
- YES NO 22. We check vaccine expiration dates and rotate our supply of each type of vaccine so that we use the vaccines that will expire soonest.
- YES NO 23. We store vaccines in their original packaging in clearly labeled uncovered containers with slotted sides that allow air to circulate.

Maintain Daily Temperature Logs

- YES NO 24. On days when our practice is open, we document refrigerator and freezer temperatures on the daily log twice a day — first thing in the morning and right before our facility closes.
- YES NO 25. We consistently record temperatures on the log in either Fahrenheit or Celsius. We NEVER mix in any way how we record our temperatures. For example, if the log prompts us to insert an "x" by the temperature that's preprinted on the log, we do not attempt to write in the actual temperature.
- YES NO 26. The logs show whom to call if the temperature in the storage unit goes out of range.
- YES NO 27. When we change the thermostat setting, we document it in the daily log sheet's note section.
- YES NO 28. If out-of-range temperatures occur in the unit, we document in the daily log sheet's note section who responded and when.
- YES NO 29. Trained staff (other than staff designated to record the temperatures) review the logs weekly.
- YES NO 30. We keep the temperature logs on file for at least 3 years.

Take Emergency Action As Needed

31. 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 move the vaccine to our planned back-up storage unit. We address the storage unit's mechanical or electrical problems according to guidance from the manufacturer or repair service.
- YES NO b. 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 c. We temporarily label exposed vaccines "Do not use" and keep them separate from any unexposed vaccines. We do not use exposed vaccines until our state health department's immunization program or the vaccine manufacturer gives us approval.
- YES NO d. We document exactly what happened, noting the temperature in the storage unit and the amount of time the vaccines were out of proper storage conditions. We contact our state health department's immunization program or the vaccine manufacturer to determine how to handle the exposed vaccines.
- YES NO e. We follow the health department or manufacturer's instructions and keep a record detailing the event. Where applicable, we mark the exposed vials with a revised expiration date provided by the manufacturer.

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!

Vaccine Refrigerator Setup

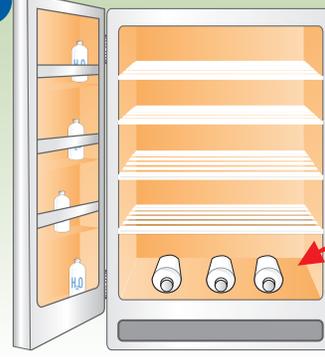
Preparing for Vaccine Storage

1



Vaccines should not be stored in refrigerator doors, drawers, or bins. Remove all drawers and bins.

2



Put a few water bottles and/or cold packs in areas where vaccines will not be stored.

3

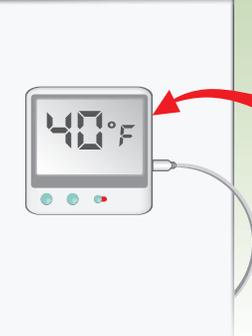


Two thermometers are needed to ensure accurate temperatures. Many practices use a digital thermometer as the primary and a liquid-filled or dial thermometer as the back-up.



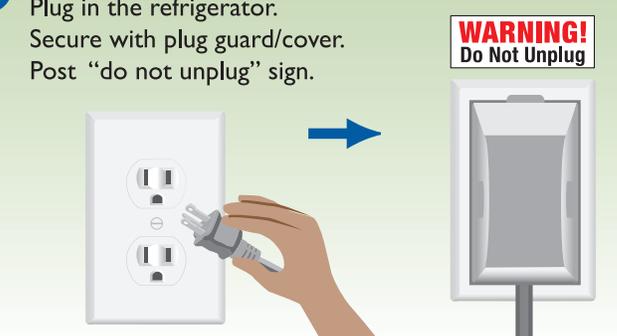
Place the probe of the digital thermometer in the center of the refrigerator. Place the back-up thermometer next to the probe.

4



Attach the display of the digital thermometer to the outside of refrigerator, either on the door or on the side. Set the temperature modes.

5



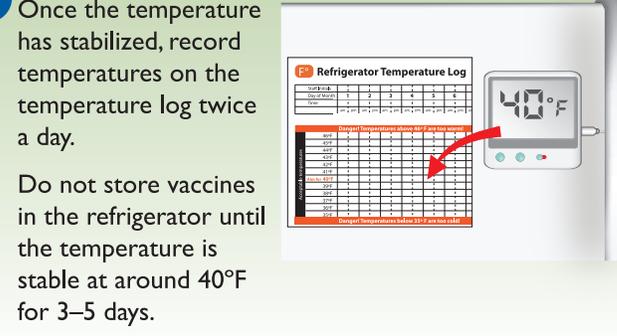
Plug in the refrigerator. Secure with plug guard/cover. Post "do not unplug" sign.

6



Set the refrigerator temperature. If the refrigerator has a thermostat, set it for 40°F. If it has a dial with a range of numbers, set it to slightly warmer than the middle of its range. The next morning, check the temperature and adjust it until it stabilizes at approximately 40°F.

7



Once the temperature has stabilized, record temperatures on the temperature log twice a day. Do not store vaccines in the refrigerator until the temperature is stable at around 40°F for 3–5 days.

Vaccine Freezer Setup

Preparing for Vaccine Storage

1 Put cold packs in areas where vaccines should not be stored, including the freezer door and on the top shelf of the freezer.



Two thermometers are needed to ensure accurate temperatures. Many practices use a digital thermometer as the primary thermometer and a liquid-filled or dial thermometer as the back-up.

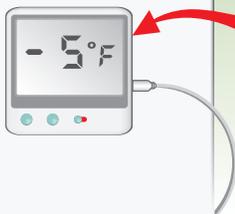


In a stand-alone freezer, place the digital thermometer probe and the back-up thermometer in the center of the freezer, next to the vaccine.



In a combination unit freezer, place the probe of the digital thermometer and the back-up thermometer in the center of the freezer floor.

3 Attach the display of the digital thermometer to the outside of refrigerator, either on the door or on the side.



Set the temperature modes.

4 Plug in the freezer. Secure with plug guard/cover. Post "Do Not Unplug" sign.



5 Set the freezer temperature. If the freezer has a thermostat, set it at -5°F.

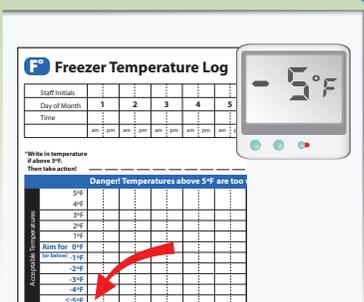


If it has a dial with a range of numbers, set it in the middle.

The next morning, check the temperature and adjust it until it stabilizes below 0°F.

6 Once the temperature has stabilized, start recording temperatures on the temperature log twice a day.

Do not store vaccines in the freezer until the temperature stays below 0°F for 3–5 days.



Vaccine Refrigerator Setup

Storing Vaccines

Carefully organizing vaccines in a refrigerator helps protect vaccine and facilitates vaccine inventory management. Refrigerate all vaccines except MMRV, Varicella, and Zoster.

Refrigerator-only Unit

Almost all of the space is usable (inside dashed lines).

✓ Place vaccine in breathable plastic mesh baskets and clearly label baskets by type of vaccine.

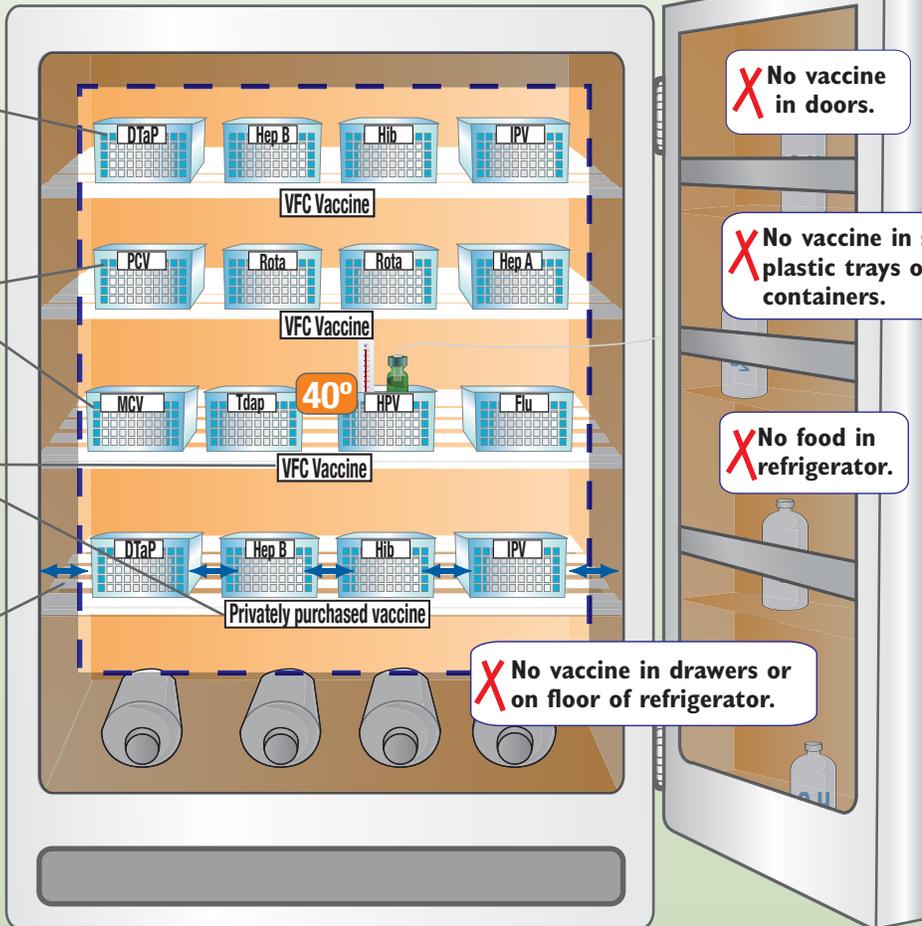
✓ Group vaccines by pediatric, adolescent, and adult types.

✓ Separate the VFC vaccine supply from privately purchased vaccine.

✓ Keep baskets 2-3 inches from walls and other baskets.

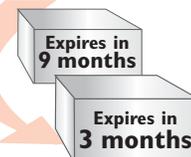
✓ Keep vaccines in their original boxes until you are ready to use them.

✓ Store only vaccine and other medication in vaccine storage units.



✓ Keep vaccines with shorter expiration dates to front of shelf.

If you have vaccine that will expire in 3 months or less that you will not be able to use, notify the VFC Program.



✓ Keep temperatures between 35°F to 46°F.



If you have any problems with your refrigerator, keep the refrigerator door shut and notify the California VFC Program.

• VFC Program Office (877) 243-8832

• VFC Field Representative

Vaccine Freezer Setup

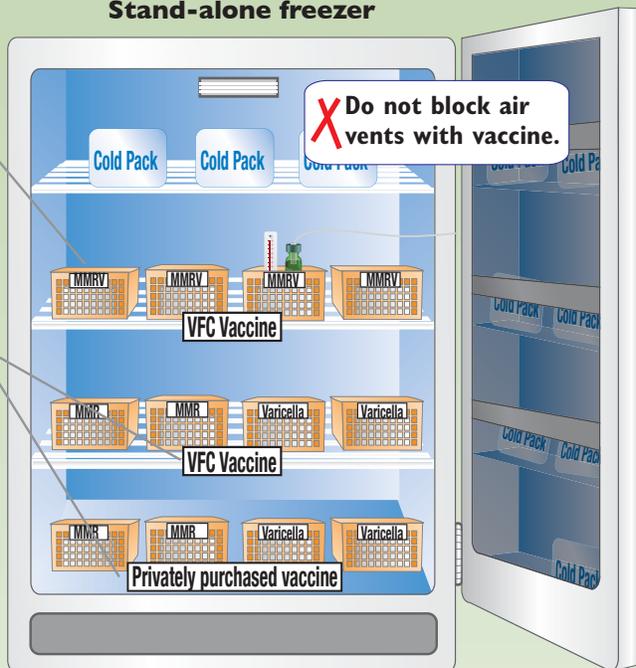
Storing Vaccines

Carefully organizing vaccines in a refrigerator helps protect vaccine and facilitates vaccine inventory management. Freeze MMR, MMRV, Varicella, and Zoster vaccines.

Stand-alone freezer

✓ Place vaccine in breathable plastic mesh baskets and clearly label baskets by type of vaccine.

✓ Separate the VFC vaccine supply from privately purchased vaccine.



✓ Keep vaccines with shorter expiration dates to front of shelf.

If you have vaccine that will expire in 3 months or less that you will not be able to use, notify the VFC Program.



✓ Keep temperatures 5°F or colder.

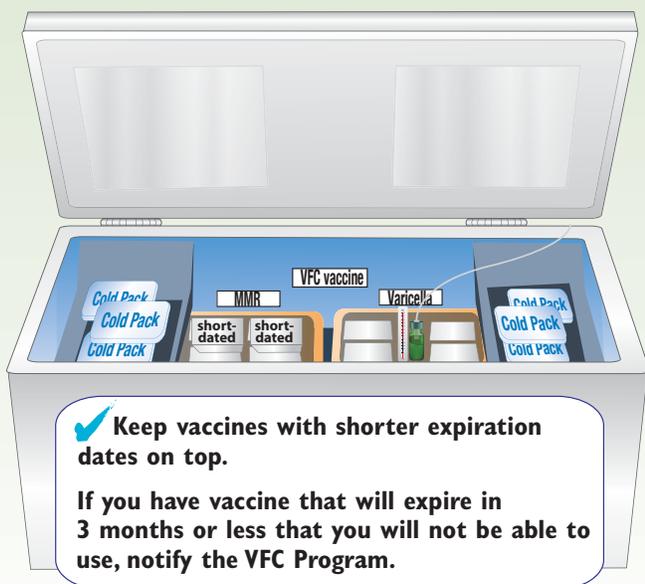
Aim for 0°F and below

Colder is better.

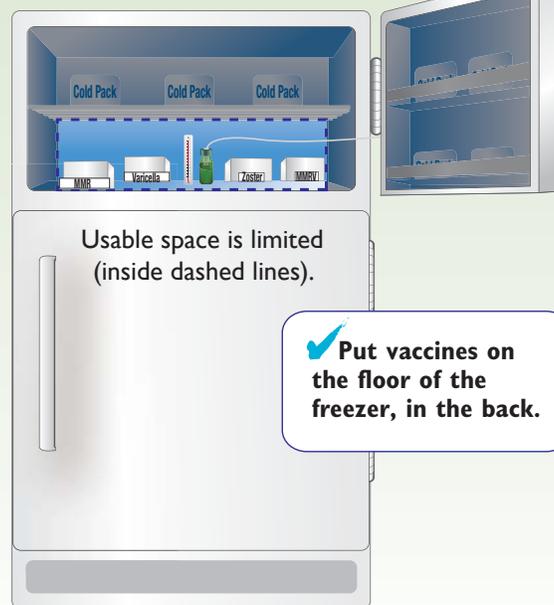


Above 5°F is too warm! Call VFC.

Chest freezer



Freezer in combination unit

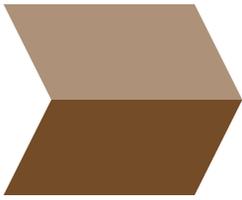


If you have any problems with your refrigerator, keep the refrigerator door shut and notify the California VFC Program.

• VFC Program Office (877) 243-8832

• VFC Field Representative

www.eziz.org



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 have questions about things they have heard that can be addressed at the visit, and others are certain that they do not want any vaccines to be given. Requests for a nonstandard schedule and to avoid particular ingredients are also made to pediatricians.

In the context of a busy schedule with a mix of well and sick children and walk-in and emergency patients, it is a challenge to address all the concerns that are raised. The following section presents resources for health care professionals to use to address common concerns of parents. It also includes resources to be provided to parents to answer their questions. The federal requirements for providing Centers for Disease Control and Prevention (CDC) Vaccine Information Statements (VISs) are provided in a separate section of this guide. A sample of a form prepared by the American Academy of Pediatrics (AAP) to document parental refusal to vaccinate is also provided.

Learning Objectives

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

- Explore parents' concerns about vaccines.
- Explain the reasons for vaccines and the schedule used.
- Describe the requirements for the use of VISs.
- Describe the AAP Refusal to Vaccinate form.
- Describe effective communication techniques for parents and adolescents about recommended vaccines.
- Understand the need for a strong recommendation for human papillomavirus (HPV) vaccine.

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

Immunization of children and adolescents 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. In the past 20 years they have seen the number of infections with hepatitis B, *Haemophilus influenzae*, varicella, *Streptococcus pneumoniae*, HPV, and rotavirus decline. In the future the number of cases of cervical cancer and other sequelae of HPV are expected to decrease.

The effectiveness of these vaccines and earlier vaccines that decreased illnesses such as diphtheria, tetanus, polio, and measles, mumps, and rubella (MMR) has led some parents to believe that all or some vaccines are no longer necessary. A study published in the April 2010 *Pediatrics* (Freed GL, Clark SJ, Butchart AT, Singer DC, Davis MM. Parental vaccine safety concerns in 2009. *Pediatrics*. 2010;125[4]:654-659) shows that 12% of parents have refused at least one vaccine. This study also found that most parents listen to their doctor's recommendations. Therefore, it is important to give a strong recommendation for all vaccines, including those for adolescents, such as HPV.

Health care professionals can address concerns, asking parents what questions they have about each vaccine being refused. VISs from the CDC provide objective information about risks of disease and benefits of vaccines for discussion with parents. Common and rare side effects can be described. Discussion within this framework can provide opportunities to correct misinformation about vaccines.

A common request is that vaccines be administered on a nonstandard schedule. Parents may want to use a schedule they read about in a book or found on the Internet, or they may want to develop their own. It is recommended that health care professionals work with these parents to make sure immunizations are provided. It is important to document that parents have been told that the vaccine schedule has been designed to protect children against diseases when they are most vulnerable and will have the ability to respond effectively to the vaccines. The standard schedule has been tested for safety and effectiveness, but nonstandard schedules have not. 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. It is important to document the request for a nonstandard schedule and discussion of its risks. It is also necessary to have a tracking system to make sure that families return for needed vaccines.

Speaking with adolescents and their parents about vaccines may require a different skill set than speaking with parents of younger children. One technique that may be effective is Motivational Interviewing. Motivational Interviewing is defined as: "a collaborative, person-centered form of guiding to elicit and strengthen motivation for change." If a strong recommendation for adolescents to receive vaccines is met with hesitation, try to use motivational interviewing to encourage a parent's own desires for his or her adolescent to be healthy and protected from

disease to influence his or her decision about vaccines. See the Tools and Resources section for Motivational Interviewing tools and information.

Some cultures and populations may be more sensitive than others when talking about specific topics such as sexual activity, and they might be particularly hesitant to allow their adolescent to receive the HPV vaccine. When communicating with families, explain the benefits and need for this vaccine in a way that affirms cultural background and doesn't challenge cultural beliefs, while including an explanation about it being an immunization to prevent cancer. See the Tools and Resources section for cultural competence tools and information.

Addressing Common Concerns

Following you will find some of the concerns that parents commonly have with vaccinating their child, as well as facts and information you can use to help calm those concerns.

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 do receive a lot of shots, the shots are given at this time because it is at this age that babies are most at risk of illness that can be prevented by vaccines. Some of the illness that vaccines prevent can lead to death or cause liver damage, cardiac disease, or hearing loss, all of which can last a lifetime. These vaccines are given to babies in series of doses to build up immunity. Many studies have been done to ensure that it is safe to give groups of vaccines at the same time. Giving a group of vaccines at the same time will not overwhelm a baby's immune system; babies are exposed to many more antigens on a daily basis than the number given in vaccines. Exposure to antigens occurs every time babies eat, put a toy in their mouth, or play on the floor.

Alternative Schedules

Some parents would prefer to spread out vaccines given to their child and believe an alternative schedule is safer. The reason for giving vaccines to babies on the recommended schedule is to protect them when they are most vulnerable to the diseases the vaccines prevent. The effectiveness and safety of the recommended schedule have been documented in many studies. Alternative schedules that spread out the timing of vaccines or start when a child is older do not provide protection against serious illnesses when infants and young children are most at risk for the diseases. These alternative schedules have not been tested for effectiveness and safety.

Vaccine Ingredients

It is understandable that parents want to know what is in the vaccines that are their children are getting.

Antigens are the substances in vaccines that stimulate the body's immune response to make *antibodies*, cells that protect against infection. Vaccines today contain antigens designed to stimulate the immune system to make antibodies that will protect the body if it comes into contact with bacteria that can cause illnesses like some kinds of

meningitis or pneumonia or if it is exposed to viruses such as MMR or chickenpox. Some of the antigens are killed, and some are live. Live virus vaccines are found in MMR and chickenpox vaccines.

An **adjuvant** is an addition to a vaccine that helps increase the body's immune response to the antigen in the vaccine. Aluminum salts or gels are the only adjuvant used in some vaccines in the United States. These adjuvants make it possible to use smaller amounts of antigens and decrease the number of doses needed. Aluminum salts have been used safely for more than 70 years. Aluminum is in our food, air, and water. Formula and breast milk include aluminum. In fact, the amount of aluminum in vaccines is similar to that found in 33 oz of infant formula. Vaccines that contain aluminum are those that prevent diphtheria, tetanus, and pertussis; hepatitis A; hepatitis B; *H influenzae* type b; HPV; and pneumococcus 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 may lead to autism. Many scientific studies have shown that there is no link between thimerosal and autism. Today, most childhood vaccines do not contain thimerosal. Rates of autism have actually increased since thimerosal was removed from vaccines in 2001. It is still often used during the manufacturing process but then removed, leaving only a very small amount. It is also used in vials that contain more than one dose of vaccine. Influenza vaccine is prepared in multidose vials that contain thimerosal and is also available in single syringes without thimerosal.

Autism

Some parents fear that vaccines might be a cause of autism. Parents want to be assured that they do not expose their child to something harmful. Assure parents that no scientific studies have shown a relationship between MMR vaccine and autism.

In 1998, Dr Andrew Wakefield published a paper about 8 children who reportedly developed autism after receiving MMR vaccine. Over the past decade his article has been retracted from the journal in which it was published. Since then, scientific studies comparing thousands of children who received the vaccine with thousands of children who have not have been completed. These scientific studies have not found a relationship between the vaccine and autism.

Scientific studies about a link between thimerosal and autism have been completed as well. These studies have reported that there is no link between thimerosal and autism. During the past decade, with thimerosal removed from most childhood vaccines, the rate of autism has continued to rise.

My Child Will Not Be Exposed to Sexually Transmitted Infections

Many parents believe that their children will not be exposed to certain diseases. These parents do not understand why hepatitis B vaccine (Hep B) is recommended for their infant, who is not participating in sexual activity or intravenous drug use, which are the typical behaviors

that spread the disease. Let parents know you realize this may be confusing but that it is important to give Hep B vaccine at birth because close contact with caregivers who are infected with hepatitis B during infancy can lead to serious and chronic liver disease. Often, babies get infected with hepatitis B at birth, when the mother doesn't know she is infected. The virus can also spread to the baby during close contact with an infected caregiver, family member, or friend. Most people who are infected with hepatitis B do not feel sick and don't know they carry the virus. Many people have no idea how they became infected with the virus. Vaccination is important to protect all babies before they leave the hospital.

Similarly, parents of adolescents find it difficult to imagine their child engaging in sexual activity, especially because most do wait until they are older. Let parents know that the AAP recommends HPV vaccination at 11 to 12 years of age for several reasons: The immune system of an 11- to 12-year-old responds better to the vaccine than that of an older teen, and a teen needs all 3 doses of the vaccine before ever coming into contact with the virus in order to be fully protected.

One study found that up to 80% of teens or preteens contracted HPV within 2 to 3 years of the first time they engaged in sexual activity, making it important that preteens receive the full series of 3 doses before their first sexual encounter. The CDC reports that as many as 64% of teen or preteen girls may be infected with HPV, and 75% of new cases of HPV are found in persons age 15 to 24 years. Even those who wait until marriage or who have only one partner in the future could still be exposed to HPV.

Using condoms can prevent pregnancy and several sexually transmitted infections. Unfortunately, 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 protection against HPV, parents should have their children vaccinated.

Receiving HPV Vaccine Will Lead My Child to Engage in Sexual Activity

As pediatricians, we understand this concern—we want teens to be mature before sexual activity and to follow their parents' advice about sexual activity. Studies show that children who receive HPV vaccine do not have sex any earlier than those who only received other teen vaccines. This tells us that children do not see this vaccine as a license to have sex.

My Child Does Not Want to Receive an Additional Shot

No one likes to cause discomfort to children or adolescents. Even though a shot may hurt, it is very quick and much easier than suffering from a serious disease such as meningitis or cancer. Talk with patients and parents about ways to reduce pain during vaccination. Stroking the skin or applying pressure to the skin before the shot reduces the pain. Consider offering medication to numb the skin.

Does My Son Really Need HPV If It Prevents Cervical Cancer?

HPV vaccine prevents cervical cancer, which only females can get. But HPV vaccine can protect both males and females from genital warts and cancers of the mouth, throat, anus, and genitals.

A preteen boy who receives HPV vaccine can also protect his future partner. Explain to parents that males who are infected with HPV can spread it without knowing it; people infected with HPV often have no symptoms. There is no routinely used HPV test for men. Completing the HPV vaccination series before the male's first exposure can protect him and his future sexual partner.

Why Is More Than One Dose Needed?

With many infant vaccines, and the HPV vaccine, more than one dose is needed for the body to build up enough immunity to protect against infection. In other cases, such as meningococcal vaccine, one is enough to protect a person, but immunity may wane over time. When this happens, an additional dose can “boost” the immunity back up so that children and adolescents are still fully protected.

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*, and *Clinical Therapeutics*.

Key Facts

- VISs 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. They are also available from state health departments. A state resource should be used if states have immunization registries so that the section about sharing data with the registry is provided to parents, who can opt out of participation in the registry if they choose. Translated VIS sheets are available in a number of languages from the IAC Web site. Remember that it is important that parents or legal representatives understand the content of any VIS sheets that they are given.
- Every discussion of vaccine risk and benefit and the risks of not vaccinating needs to be documented in the chart. The AAP offers a Refusal to Vaccinate form for parents to sign after discussion. It can be updated annually and kept in the chart. Refusal is reversible and should not prevent discussion of vaccines at future visits. The form is accompanied by a list of resources for parents.
- Each vaccine should be strongly recommended by the pediatrician to parents, including HPV vaccine.

Tools and Resources

- Links for additional learning:
 - American Academy of Pediatrics (www.aap.org)
 - Autism Facts (www.aap.org/immunization/families/autismfacts.html)
 - Communicating With Families (www.aap.org/immunization/pediatricians/communicating.html)
 - Ingredients (www.aap.org/immunization/families/ingredients.html)
 - MMR Vaccine & Autism (www.aap.org/immunization/families/mmr.html)
 - Too Many Vaccines? (www.aap.org/immunization/families/toomany.html)
- Centers for Disease Control and Prevention (www.cdc.gov)
 - Addressing Common Concerns (www.cdc.gov/vaccinesafety/Concerns)
 - Human Papillomavirus Pink Book (<http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/hpv.pdf>)
 - Press Briefing: ACIP recommends all 11-12 year-old males get vaccinated against HPV (http://www.cdc.gov/media/releases/2011/t1025_hpv_12yoldvaccine.html)
 - Provider Resources for Vaccine Conversations With Parents (www.cdc.gov/vaccines/spec-grps/hcp/conversations.htm)
- The Children's Hospital of Philadelphia (www.chop.edu)
 - Vaccine Safety FAQs (www.chop.edu/service/vaccine-education-center/vaccine-safety)
- National Network for Immunization Information (<http://www.immunizationinfo.org/parents>)
- Shotbyshot.org: Why Use a Story? (<http://shotbyshot.org/use-a-story>)
- *Pediatrics* (<http://pediatrics.aappublications.org>)
 - “On-time Vaccine Receipt in the First Year Does Not Adversely Affect Neuropsychological Outcomes” (<http://pediatrics.aappublications.org/content/125/6/1134.full>; login required)
 - “The Problem With Dr Bob’s Alternative Vaccine Schedule” (<http://pediatrics.aappublications.org/content/123/1/e164.full>; login required)
 - “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>; login may be required)

- HealthyChildren.org
(<http://www.healthychildren.org>)
- Human Papillomavirus
(<http://www.healthychildren.org/English/health-issues/vaccine-preventable-diseases/Pages/Human-Papillomavirus-%28HPV%29.aspx>)
- HPV Vaccination Does Not Lead to Increased Sexual Activity
(<http://www.healthychildren.org/English/news/Pages/HPV-Vaccination-Does-Not-Lead-to-Increased-Sexual-Activity.aspx>)
- Preteen Immunization: Addressing Common Concerns
(<http://www.healthychildren.org/English/safety-prevention/immunizations/Pages/Vaccinating-Your-Preteen-Addressing-Common-Concerns.aspx>)
- *Disease Markers: "HPV Infections in Adolescents"*
(<http://iospress.metapress.com/content/1257p32552720081/>; login may be required)
- MotivationalInterview.org: Motivational Interview Basics
(http://www.motivationalinterview.org/quick_links/about_mi.html)
- Providers Guide to Quality and Culture
(<http://erc.msh.org/mainpage.cfm?file=1.0.htm&module=provider&language=English&ggroup=&mgroup>)
- Culture, Language and Health Literacy
(<http://www.hrsa.gov/culturalcompetence/index.html>)
- *Clinical Therapeutics: "Physical Interventions and Injection Techniques for Reducing Injection Pain During Routine Childhood Immunization: Systematic Review of Randomized Controlled Trials"*
(<http://www.clinicaltherapeutics.com/article/S0149-2918%2809%2900263-X/abstract>)
- Documents you may include in your personalized manual (included below):
- Strategies for Pediatricians: Addressing Common Concerns of Vaccine-Hesitant Parents
(www.aap.org/immunization/pediatricians/pdf/Vaccine-Hesitant%20Parent_Final.pdf)
- Preteen Immunization: Addressing Common Concerns
(<http://www2.aap.org/immunization/families/faq/AdolescentIZCommonConcerns.pdf>)
- Questions and Answers About Vaccine Ingredients
(www.aap.org/immunization/families/faq/Vaccineingredients.pdf)
- Documenting Parental Refusal to Have Their Child Vaccinated
(<http://www.aap.org/immunization/pediatricians/pdf/RefusaltoVaccinate.pdf>)
- Talking with Parents about Vaccines for Infants
(<http://www.cdc.gov/vaccines/hcp/patient-ed/conversations/downloads/talk-infants-bw-office.pdf>)
- Immunization Action Coalition: MMR Vaccine Does Not Cause Autism
(www.immunize.org/catg.d/p4026.pdf)
- MotivationalInterview.org: An Overview of Motivational Interviewing
(<http://www.motivationalinterview.org/Documents/1%20A%20MI%20Definition%20Principles%20&%20Approach%20V4%20012911.pdf>)



Parental concerns about vaccine safety have risen, posing significant challenges for today's pediatricians. Anti-vaccine Web sites, media attention to false claims about vaccine safety, and a decrease in once-common vaccine-preventable diseases has contributed to the number of parents who question vaccines. Pediatricians are faced with a new challenge of educating parents about the importance of vaccination, benefits and risks of vaccination, and vaccine safety. This resource will assist pediatricians in understanding why parents are hesitant to vaccinate, explain common concerns, and provide resources for addressing parental concerns. A complementary piece to address common concerns is available at:

http://www2.aap.org/immunization/families/faq/FAQ_Safety.pdf

Characteristics of Vaccine-Hesitant Parents

Concerns about vaccine safety are more common among parents of under-immunized children, but many parents of fully immunized children have also expressed concerns.¹ Vaccine-hesitant parents tend to believe they can control their child's susceptibility to disease, have doubts about the reliability of vaccine information, prefer negative outcomes due to inaction (not vaccinating) versus negative outcomes due to action (vaccinating), or rely on herd immunity to protect their child.² Studies show that some parents and physicians follow invalid contraindications, such as not vaccinating a child with a mild illness (e.g., low grade fever), leading to undervaccination. Other characteristics include parents with alternative medical beliefs, those with direct experience with adverse events to vaccines, college graduates, females, and whites.³

Why Some Parents Hesitate to Vaccinate

Vaccine hesitation is associated with perceived risk. Since vaccine-preventable diseases are rare, an adverse event from a vaccine is perceived by the parent to be of greater risk. Risk perception is critical. To illustrate, it is unlikely that anyone in the United States (US) will die of smallpox, but approximately 36,000 people will die of influenza. Yet, parents who question the influenza vaccine express interest in the smallpox vaccine because of risk perception.⁴

Additional characteristics that have been associated with parental hesitance include false beliefs about contraindications, not wanting to deliberately expose healthy children to diseases,⁵ exposure to negative media messages, beliefs that the disease is not harmful, and philosophical and religious beliefs.⁶



¹ Gust DA, Strine TW, Maurice E, et al. Underimmunization among children: effects of vaccine safety concerns on immunization status. *Pediatrics*. 2004; 114:e16-e22

² Meszaros JR, Asch DA, Baron J, Hershey JC, Kunreuther H, Schwartz-Buzaglo J. Cognitive processes and the decisions of some parents to forego pertussis vaccination for their children. *J Clin Epidemiol*. 1996; 49:697-703

³ Gellin BG, Maibach EW, Marcuse EK. Do parents understand immunizations? A national telephone survey. *Pediatrics* 2000; 106(5):1097-1102.

⁴ CDC. Key Facts About Influenza (Flu) & Flu Vaccine. Last updated 2010. <http://www.cdc.gov/flu/keyfacts.htm>.

⁵ Bedford H, Elliman D. Concerns about immunization. *BMJ*. 2000; 320:240-243

⁶ Fredrickson DD, Davis TC, Arnold CL, Kennen EM, Humiston SG, Cross JT, Bocchini JA. Childhood immunization refusal: provider and parent perceptions. *Clinical Research and Methods*. 2004; 36:431-439



Specific Concerns of Parents and Responses

Too Many Shots Too Soon

The CDC and the American Academy of Pediatrics (AAP) recommend vaccination against 16 diseases (including influenza). To be most effective some of these vaccines need to be given more than once. As a result, children may receive up to 29 vaccinations by the time they are 2 years old. A child may receive up to 6 shots during one visit to the doctor. Combination vaccines are a way to protect children from disease, but require fewer needle sticks.

Studies and years of experience show that vaccines used for routine childhood immunizations can be safely given together, at one visit. The vaccines work just as well, and this does not increase the risk of side effects. In addition, the scientific data show that receiving multiple vaccines has no harmful effect on a healthy child's immune system. In a study published in the June 2010 issue of *Pediatrics*, M.J. Smith, et al., conducted a retrospective cohort study of 1,047 children. The children were studied for neurological outcomes, when they were between 7-10 years of age. Researchers found no evidence that receipt of all vaccines on time, during infancy is associated with any undesirable neuropsychological outcomes compared to children who received vaccines on a delayed schedule. They recommend that communicating the information in this study may be helpful to vaccine-hesitant parents.

Resources

Smith, MJ, Woods, CR. On-time Vaccine Receipt in the First Year Does Not Adversely Affect Neuropsychological Outcomes. *Pediatrics*. 2010; 125, 4; 1134-1141-711. Available at: <http://pediatrics.aappublications.org/cgi/content/full/125/6/1134>.

Offitt, PA, et al. Addressing Parents' Concerns: Do Multiple Vaccines Overwhelm or Weaken the Infant's Immune System? *Pediatrics*. 2002; 109, 1: 124-129. Available at: <http://www.pediatrics.org/cgi/content/full/109/1/124>.

AAP. The Childhood Immunization Schedule: Why Is It Like That? Available at: <http://www2.aap.org/immunization/families/faq/Vaccineschedule.pdf>.

Use of Thimerosal as an Additive in Vaccines

Some parents have expressed concerns about a potential link between health problems, particularly autism, and vaccines containing thimerosal. Thimerosal is a preservative that contains a form of mercury (organomercurial). Beginning in the 1930s, thimerosal was used in very small amounts as a preservative in vaccines. Thimerosal is effective in preventing bacterial and fungal contamination, particularly in opened multi-dose vaccine containers. In 1999, the Public Health Service agencies and the AAP recommended that thimerosal be taken out of vaccines as a precautionary measure. By the end of 2001, all routine pediatric vaccines contained no thimerosal or only trace amounts, except for some influenza and Td vaccines. Rates of autism have not fallen since the removal of thimerosal in vaccines. There is no convincing evidence of harm caused by the small amounts of thimerosal in vaccines, except for minor effects like swelling and redness at the injection site due to sensitivity to thimerosal.



Prior to the recent initiative to reduce or eliminate thimerosal from childhood vaccines, the maximum cumulative exposure to mercury via routine childhood vaccinations during the first six months of life was 187.5 micrograms. With the newly formulated vaccines, the maximum cumulative exposure during the first six months of life is less than 3 micrograms of mercury; this represents a greater than 98 percent reduction in the amount of mercury a child would receive from vaccines in the first six months of life. [Influenza (flu) vaccine is not given until six months or older.]

Resources

Ofit PA, Jew RK. Addressing parents' concerns: do vaccines contain harmful preservatives, adjuvants, additives, or residuals? *Pediatrics*. 2003; 112: 1394 – 1397. Available at: <http://pediatrics.aappublications.org/cgi/content/full/112/6/1394>.

AAP. What Parents Should Know About Thimerosal. Available at: <http://www2.aap.org/immunization/families/ingredients.html>.

CDC. Thimerosal. Available at: <http://www.cdc.gov/vaccinesafety/Concerns/thimerosal/>.

CDC. Infant and Environmental Exposures to Thimerosal and Neuropsychological Outcomes at Ages 7 to 10 years. Available at: http://www.cdc.gov/vaccinesafety/vsd/thimerosal_outcomes.

MMR Vaccine and Autism

Autism is a common developmental disability, affecting an estimated 1 in 150 children. Because the MMR vaccine is first given at age 12-15 months, and the first signs of autism (eg, poor social interaction and speech, repetitive behaviors) often appear at 15-18 months of age, concerns have been raised about a possible link between the vaccine and the development of autism.

Studies conducted in the US and Europe have found no association between the MMR vaccine and autism. Over the years, the Institute of Medicine and the AAP have organized several panels of independent scientists to study MMR and autism –all concluded no association between MMR and autism. Research on this topic continues in an effort to assure the safety of vaccines and based in part on this research. Recently the *Lancet*, a prominent British medical journal, retracted a 1998 article linking the MMR vaccines to autism.

Although the cause of autism is unknown in most instances, the theory favored by many experts is that it is a genetically based disorder that occurs before birth. Evidence that genetics is an important, but not exclusive, cause of autism includes a 3-8% risk of recurrence in families with one affected child. Research on the cause of autism is ongoing.



Resources

Halsey NA, Hyman SL, and the Conference Writing Panel. Measles-Mumps-Rubella Vaccine and Autism Spectrum Disorder: A Report from the New Challenges in Childhood Immunizations. Pediatrics. 2001; 107:84. Available at:

<http://pediatrics.aappublications.org/cgi/content/full/107/5/e84>.

Institute of Medicine. Immunization Safety Review. Available at:

<http://www.immunize.org/catg.d/p4026.pdf>.

AAP. MMR Vaccine and Autism: What Parents Need to Know. Available at:

<http://www.aap.org/immunization/families/mmr.html>.

Immunization Action Coalition (IAC). Does MMR Cause Autism? Examine the Evidence.

Available at: <http://www.immunize.org/catg.d/p4026.pdf>.

CDC. Vaccines and Autism Theory. Available at:

<http://www.cdc.gov/vaccinesafety>.

Importance of Hepatitis B Vaccine in Infancy

Some parents believe that the hepatitis B vaccine should not be given to infants and children since it is associated with high-risk behavior including intravenous drug use and sexual activity.

The hepatitis B vaccine is the best protection a child can have against a dangerous and lifelong disease. Before the vaccine was introduced, 20,000 children under the age of 10 became infected each year in the US. Vaccinating early against hepatitis B assures children's immunity when they are the most vulnerable to the worst complications of the disease and before they enter the high-risk adolescent years. Because of common scrapes, falls, and lack of personal hygiene, children (particularly in child care settings) are more exposed to bodily fluids than some adults. Infants who catch hepatitis B from their mothers at birth are at a greater risk of suffering a premature death from liver cancer or liver failure later in life. Even if the mother and the baby are both negative for hepatitis B at birth, it is important to get the vaccine. Since individuals that are infected with hepatitis B often do not feel sick or show symptoms of the disease, they can pass the virus on unknowingly. In two-thirds of the cases of childhood transmission of the virus, the mother was HBsAg (hepatitis B surface antigen) negative but the unvaccinated infant was exposed from a family member or caregiver.

Resources

AAP. Summary - AAP Preference for Birth Dose of Hepatitis B. Available at:

<http://www2.aap.org/immunization/illnesses/hepb/hepb.html>

IAC. Give the Birth Dose: Hepatitis B Vaccine at Birth Saves Lives. Available at:

<http://www.immunize.org/catg.d/p2125.pdf>.

CDC. Hepatitis B. Available at:

<http://www.cdc.gov/vaccines/vpd-vac/hepb/default.htm>.



Relative Danger of Influenza (need for yearly vaccination)

Some parents question the need for a yearly dose of the flu vaccine. They believe that influenza is a relatively mild disease (one that they have had and have survived) and that the risk of vaccination outweighs the risk of the disease. Parents also may have concerns about thimerosal in the flu vaccine (see above).

Influenza is a serious disease, and people of any age can get it. In an average year, the flu causes 36,000 deaths and 200,000 hospitalizations in the US. The “flu season” is usually from November-April each year. An annual flu vaccine (either the flu shot or the nasal-spray flu vaccine [in recommended age groups]) is the best way to reduce circulation of the flu. Annual shots are necessary because flu viruses change from year to year. This means that a person can get the flu more than once during their lifetime. The immunity that is built up from having the flu caused by one virus strain doesn’t always provide protection when a new strain is circulating. In other words, a vaccine made against flu viruses circulating last year may not protect against the newer viruses. Further, immunity to the disease declines over time and may be too low to provide protection after one year.

Resources

CDC. Questions & Answers: Thimerosal-Containing Influenza Vaccine. Available at:
<http://www.cdc.gov/flu/about/qa/thimerosal.htm>.

CDC. Influenza Web site. Available at:
<http://www.cdc.gov/flu>.

AAP Childhood Immunization Support Program. Influenza Guidance Web site. Available at:
<http://www2.aap.org/immunization/pediatricians/influenzguidance.html>

Relative Danger of Varicella Vaccine

Some parents question the need for the varicella vaccine. Like influenza, they believe that chickenpox is a harmless illness and that the risk of vaccination outweighs the risk of the disease.

In 1999, an average of 1 child per week died in the US from complications of chickenpox. These complications include encephalitis, a brain infection; severe staph and strep secondary infections (flesh-eating strep and toxic shock syndrome); hepatitis; and pneumonia.

Before the vaccine, there were 4 million cases of chickenpox, 11,000 hospitalizations, and 100 deaths per year in the US. The varicella vaccine prevents chickenpox in about 70-90% of people who get the shot and prevents severe chickenpox in over 95%.



Resources

CDC. Varicella Vaccine Web site. Available at:

<http://www.cdc.gov/vaccines/vpd-vac/varicella/default.htm>.

AAP Committee on Infectious Diseases. Prevention of Varicella: Recommendations for Use of Varicella Vaccines in Children, Including a Recommendation for a Routine 2-Dose Varicella Immunization Schedule. *Pediatrics*. 2007; 120: 221-231. Available at:

<http://pediatrics.aappublications.org/cgi/content/full/120/1/221>.

Strategies for Communicating with Vaccine-Hesitant Parents

As the occurrence of vaccine-preventable diseases declines, the challenge of communicating the risk of not being immunized increases.⁷ Every situation is unique; parents have diverse concerns for various reasons. Including:

- To determine parental concerns, ask the following questions:⁸
 - Do you have any cultural, religious, or personal belief regarding immunization?
 - Has your child or any child you know has a serious adverse event after an immunization?
 - Do you have any vaccine safety concerns?
 - What vaccine safety information can I provide?
- Be sure to listen to parents' concerns and acknowledge them in a nonconfrontational manner. Allowing parents to express their concerns will increase their willingness to listen to the pediatrician's views.⁹
- 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.¹⁰ The majority of parents believe immunization is important and trust pediatricians as the most important source of immunization information.

If, after discussion about the benefits of vaccination and the risks of not vaccinating, the parent refuses, you should document the discussion and have the parent sign a waiver affirming the decision not to vaccinate. If the situation becomes such that you are no longer comfortable treating the parent/patient, the AAP manual, "Medical Liability for Pediatricians," offers resources for termination of the physician-patient relationship.

⁷ Bostrom A. Vaccine risk communication: lessons from risk perception, decision making and environmental risk communication research. *Risk: Health Safety Environ*. 1997; spring: 173-200

⁸ Red Book 2003: Report of the Committee on Infectious Diseases. American Academy of Pediatrics, 6-7

⁹ Kimmel SR, Wolfe RM. Communicating the benefits and risks of vaccines. *The Journal of Family Practice*. 2005; 54:S51-S57

¹⁰ 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



Additional Resources

AAP Refusal to Vaccinate Form. Available at:

<http://www2.aap.org/immunization/pediatricians/pdf/RefusaltoVaccinate.pdf>

AAP Policy Statement: *Responding to Parental Refusals of Immunization of Children* Available at: <http://pediatrics.aappublications.org/content/115/5/1428.abstract?sid=9024f777-2348-4779-8b64-66666d57ba1a>.

CDC. Provider Resources for Vaccine Conversations with Parents. Available at:

<http://www.cdc.gov/vaccines/hcp/patient-ed/conversations/index.html>

Immunization Action Coalition. Responding to Concerns About Vaccines. Available at:

<http://www.immunize.org/concerns>.

CDC. Six Common Misconceptions About Vaccinations and How to Respond to Them.

Available at: <http://www.cdc.gov/vaccines/vac-gen/6mishome.htm>.

IAC. Reliable Sources of Immunization Information. Available at:

www.immunize.org/catg.d/p4012.pdf.

National Network for Immunization Information. Evaluating Information on the Web. Available at: www.immunizationinfo.org/parents/evaluatingWeb.cfm.



As a parent, you may have questions about vaccines for your pre-teen. Below is the information you need from pediatricians to be confident about your decision to vaccinate.

HPV Vaccine

If my child is not sexually active, why does he/she need HPV vaccine?

While it's difficult to imagine your child engaging in sexual activity, especially since most do wait until they are in the second half of their teen years to have sex, the AAP recommends HPV vaccination at 11-12 years of age for several reasons. HPV is spread by intimate skin-to-skin contact, not just sex. People need all 3 doses of the vaccine *before* ever coming into contact with the virus in order to be protected. Also, the immune system of an 11-12 year old responds better to the vaccine than that of an older teen.^{1,2}

One study found that up to 80% of teens or pre-teens contracted HPV within 2-3 years of the first time they engaged in sexual activity,³ making it important that pre-teens receive the full series of 3 doses before first sexual activity. The Centers for Disease Control and Prevention (CDC) reports that as many as 64% of teen or pre-teen girls may be infected with HPV, and 75% of new cases of HPV are found in persons age 15-24 years.⁴ Even if your child waits until he/she is married and/or only has one partner in the future, your child could still be exposed to HPV by that partner.

Will receiving HPV vaccine give my child permission to engage in sexual activity?

As pediatricians, we understand this concern—we want teens to be mature before sexual activity and to follow their parents' advice about sexual activity. Studies show that children who receive HPV vaccine do not have sex any earlier than those who only received other teen vaccines. This tells us that children do not see this vaccine as a license to have sex.⁵

Why does my son need HPV vaccine if it protects against cervical cancer?

HPV vaccine prevents cervical cancer, which, of course, only females can get. But HPV vaccine can protect both males and females by preventing genital warts and cancers of the mouth, throat, anus, and genitals.

A pre-teen boy who receives HPV vaccine can also protect his future partner. Men and women infected with HPV often have no symptoms. Women can get cervical cancer screening, but there is no such test for men. Men who are infected and don't know it can spread HPV to a partner.

Don't condoms prevent the spread of HPV?

Using condoms can prevent pregnancy and protect against several sexually transmitted infections. Unfortunately, HPV can be spread by intimate skin-to-skin contact and oral sex, not just sexual intercourse. Condoms only cover a limited amount of skin and HPV can be spread even if a condom is used every time a person has sex. For the best protection against HPV, parents should have their children vaccinated.



¹ CDC Press Briefing. ACIP recommends all 11-12 year-old males get vaccinated against HPV. Tuesday, October 25, 2011 – 12:45pm ET. Access on April 4, 2013 at: http://www.cdc.gov/media/releases/2011/t1025_hpv_12yroldvaccine.html.

² Food and Drug Administration. Highlights of prescribing information. Gardasil (human papillomavirus quadrivalent [types 6, 11, 16 and 18]). 2011. Available at <http://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm111263.pdf>. Accessed April 5, 2013.

³ Moscicki AB. HPV infections in adolescents. 207. *Disease Markers*, 23, 4, 229-34.

⁴ Human Papillomavirus. Pink Book. CDC. Available at: <http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/hpv.pdf>. Accessed April 9, 2013.

⁵ Bednarczyk RA, Davis R, Ault K, Orenstein W, Omer Saad. Sexual Activity–Related Outcomes After Human Papillomavirus Vaccination of 11- to 12-Year-Olds. 2012. *Pediatrics*. <http://pediatrics.aappublications.org/content/early/2012/10/10/peds.2012-1516.abstract> (login may be required)



Do adolescent vaccines have serious side effects?

Pain: Pediatricians do not like to cause discomfort to children of any age. Even though shots may hurt, getting a vaccine is not as bad as suffering from a serious disease such as meningitis or cancer. Talk with your pediatrician about ways to reduce pain during vaccination. Stroking the skin or applying pressure to the skin before the shot reduces the pain.⁶ In some offices, medication to numb the skin may be available.

Fainting: Your pediatrician may ask your child to sit for 15 minutes after getting a shot in case your child faints (syncope). Staying seated for 15 minutes reduces the main risk from fainting-- getting hurt from falling.

Vaccination at sick visits: Many families are busy and it is hard to find time to visit the pediatrician's office to get a shot. It is smart to get any vaccines that are due when your child is in the pediatrician's office. This will reduce the chance that your child has to miss school, work, or other activities to receive vaccines.

Safety: All vaccines routinely recommended for pre-teens have been licensed by the Food and Drug Administration and found to be safe. The safety of each vaccine continues to be checked after it is licensed. Your pediatrician can provide you with a Vaccine Information Statement that explains the mild side effects that can occur after receiving shots.

Why is more than one dose of vaccine needed?

HPV vaccine: It is recommended that your child receives 3 doses of HPV vaccine at ages 11-12 for full protection. All 3 doses of the HPV vaccine are needed for the body to build up enough immunity to protect against infection. This is also true of many of the vaccines that babies get.

Meningococcal vaccine: One dose of meningococcal vaccine protects a person, but immunity may wane over time. A booster dose can "boost" immunity so that your child is still fully protected. Children should receive meningococcal vaccine as pre-teens to be fully protected for a few years and another dose at age 16 to boost immunity levels.

Tdap: Recently, there have been several outbreaks of pertussis (whooping cough) throughout the United States. One study has shown that this is due, in part, to waning immunity.⁸ It is possible that booster doses of pertussis vaccine (in Tdap) will be recommended in the future. Studies are still underway to determine exactly if and when they will be needed.

What is the cost of these vaccines? I'm not sure if I can afford them or if my insurance will cover them.

Pediatricians realize that healthcare can be costly for families. The Affordable Care Act (ACA) requires insurance companies to cover the cost of all recommended vaccines, which include those for teens and pre-teens. If your insurance plan has been unchanged since March 23, 2010, it may not have to follow these new rules. If this is the case, your insurance plan may require you to pay part of the vaccination cost or meet your deductible before it will pay for vaccinations. Talk with your pediatrician about options for paying this.

If your child does not have health insurance, has Medicaid or insurance that does not cover vaccines, or is American Indian or Alaskan Native, he/she qualifies to receive vaccines at no cost through the Vaccines for Children (VFC) Program. Most pediatricians provide VFC vaccines. If your pediatrician is not a VFC provider, your child should be able to receive vaccines at your local health department. Speak with your child's pediatrician to learn more about the VFC program or visit: <http://www.cdc.gov/vaccines/programs/vfc/parents/ga-detailed.html>. To contact your VFC state, city or territory coordinator visit: <http://www.cdc.gov/vaccines/programs/vfc/contacts-state.html>.

Last updated 7/2013

⁶ Taddio A, Ilersich AL, Ipp M, Kikuta A, Shah V. 2009. Physical Interventions and Injection Techniques for Reducing Injection Pain During Routine Childhood Immunization: Systematic Review of Randomized Controlled Trials. *Clinical Therapeutics*, 31, Supplement 2, S48-76.

⁷ Reis EC, Holubkov R. Vapocoolant Spray Is Equally Effective as EMLA Cream in Reducing Immunization Pain in School-aged Children. 1997. *Pediatrics*, 100, 6, e5.

⁸ Tartof SY, Lewis M, Kenyon C, White K, Osborn A, Liko J, Zell E, Martin S, Messonnier NE, Clark TA, and Skoff TH. Waning Immunity to Pertussis Following 5 Doses of DTaP. 2013. *Pediatrics*, 131, 4, e1047-52.



Questions and Answers about Vaccine Ingredients

Q. What ingredients are in vaccines?

A. 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 vaccines 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. In the United States, the polio, hepatitis A, influenza 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 vaccines.
- **Partial bacteria.** These 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, 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 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 Centers for Disease Control and Prevention 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>.

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 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 the ingredients in vaccines continue to be the safest and best available for children.

The information contained in this publication should not be used as a substitute for the medical care and advice of your pediatrician. There may be variations in treatment that your pediatrician may recommend based on individual facts and circumstances.



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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/

Dennis Murray, MD, FAAP
Chairperson

AAP Section on Infectious Diseases

/s/

Ed Rothstein, MD, FAAP

AAP Section on Infectious Diseases

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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 vaccine | <input type="checkbox"/> |
| <input type="checkbox"/> Other _____ | <input type="checkbox"/> |

- 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.

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).

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 and

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*. 4th ed. West Islip, NY: Professional Communications, Inc; 2012

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.

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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

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.



American Academy
of Pediatrics



DEDICATED TO THE HEALTH OF ALL CHILDREN™

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!

In February 1998, *The Lancet* published an article titled “Ileal-Lymphoid-Nodular Hyperplasia, Non-Specific Colitis, and Pervasive Developmental Disorder in Children,” which suggested that MMR vaccine could contribute to the development of autism. Intense media coverage of the article followed its publication, and many parents, particularly in the UK, refused MMR vaccination of their children.

In 2004, *The Lancet* published a retraction submitted by 10 of the 13 original authors. The authors stated that there was no connection between the MMR vaccine and the bowel disease/autism syndrome.

In 2008, the number of articles published in peer-reviewed medical journals that refute a connection between MMR vaccine and autism totals more than 20; whereas the number of articles that suggest a connection between the vaccine and autism stands at 3.

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

25 studies that refute a connection between MMR vaccine and the development of autism

25. *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 doi:10.1371/journal.pone.0003140 *Subjects: 25 children with autism and GI disturbances and 13 children with GI disturbances alone (controls)
24. *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
23. *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.)
22. *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
21. *Immunizations and Autism: A Review of the Literature.* Doja A, Roberts W. Can J Neurol Sci. 2006; 33(4):341-6 *Literature review
20. *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
19. *Relationship between MMR Vaccine and Autism.* Klein KC, Diehl EB. Ann Pharmacother. 2004; 38(7-8):1297-300 *Literature review of 10 studies
18. *Immunization Safety Review: Vaccines and Autism.* Institute of Medicine. The National Academies Press: 2004 (www.nap.edu/books/030909237X/html) *Literature review
17. *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

(continued on next page)

3 studies that suggested a connection between MMR vaccine and the development of autism

3. *Potential Viral Pathogenic Mechanism for a New Variant Inflammatory Bowel Disease.* Uhlmann V et al. Mol Pathol 2002; 55(2):84-90 *Subjects: 91 patients with a confirmed diagnosis of ileal lymphonodular hyperplasia and enterocolitis and 70 controls
★ Read about limitations of this study:
www.cdc.gov/vaccinesafety/concerns/mmr_autism_factsheet.htm
2. *Ileal-Lymphoid-Nodular Hyperplasia, Non-Specific Colitis, and Pervasive Developmental Disorder in Children.* Wakefield AJ et al. Lancet 1998; 351(9103):637-41 *Subjects: 12 children with chronic enterocolitis and regressive developmental disorder
★ Read about limitations of this study:
www.immunize.org/catg.d/p2065.pdf
★ “A Statement by the Editors of the Lancet,” Lancet 2004; 363(9411):820-1, regarding this paper and an undisclosed potential conflict of interest: [www.thelancet.com/journals/lancet/article/PIIS0140-6736\(04\)15699-7/fulltext](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(04)15699-7/fulltext)
★ “Retraction of an Interpretation,” Lancet 2004; 363(9411):750
Go to www.thelancet.com and register (no charge) to access this article.
1. *Evidence of Persistent Measles Virus Infection in Crohn's Disease.* Wakefield AJ et al. J Med Virol 1993; 39(4):345-53 *Subjects: Electron microscopy specimens from Crohn's disease and control patients
★ The validity of this finding has been called into question when it could not be reproduced by other researchers (Nielsen et al., Jones et al., Feeney et al., Hermon-Taylor, Liu et al., Haga, Iizuka, Afzal).

(page 1 of 2)

25 studies that refute a connection between MMR vaccine and the development of autism

16. *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
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
14. *Neurologic Disorders after Measles-Mumps-Rubella Vaccination.* Make-la A et al. *Pediatrics* 2002; 110:957-63 *Subjects: 535,544 children vaccinated between November 1982 and June 1986 in Finland
13. *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
12. *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
11. *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
10. *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)
9. *Measles-Mumps-Rubella and Other Measles-Containing Vaccines Do Not Increase the Risk for Inflammatory Bowel Disease: A Case-Control Study from the Vaccine Safety Datalink Project.* Davis RL et al. *Arch Pediatr Adolesc Med* 2001;155(3):354-9 *Subjects: 155 persons with IBD with up to 5 controls each
8. *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)
7. *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
6. *Further Evidence of the Absence of Measles Virus Genome Sequence in Full Thickness Intestinal Specimens from Patients with Crohn's Disease.* Afzal MA, et al. *J Med Virol* 2000; 62(3):377-82 *Subjects: Specimens from patients with Crohn's disease
5. *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
4. *Absence of Detectable Measles Virus Genome Sequence in Inflammatory Bowel Disease Tissues and Peripheral Blood Lymphocytes.* Afzal MA et al. *J Med Virol* 1998; 55(3):243-9 *Subjects: 93 colonoscopic biopsies and 31 peripheral blood lymphocyte preparations
3. *No Evidence for Measles, Mumps, and Rubella Vaccine-Associated Inflammatory Bowel Disease or Autism in a 14-year Prospective Study.* Peltola H et al. *Lancet* 1998; 351:1327-8 *Subjects: 3,000,000 doses of MMR vaccine
2. *Exposure to Measles in Utero and Crohn's Disease: Danish Register Study.* Nielsen LL et al. *BMJ* 1998; 316(7126):196-7 *Subjects: 472 women with measles
1. *Immunocytochemical Evidence of Listeria, Escherichia coli, and Streptococcus Antigens in Crohn's Disease.* Liu Y et al. *Gastroenterology* 1995; 108(5):1396-1404 *Subjects: Intestines and mesenteric lymph node specimens from 21 persons from families with a high frequency of Crohn's disease

A Definition of Motivational Interviewing

The definition of Motivational Interviewing (MI) has evolved and been refined since the original publications on its utility as an approach to behavior change. The initial description, by William R. Miller in 1983, developed from his experience in the treatment of problem drinkers. Through clinical experience and empirical research, the fundamental principles and methodologies of MI have been applied and tested in various settings and research findings have demonstrated its efficacy. MI is now established as an evidence-based practice in the treatment of individuals with substance use disorders.

Motivational Interviewing focuses on exploring and resolving ambivalence and centers on motivational processes within the individual that facilitate change. The method differs from more “coercive” or externally-driven methods for motivating change as it does not impose change (that may be inconsistent with the person's own values, beliefs or wishes); but rather supports change in a manner congruent with the person's own values and concerns.

The most recent definition of Motivational Interviewing (2009) is:

“ . . . a collaborative, person-centered form of guiding to elicit and strengthen motivation for change.”

The Motivational Interviewing Approach

Motivational Interviewing is grounded in a respectful stance with a focus on building rapport in the initial stages of the counseling relationship. A central concept of MI is the identification, examination, and resolution of ambivalence about changing behavior.

Ambivalence, feeling two ways about behavior change, is seen as a natural part of the change process. The skillful MI practitioner is attuned to client ambivalence and “readiness for change” and thoughtfully utilizes techniques and strategies that are responsive to the client.

Recent descriptions of Motivational Interviewing include three essential elements:

1. MI is a particular kind of conversation about change (counseling, therapy, consultation, method of communication)
2. MI is collaborative (person-centered, partnership, honors autonomy, not expert-recipient)
3. MI is evocative (seeks to call forth the person's own motivation and commitment)

These core elements are included in three increasingly detailed levels of definition:

Lay person's definition (What's it for?): Motivational Interviewing is a collaborative conversation to strengthen a person's own motivation for and commitment to change.

A pragmatic practitioner's definition (Why would I use it?): Motivational Interviewing is a person-centered counseling method for addressing the common problem of ambivalence about change.

A technical therapeutic definition (How does it work?): Motivational Interviewing is a collaborative, goal-oriented method of communication with particular attention to the language of change. It is designed to strengthen an individual's motivation for and movement toward a specific goal by eliciting and exploring the person's own arguments for change.

The "Spirit" of Motivational Interviewing

MI is more than the use of a set of technical interventions. It is characterized by a particular "spirit" or clinical "way of being" which is the context or interpersonal relationship within which the techniques are employed.

The spirit of MI is based on three key elements: **collaboration** between the therapist and the client; **evoking or drawing out** the client's ideas about change; and emphasizing the **autonomy** of the client.

- **Collaboration (vs. Confrontation)**

Collaboration is a partnership between the therapist and the client, grounded in the point of view and experiences of the client.

This contrasts with some other approaches to substance use disorders treatment, which are based on the therapist assuming an "expert" role, at times confronting the client and imposing their perspective on the client's substance use behavior and the appropriate course of treatment and outcome.

Collaboration builds rapport and facilitates trust in the helping relationship, which can be challenging in a more hierarchical relationship. This does not mean that the therapist automatically agrees with the client about the nature of the problem or the changes that may be most appropriate. Although they may see things differently, the therapeutic process is focused on mutual understanding, not the therapist being right.

- **Evocation (Drawing Out, Rather Than Imposing Ideas)**

The MI approach is one of the therapist's drawing out the individual's own thoughts and ideas, rather than imposing their opinions as motivation and commitment to change is most powerful and durable when it comes from the client. No matter what reasons the therapist might offer to convince the client of the need to change their behavior or how much they might want the person to do so, lasting change is more likely to occur when the client discovers their own reasons and determination to change. The therapist's job is to "draw out" the person's own motivations and skills for change, not to tell them what to do or why they should do it.

- **Autonomy (vs. Authority)**

Unlike some other treatment models that emphasize the clinician as an authority figure, Motivational Interviewing recognizes that the true power for change rests within the client. Ultimately, it is up to the individual to follow through with making changes happen. This is empowering to the individual, but also gives them responsibility for their actions. Counselors reinforce that there is no single "right way" to change and that there are

multiple ways that change can occur. In addition to deciding whether they will make a change, clients are encouraged to take the lead in developing a “menu of options’ as to how to achieve the desired change.

The Principles of Motivational Interviewing

Building on and bringing to life the elements of the MI “style”, there are four distinct principles that guide the practice of MI. The therapist employing MI will hold true to these principles throughout treatment.

- **Express Empathy**

Empathy involves seeing the world through the client's eyes, thinking about things as the client thinks about them, feeling things as the client feels them, sharing in the client's experiences. This approach provides the basis for clients to be heard and understood, and in turn, clients are more likely to honestly share their experiences in depth. The process of expressing empathy relies on the client’s experiencing the counselor as able to see the world as they (the client) sees it.

- **Support Self-Efficacy**

MI is a strengths-based approach that believes that clients have within themselves the capabilities to change successfully. A client's belief that change is possible (self-efficacy) is needed to instill hope about making those difficult changes. Clients often have previously tried and been unable to achieve or maintain the desired change, creating doubt about their ability to succeed. In Motivational Interviewing, counselors support self-efficacy by focusing on previous successes and highlighting skills and strengths that the client already has.

- **Roll with Resistance**

From an MI perspective, resistance in treatment occurs when then the client experiences a conflict between their view of the “problem” or the “solution” and that of the clinician or when the client experiences their freedom or autonomy being impinged upon. These experiences are often based in the client’s ambivalence about change. In MI, counselors avoid eliciting resistance by not confronting the client and when resistance occurs, they work to de-escalate and avoid a negative interaction, instead "rolling with it." Actions and statements that demonstrate resistance remain unchallenged especially early in the counseling relationship. By rolling with resistance, it disrupts any “struggle” that may occur and the session does not resemble an argument or the client’s playing "devil's advocate" or “yes, but” to the counselor's suggestions. The MI value on having the client define the problem and develop their own solutions leaves little for the client to resist. A frequently used metaphor is “dancing” rather than “wrestling” with the client. In exploring client concerns, counselors invite clients to examine new points of view, and are careful not to impose their own ways of thinking. A key concept is that counselor’s avoid the “righting

reflex”, a tendency born from concern, to ensure that the client understands and agrees with the need to change and to solve the problem for the client.

- **Develop Discrepancy**

Motivation for change occurs when people perceive a mismatch between “where they are and where they want to be”, and a counselor practicing Motivational Interviewing works to develop this by helping clients examine the discrepancies between their current circumstances/behavior and their values and future goals. When clients recognize that their current behaviors place them in conflict with their values or interfere with accomplishment of self-identified goals, they are more likely to experience increased motivation to make important life changes. It is important that the counselor using MI does not use strategies to develop discrepancy at the expense of the other principles, yet gradually help clients to become aware of how current behaviors may lead them away from, rather than toward, their important goals.

Motivational Interviewing Skills and Strategies

The practice of Motivational Interviewing involves the skillful use of certain techniques for bringing to life the “MI spirit”, demonstrating the MI principles, and guiding the process toward eliciting client change talk and commitment for change. Change talk involves statements or non-verbal communications indicating the client may be considering the possibility of change.

OARS

Often called micro counseling skills, OARS is a brief way to remember the basic approach used in Motivational Interviewing. **Open Ended Questions, **Affirmations, Reflections, and Summaries** are core counselor behaviors employed to move the process forward by establishing a therapeutic alliance and eliciting discussion about change.**

- **Open-ended questions** are those that are not easily answered with a "yes/no" or short answer containing only a specific, limited piece of information. Open-ended questions invite elaboration and thinking more deeply about an issue. Although closed questions have their place and are at times valuable (e.g., when collecting specific information in an assessment), open-ended questions create forward momentum used to help the client explore the reasons for and possibility of change.
- **Affirmations** are statements that recognize client strengths. They assist in building rapport and in helping the client see themselves in a different, more positive light. To be effective they must be congruent and genuine. The use of affirmations can help clients feel that change is possible even when previous efforts have been unsuccessful. Affirmations often involve reframing behaviors or concerns as evidence of positive client qualities. Affirmations are a key element in facilitating the MI principle of Supporting Self-efficacy.

- **Reflections** or reflective listening is perhaps the most crucial skill in Motivational Interviewing. It has two primary purposes. First is to bring to life the principle of Expressing Empathy. By careful listening and reflective responses, the client comes to feel that the counselor understands the issues from their perspective. Beyond this, strategic use reflective listening is a core intervention toward guiding the client toward change, supporting the goal-directed aspect of MI. In this use of reflections, the therapist guides the client towards resolving ambivalence by a focus on the negative aspects of the status quo and the positives of making change. There are several levels of reflection ranging from simple to more complex. Different types of reflections are skillfully used as clients demonstrate different levels of readiness for change. For example, some types of reflections are more helpful when the client seems resistant and others more appropriate when the client offers statements more indicative of commitment to change.
- **Summaries** are a special type of reflection where the therapist recaps what has occurred in all or part of a counseling session(s). Summaries communicate interest, understanding and call attention to important elements of the discussion. They may be used to shift attention or direction and prepare the client to “move on.” Summaries can highlight both sides of a client’s ambivalence about change and promote the development of discrepancy by strategically selecting what information should be included and what can be minimized or excluded.

Change Talk

Change talk is defined as statements by the client revealing consideration of, motivation for, or commitment to change. In Motivational Interviewing, the therapist seeks to guide the client to expressions of change talk as the pathway to change. Research indicates a clear correlation between client statements about change and outcomes - client-reported levels of success in changing a behavior. The more someone talks about change, the more likely they are to change. Different types of change talk can be described using the mnemonic DARN-CAT.

Preparatory Change Talk

- Desire (I want to change)
- Ability (I can change)
- Reason (It’s important to change)
- Need (I should change)

And most predictive of positive outcome:

Implementing Change Talk

- Commitment (I will make changes)
- Activation (I am ready, prepared, willing to change)
- Taking Steps (I am taking specific actions to change)

Strategies for Evoking Change Talk

There are specific therapeutic strategies that are likely to elicit and support change talk in Motivational Interviewing:

- 1. Ask Evocative Questions:** Ask an open question, the answer to which is likely to be change talk.
- 2. Explore Decisional Balance:** Ask for the pros and cons of both changing and staying the same.
- 3. Good Things/Not-So-Good Things:** Ask about the positives and negatives of the target behavior.
- 4. Ask for Elaboration/Examples:** When a change talk theme emerges, ask for more details. "In what ways?" "Tell me more?" "What does that look like?" "When was the last time that happened?"
- 5. Look Back:** Ask about a time before the target behavior emerged. How were things better, different?
- 6. Look Forward:** Ask what may happen if things continue as they are (status quo). Try the miracle question: If you were 100% successful in making the changes you want, what would be different? How would you like your life to be five years from now?
- 7. Query Extremes:** What are the worst things that might happen if you don't make this change? What are the best things that might happen if you do make this change?
- 8. Use Change Rulers:** Ask: "On a scale from 1 to 10, how important is it to you to change [the specific target behavior] where 1 is not at all important, and a 10 is extremely important?
Follow up: "And why are you at ___ and not ____ [a lower number than stated]?" "What might happen that could move you from ___ to [a higher number]?"
Alternatively, you could also ask "How confident are that you could make the change if you decided to do it?"
- 9. Explore Goals and Values:** Ask what the person's guiding values are. What do they want in life? Using a values card sort activity can be helpful here. Ask how the continuation of target behavior fits in with the person's goals or values. Does it help realize an important goal or value, interfere with it, or is it irrelevant?
- 10. Come Alongside:** Explicitly side with the negative (status quo) side of ambivalence. "Perhaps _____ is so important to you that you won't give it up, no matter what the cost."

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Vaccine Administration

Introduction

Administering immunizations correctly is a critical part of the health care professional's job. Immunizations are required to be administered in various methods, including intramuscular (IM), subcutaneous (SQ), oral, and nasal. Some immunizations 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 immunizations. If immunizations are given improperly, the patient may not develop immunity.

Learning Objectives

On completion of this unit, the health 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 workers most commonly administering immunizations. There are a few states that 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 immunizations 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 immunizations 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.

VISs, 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 vaccination is given. These can be obtained on the CDC (www.cdc.gov/vaccines/pubs/vis) and Immunization Action Coalition (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 the wording of the VIS are made. For more information on VISs, see the VIS section of this guide.

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

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 based on the 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; meningococcal polysaccharide (MPSV); and rotavirus vaccines all require reconstitution.

The CDC does not advise the use of predrawn syringes. These are vaccines that are 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 okay. With predrawn syringes, there is a danger of administering the wrong vaccine. Medication guidelines state that the one who is administering the injection should be the one who draws up the medication to prevent medication error. If multiple immunizations are to be administered on the same day, once vaccines are drawn up, they should be labeled in some way. Documentation of where each immunization is administered is important. If syringes are not labeled, this may be difficult. Predrawing 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 inches apart so that any reactions can be determined. In most cases, a separate anatomic site should be used for each injection.

The majority of immunizations are administered IM, but MMR, varicella, zoster, and MPSV 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 Immunization Action Coalition Web sites. For newborns, a 5/8-inch needle should be used in the vastus lateralis muscle of the upper thigh. For infants up to age 1 year, a 1-inch needle should be used in the same location. For toddlers, children, and adults, length varies based on the injection site (vastus lateralis or deltoid) and the patient's weight (5/8 to 1+ inches in length). For SQ injections, needle length should be 5/8 inch.

When administering IM injections, the needle should be inserted at a 90° angle—and quickly. It is not necessary to aspirate after needle insertion. SQ injections are administered at a 45° angle, and the SQ tissue is pinched up to prevent injection into the muscle. It is not necessary to aspirate after needle insertion. Multiple immunizations should be a minimum of 1 inch 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 has recently become 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.

After a vaccine is administered to an adolescent or teen (ages 11 to 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 immunizations.
- Always check the expiration date before drawing up the vaccine.
- VISs 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 or SQ) 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 immunizations to a patient and prevents duplication of immunizations.

Tools and Resources

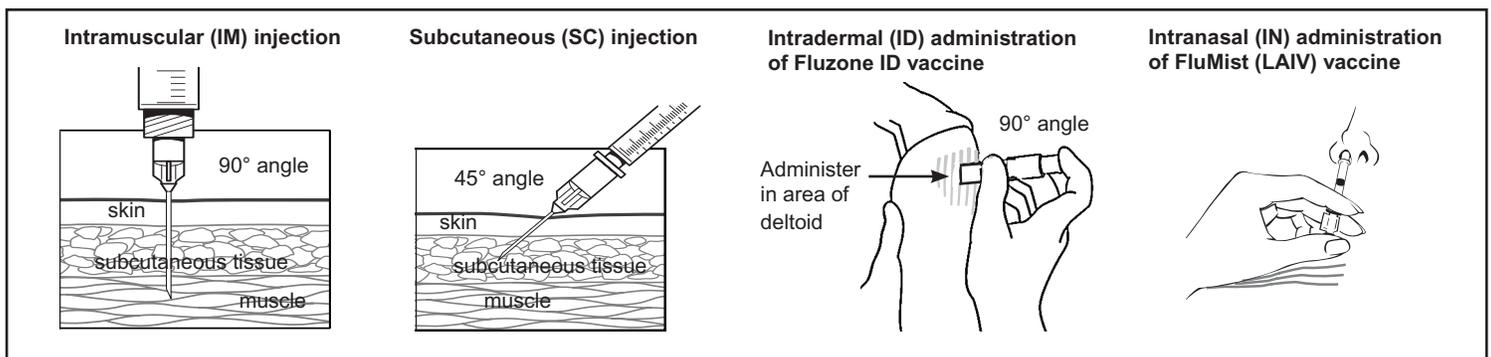
- For additional learning:
 - Lindh WQ, Pooler MS, Tamparo CD, Dahl BM. *Delmar's Comprehensive Medical Assisting: Administrative and Clinical Competencies*. 4th ed. Clifton Park, NY: Delmar, Cengage Learning; 2010
 - National Network for Immunization Information (<http://www.immunizationinfo.org/vaccines>)
- **Documents you may include in your personalized manual (included below):**
 - Immunization Action Coalition
 - Administering Vaccines: Dose, Route, Site, and Needle Size (www.immunize.org/catg.d/p3085.pdf)
 - How to Administer Intramuscular (IM) Vaccine Injections and How to Administer Subcutaneous (SC) Injections (www.immunize.org/catg.d/p2020.pdf)
 - How to Administer IM and SC 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 |
| <i>Haemophilus influenzae</i> 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> | <19yrs: 0.5 mL | IM |
| | ≥20 yrs: 1.0 mL | |
| Human papillomavirus (HPV) | 0.5 mL | IM |
| Influenza, live attenuated (LAIV) | 0.2 mL | Intranasal spray |
| Influenza, trivalent inactivated (TIV) | 6-35 mos: 0.25 mL | IM |
| | ≥3 yrs: 0.5 mL | |
| TIV: Fluzone intradermal (18–64 yrs) | 0.1 mL | ID |
| Measles, Mumps, Rubella (MMR) | 0.5 mL | SC |
| Meningococcal – conjugate (MCV) | 0.5 mL | IM |
| Meningococcal – polysaccharide (MPSV) | 0.5 mL | SC |
| Pneumococcal conjugate (PCV) | 0.5 mL | IM |
| Pneumococcal polysaccharide (PPSV) | 0.5 mL | IM or SC |
| Polio, inactivated (IPV) | 0.5 mL | IM or SC |
| Rotavirus (RV) | Rotarix: 1.0 mL | Oral |
| | Rotateq: 2.0 mL | |
| Varicella (Var) | 0.5 mL | SC |
| Zoster (Zos) | 0.65 mL | SC |
| Combination Vaccines | | |
| DTaP-HepB-IPV (Pediarix) DTaP-IPV/Hib (Pentacel) DTaP-IPV (Kinrix) Hib-HepB (Comvax) | 0.5 mL | IM |
| MMRV (ProQuad) | ≤12 yrs: 0.5 mL | SC |
| HepA-HepB (Twinrix) | ≥18 yrs: 1.0 mL | IM |

| Injection Site and Needle Size | | |
|---|----------------------|---|
| Subcutaneous (SC) 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 appropriate to the person's age and body mass. | | |
| Age | Needle Length | Injection Site |
| Newborns (1 st 28 days) | 5/8"* | Anterolateral thigh muscle |
| Infants (1–12 mos) | 1" | Anterolateral thigh muscle |
| Toddlers (1–2 yrs) | 1–1 1/4" 5/8–1"* | Anterolateral thigh muscle or deltoid muscle of arm |
| Children & teens (3–18 years) | 5/8–1"* 1"–1 1/4" | Deltoid muscle of arm or anterolateral thigh muscle |
| Adults 19 yrs or older | | |
| Male or female less than 130 lbs | 5/8–1"* | Deltoid muscle of arm |
| Female 130–200 lbs Male 130–260 lbs | 1–1 1/2" | Deltoid muscle of arm |
| Female 200+ lbs Male 260+ lbs | 1 1/2" | 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 is stretched tight, the subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle.

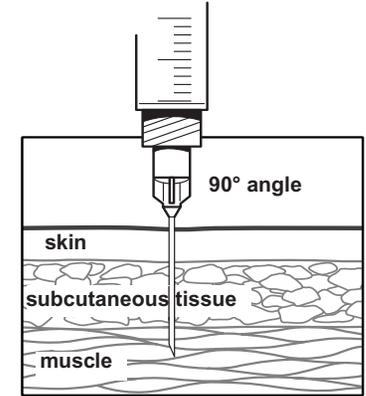


Please note: Always refer to the package insert included with each biologic for complete vaccine administration information. CDC's Advisory Committee on Immunization Practices (ACIP) recommendations for the particular vaccine should be reviewed as well (see www.immunize.org/acip).

How to Administer Intramuscular (IM) Vaccine Injections

Administer these vaccines by the intramuscular (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 (TIV); quadrivalent meningococcal conjugate (MCV4); and pneumococcal conjugate (PCV). Administer inactivated polio (IPV) and pneumococcal polysaccharide (PPSV23) either IM or SC.

| Patient age | Injection site | Needle size | Needle insertion |
|---------------------------|--|----------------------|---|
| Newborn (0–28 days) | Anterolateral thigh muscle | 5/8" (22–25 gauge) | <p>Use a needle long enough to reach deep into the muscle.</p> <p>Insert needle at a 90° angle to the skin with a quick thrust.</p> <p>(Before administering an injection of vaccine, it is not necessary to aspirate, i.e., to pull back on the syringe plunger after needle insertion.[†])</p> <p>Multiple injections given in the same extremity should be separated by a minimum of 1", if possible.</p> |
| Infant (1–12 months) | Anterolateral thigh muscle | 1" (22–25 gauge) | |
| Toddler (1–2 years) | Anterolateral thigh muscle | 1–1¼" (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 | 1–1¼" (22–25 gauge) | |
| Adults 19 years and older | Deltoid muscle (upper arm) | 1–1½" (22–25 gauge) | |
| | Alternate site: Anterolateral thigh muscle | 1–1½" (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 5/8" needle is sufficient in adults weighing less than 130 lbs (<60 kg) if the subcutaneous tissue is not bunched and the injection is made at a 90-degree angle; a 1" needle is sufficient in adults weighing 130–152 lbs (60–70 kg); a 1–1¼" needle is recommended in women weighing 152–200 lbs (70–90 kg) and men weighing 152–260 lbs (70–118 kg); a 1½" needle is recommended in women weighing more than 200 lbs (>90 kg) or men weighing more than 260 lbs (>118 kg).

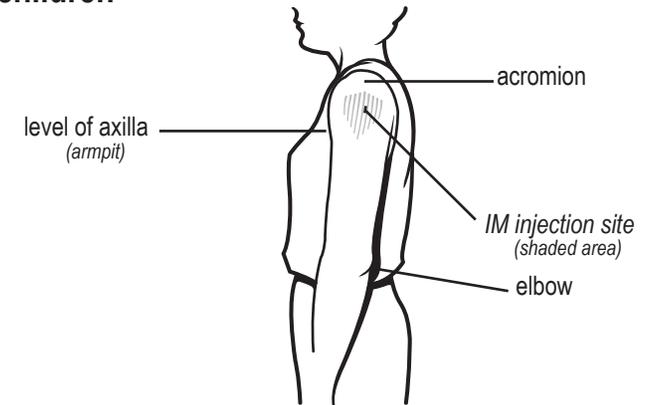
[†]CDC. "ACIP General Recommendations on Immunization" at www.immunize.org/acip

IM site for infants and toddlers



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

IM site for children and adults

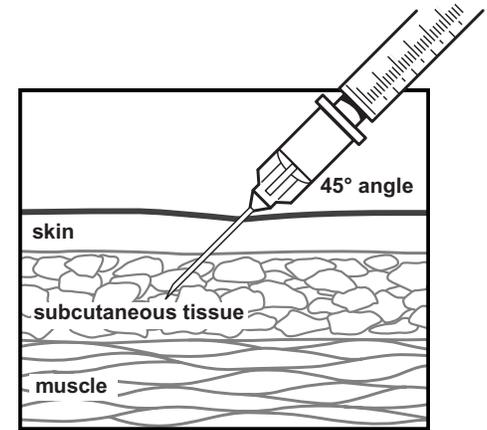


Insert needle at a 90° angle into thickest portion of deltoid muscle — above the level of the axilla and below the acromion.

How to Administer Subcutaneous (SC) Vaccine Injections

Administer these vaccines by the subcutaneous (SC) route: measles, mumps, and rubella (MMR), varicella (VAR), meningococcal polysaccharide (MPSV4), and zoster (shingles [ZOS]). Administer inactivated polio (IPV) and pneumococcal polysaccharide (PPSV23) vaccines either SC or IM.

| Patient age | Injection site | Needle size | Needle insertion |
|-------------------|--|--------------------------|--|
| Birth to 12 mos. | Fatty tissue over the anterolateral thigh muscle | 5/8" needle, 23–25 gauge | <p>Pinch up on subcutaneous (SC) tissue to prevent injection into muscle.</p> <p>Insert needle at 45° angle to the skin.</p> <p>(Before administering an injection of vaccine, it is not necessary to aspirate, i.e., to pull back on the syringe plunger after needle insertion.*)</p> <p>Multiple injections given in the same extremity should be separated by a minimum of 1".</p> <p>*CDC. "ACIP General Recommendations on Immunization" at www.immunize.org/acip</p> |
| 12 mos. and older | Fatty tissue over anterolateral thigh or fatty tissue over triceps | 5/8" needle, 23–25 gauge | |

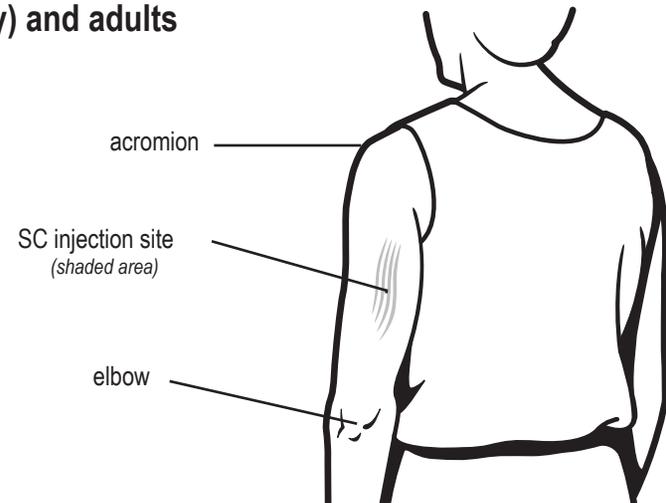


SC site for infants



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

SC site for children (after the 1st birthday) and adults



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

How to Administer IM and SC Vaccine Injections to Adults

Intramuscular (IM) Injections

Administer these vaccines via IM route

Tetanus, diphtheria (Td), or with pertussis (Tdap); hepatitis A; hepatitis B; human papillomavirus (HPV); trivalent inactivated influenza (TIV); pneumococcal conjugate (PCV13); and quadrivalent meningococcal conjugate (MCV4). Administer polio (IPV) and pneumococcal polysaccharide vaccine (PPSV23) either IM or SC.

Injection site

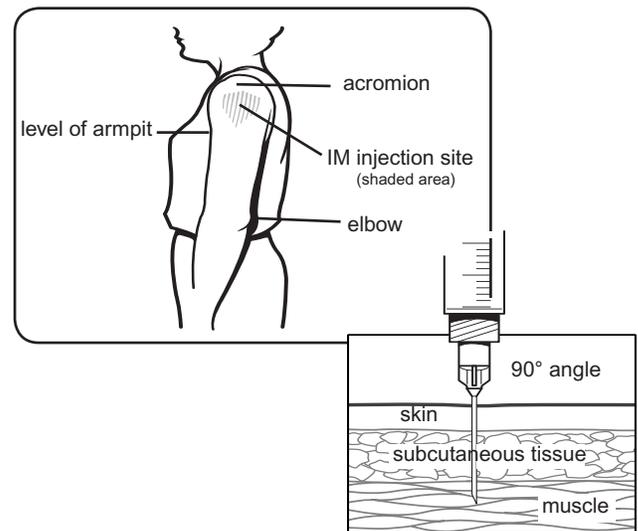
Give in the central and thickest portion of the deltoid—above the level of the armpit and below the acromion (see the diagram).

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 5/8" 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-degree angle; a 1" needle is sufficient in adults weighing 130–152 lbs (60–70 kg); a 1–1½" needle is recommended in women weighing 152–200 lbs (70–90 kg) and men weighing 152–260 lbs (70–118 kg); a 1½" needle is recommended in women weighing more than 200 lbs (90 kg) or men weighing more than 260 lbs (more than 118 kg).*

Subcutaneous (SC) Injections

Administer these vaccines via SC route

MMR, varicella, meningococcal polysaccharide (MPSV4), and zoster (shingles). Administer polio (IPV) and pneumococcal polysaccharide vaccine (PPSV23) either SC or IM.

Injection site

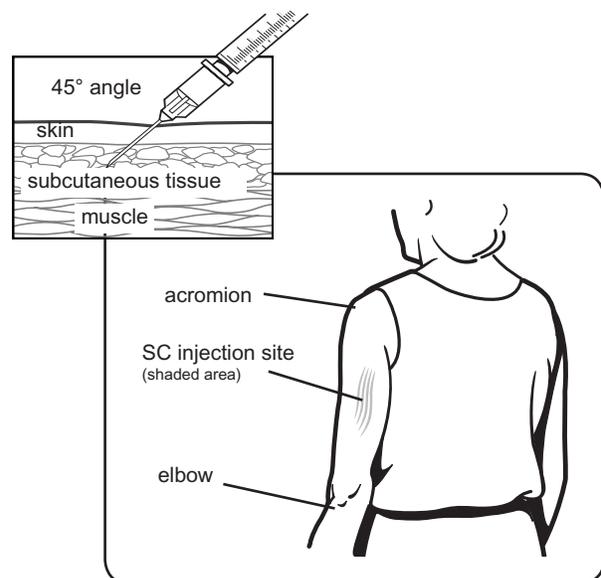
Give in fatty tissue over the triceps (see the diagram).

Needle size

23–25 gauge, 5/8" 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".



Adapted by the Immunization Action Coalition, courtesy of the Minnesota Department of Health

Vaccines with Diluents: How to Use Them

The following vaccines must be reconstituted correctly before they are administered. 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* | 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 | 30 min (single-dose vial) 35 days (multidose vial) | Refrigerator |
| Menveo (MCV4) | Novartis | MenA | MenCWY | 8 hrs | Refrigerator |
| Pentacel (DTaP-IPV/Hib) | sanofi pasteur | Hib | DTaP-IPV | Immediately (i.e., within 30 minutes or less) | 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 | 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 or room temp |
| 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 these steps:

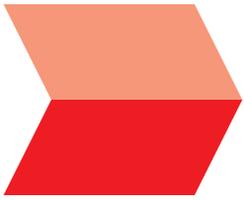
- For single-dose vaccine products (exceptions are Menomune in the multi-dose vial and Rotarix[‡]), select a syringe and a needle of proper length to be used for both reconstitution and administration of the vaccine. Following reconstitution, Menomune in a multidose vial will require a new needle and syringe for each dose of vaccine to be administered. For Rotarix, see the package insert.[‡]
- Before reconstituting, check labels on both the lyophilized vaccine vial and the diluent to verify the following:
 - that they are the correct two products to mix together
 - that the diluent is the correct volume (especially for Menomune in the multidose vial)
 - that neither vaccine nor diluent has expired
- 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
 - injecting diluent into lyophilized vaccine vial and rotating or agitating to thoroughly dissolve the lyophilized powder
- 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 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.
- If reconstituted vaccine is not used immediately or comes in a multidose vial (i.e., multi-dose Menomune),
 - 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
 - protect reconstituted vaccines from light
 - use only within the time indicated on chart above

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

[†] MMRV contains seven times as much varicella component as does the single antigen VAR.

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

[§] HZV contains fourteen times as much varicella component as does the single antigen VAR.



Immunization Information Systems/Registries

Introduction

In an effort to ensure that 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. Although some are more useful and integrative, all registries offer an opportunity for confidential, secure, centralized, and immediate access to immunization records for authorized providers.

Learning Objectives

On completion of this unit, the health 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?

IISs 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.” 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 electronic medical records (see “References”).

There is good research to support the development and refinement of IISs. Every Child by Two states that 21% of children are overimmunized and more than 2 million children are underimmunized, leaving themselves and others at risk of vaccine-preventable diseases. Furthermore, as more new immunizations are continually added to recommended schedules and given the fact 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 <http://www.cdc.gov/vaccines/programs/iis/index.html>.)

Are There Common Standards for Immunization Information Systems?

The American Immunization Registry Association (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.” It has outlined 27 functional standards that an effective IIS should meet. The standards are as follows:

1. The IIS provides individual immunization records accessible to authorized users at the point and time where immunization services are being delivered.
2. The IIS has an automated function that determines vaccines due, past due, or coming due (“vaccine forecast”) in a manner consistent with current Advisory Committee on Immunization Practices (ACIP) recommendations. Any deficiency is visible to the clinical user each time an individual’s record is viewed.
3. The IIS automatically identifies individuals due and past due for immunization(s) to enable the production of reminder/recall notifications from within the IIS itself or from interoperable systems.
4. When the IIS receives queries from other health information systems, it can generate an automatic response in accordance with interoperability standards endorsed by the CDC for message content/format and transport.
5. The IIS can receive submissions in accordance with interoperability standards endorsed by the CDC for message content/format and transport.
6. The IIS has a vaccine inventory function that tracks and decrements inventory at the provider site level according to Vaccines for Children (VFC) program requirements.
7. The IIS vaccine inventory function is available to direct data entry users and can interoperate with electronic health records (EHRs) or other inventory systems.
8. The IIS vaccine inventory function automatically decrements as vaccine doses are recorded.
9. Eligibility is tracked at the dose level for all doses administered.
10. The IIS interfaces with the national vaccine ordering, inventory, and distribution system (currently VTrackS).
11. The IIS can provide data and/or produce management reports for VFC and other public vaccine programs.
12. 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.
13. The IIS can regularly evaluate incoming and existing patient records to identify, prevent, and resolve duplicate and fragmented records.
14. The IIS can regularly evaluate incoming and existing immunization information to identify, prevent, and resolve duplicate vaccination events.
15. The IIS can store all IIS Core Data Elements.
16. 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.
17. The IIS records and makes available all submitted vaccination and/or demographic information in a timely manner.
18. The IIS documents active/inactive status of individuals at both the provider organization/site and geographic levels.
19. 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.
20. The IIS has user access controls and logging, including distinct credentials for each user, least-privilege access, and routine maintenance of access privileges.
21. 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.

22. The IIS can provide immunization data access to health care providers, public health, and other authorized stakeholders (eg, schools, public programs, payers) according to law, regulation, or policy.
23. The IIS can generate predefined and/or ad hoc reports (eg, immunization coverage, vaccine usage, and other important indicators by geographic, demographic, provider, or provider groups) for authorized users without assistance from IIS personnel.
24. With appropriate levels of authentication, IIS can provide copies of immunization records to individuals or parents/guardians with custodial rights.
25. The IIS can produce an immunization record acceptable for official purposes (eg, school, child care, camp).
26. The IIS can 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.
27. The IIS facilitates reporting and/or investigation of adverse events following immunization.

Please visit the AIRA Web site for more information on functional standards (<http://www.immregistries.org/resources/standards/functional-standards>).

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.” Because of that, there is a bare minimum set of data that 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/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 immunizations 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?

Many states have a Chapter Initiatives page for immunizations through the AAP. They often include information about the state IIS (<http://www2.aap.org/immunization/about/chapterinitiatives.html>).

Furthermore, the CDC has contact information on its IIS State/Territory/Registry Staff–Main and Technical Contacts page (<http://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 page (<http://www.cdc.gov/vaccines/programs/iis/legislation-survey.html>).

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

Key Facts

- IISs 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.
- IISs or registries are guided by basic principles to protect patients.

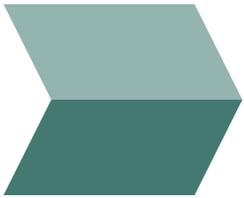
References

American Academy of Pediatrics Committee on Practice and Ambulatory Medicine. Immunization information systems. *Pediatrics*. 2006;118(3): 1293-1295

American Immunization Registry Association. Immunization Registry Functional Standards Resources. <http://www.immregistries.org/resources/standards/functional-standards>. Accessed April 24, 2013

Tools and Resources

- Links for additional learning:
 - CDC
www.cdc.gov
 - Immunization Information Systems (IIS) (<http://www.cdc.gov/vaccines/programs/iis/index.html>)
 - Implementation Guide for Immunization Data Transactions using Version 2.3.1 of the Health Level Seven (HL7) Standard Protocol (<http://www.cdc.gov/vaccines/programs/iis/technical-guidance/downloads/hl7guide.pdf>)
- Every Child by Two: About Registries (Immunization Information Systems)
www.ecbt.org/registries



Reminder/ Recall Systems

Introduction

Immunization reminder/recall systems are cost-effective methods whereby children in need of vaccination are identified and contacted to come to the physician's office. Reminder systems track future appointments, whereas recall systems track missed appointments during which immunizations would have been given. Combining reminder and recall systems is a powerful way to ensure optimal vaccination rates.

Learning Objectives

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

- Describe methods for tracking immunization appointments.
- Describe methods for reminding parents of impending immunizations.
- Describe methods for recalling patients overdue for vaccinations.
- Implement a reminder/recall system if one is not in place at his or her practice.
- Manage or update current reminder/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.

About Reminder/Recall Systems

Good immunization practices in pediatric offices are important, because they are the most common place for a child to receive vaccinations. In general, pediatricians are doing a good job delivering routine vaccines—more than 70% of children receive their vaccines from pediatricians, and more than 80% receive vaccines in the private sector. However, more than one-fourth of preschool children lack at least 1 routine vaccination, and many adolescents are not protected against human papillomavirus (HPV), meningitis, and hepatitis B.

Using reminder/recall systems within a medical home has been shown to improve not only immunization rates but also overall health care. Children and adolescents who are behind on immunizations are at greater risk of being behind on other preventive services. Studies suggest that fewer than 1 in 5 pediatric or multispecialty group practices are using reminder/recall systems. By using these systems, physicians can increase vaccination rates and promote other important clinical services, such as lead and vision screening.

To implement a reminder/recall system, consider the following:

- An immunization information gap exists. Parents often do not know the vaccination status of their children or adolescents, and pediatricians sometimes perceive coverage among their patients as higher than it really is.
- Adolescents are less likely to visit the pediatrician regularly, and vaccines they receive, such as HPV and meningococcal vaccine, require more than one dose. Because of this, reminder/recall efforts are especially effective to keep this group of patients up to date.
- Pediatricians should ask themselves, “How well am I doing at vaccinating my patients?” To know for certain, contact the local state health department to request an office assessment of coverage and follow-up.
- Organization is essential. Offices use varied reminder systems, such as postcards and telephone calls. The key is to create a system that allows personnel to identify children in need of vaccinations. For examples of how pediatricians can implement reminder/recall systems, refer to the “Effective Models and Strategies” portion of the American Academy of Pediatrics: Immunizations Reminder/Recall Systems fact sheet.
- One size does not fit all. Successful immunization tracking systems vary from tickler files to community-based immunization registries. These systems are dependent on office personnel’s ability to use the system and fine-tune it to meet specific needs of the practice.

Reminder/Recall and Provider Prompt Systems Suggestions

For many of the methods below, staff must first pull a list containing names and contact information of patients who are due or overdue for immunizations before attempting contact. Many state IIS and electronic health record (EHR) systems can run such reports easily—if immunization records and family contact information are updated at every visit. Building those practices into patient flow is key.

Chart Reminders and Electronic Health Record Prompts

Chart reminders can be as simple as a colorful sticker or as comprehensive as a checklist of preventive services, including vaccinations. Reminders to physicians should be prominently placed in the chart. Reminders that require some type of acknowledgment (eg, check mark) are more effective. EHR prompts are another method that pediatricians can use to alert themselves or their staff of an immunization that is due. Be sure to take advantage of this function, and don’t remove the prompt option.

Phone Calls by Office Staff

Staff phone the patient or parent and remind them that a vaccination is due and offer 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 also can be used for appointment reminders.

Mail Reminder Cards or Letter (Snail Mail)

Staff send a postcard or letter to the patient or their family reminding them that a vaccination is due and offer the opportunity to schedule an appointment. Again, your IIS or EHR system may print these for you. Another approach is to have the family fill out the reminder card for the next visit (eg, dose 2 or 3 of HPV vaccine) when in your office.

Card File

A 3" x 5" 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.

Electronic Reminders

Sending reminders via e-mail or text message could be a good way to reach patients or parents. An automated system could save office staff a lot of time, but even sending one e-mail to a group would also be a time-saver. These methods have been shown to be effective at increasing immunization coverage rates 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

One method with some of the best evidence for effectiveness includes a tiered approach. 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 was no response.

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

Key Facts

- Using reminder/recall systems within a medical home has been shown to improve not only immunization rates but also overall health care.
- By using reminder/recall systems, physicians can increase vaccination rates and promote other important clinical services, such as lead and vision screening

The role of office staff is to overcome the immunization information gap and ensure that children are vaccinated on time. There are many ways to assist the health care professional in this task.

Tools and Resources

- Links for additional learning:
 - The Community Guide Branch; Epidemiology Analysis Program Office; Office of Surveillance, Epidemiology, and Laboratory Services; Centers for Disease Control and Prevention: Universally Recommended Vaccinations: Client Reminder & Recall Systems (<http://www.thecommunityguide.org/vaccines/universally/clientreminder.html>)
 - Washington State Department of Health: Sample Reminder Card (<http://here.doh.wa.gov/materials/immunization-reminder-recall-card/?searchterm=reminder%20recall%20card>)
- Documents you may include in your personalized manual:
 - American Academy of Pediatrics: Immunizations Reminder/Recall Systems (www.aap.org/immunization/pediatricians/pdf/ReminderRecall.pdf)
 - American Academy of Pediatrics: Adolescent Immunizations: Strategies for Increasing Coverage Rates (<http://www2.aap.org/immunization/pediatricians/pdf/TopStrategiesforIncreasingCoverage.pdf>)
 - Florida State: Manual Reminder Recall System—how to set up (http://www.doh.state.fl.us/Disease_ctrl/immune/files/Manual_reminder-recall_syst_instructions.pdf)
 - Sample Reminder/Recall Systems (<http://www.doh.wa.gov/Portals/1/Documents/Pubs/348-310-ReminderRecallResources.pdf>)

Immunization Reminder/Recall Systems

What are reminder/recall systems?



Immunization reminder/recall systems are cost-effective methods whereby children in need of vaccination are identified and contacted to come to the physician's office.

Reminder systems track future appointments, whereas recall systems track missed appointments during which immunizations would have been given. Combining reminder and recall systems is a powerful method for ensuring optimal vaccination rates.

Why are reminder/recall systems important?

Good immunization practices in private offices are important because of the reliance on office-based pediatricians and family physicians for childhood vaccinations. In general, pediatricians are doing a good job delivering routine vaccines – greater than 70% of children receive their vaccines from pediatricians and greater than 80% receive vaccines in the private sector. However, more than one-fourth of preschool children lack at least 1 routine vaccination, and many adolescents are not protected against hepatitis B.

What are the benefits of these systems?

Using reminder/recall systems within a medical home has been shown to improve not only immunization rates but also overall health care. Children who are behind on immunizations are at greater risk of being behind on other preventive services. Studies suggest that fewer than 1 in 5 pediatric or multi-specialty group practices are using reminder/recall systems. By utilizing these systems, physicians can increase vaccination rates and promote other important clinical services, such as lead and vision screening.

How can reminder/recall systems be implemented?

To implement a reminder/recall system, consider the following:

- An “immunization information gap” exists. Parents often do not know the vaccination status of their children and pediatricians sometimes perceive coverage among their patients as higher than it really is.
- Pediatricians should ask themselves, “How well am I doing at vaccinating my patients?” To know for certain, contact the local state health department to request an office assessment of coverage and follow-up.
- Organization is essential. Offices utilize varied record-keeping systems, such as postcards, telephone calls, or a variety of techniques. The key is to create a system that allows personnel to identify children in need of vaccinations. For examples on how pediatricians can implement reminder/recall systems, refer to the “Effective Models and Strategies” portion of this fact sheet.
- One size does not fit all. Successful recall systems vary from tickler files to community-based immunization registries. These systems are dependent upon office personnel's ability to utilize the system and fine-tune it to meet the specific needs of the practice.

Effective Models and Strategies

The pediatrician's role is to overcome the immunization information gap and ensure that children are vaccinated on time. By adopting the National Vaccine Advisory Committee *Standards for Child and Adolescent Immunization Practices* and AAP policy statements on immunizations, physicians can enhance their policies and practices and improve the health and welfare of children, adolescents, and their community.



To learn more about the AAP Childhood Immunization Support Program, send an email to cispimmunize@aap.org

The American Academy of Pediatrics (AAP) endorses reminder/recall systems through policy statements and reports. The following examples of reminder/recall systems were adapted from the work of the Task Force on Community Preventive Services.

Making Reminder/Recall Systems Work!

Physicians do not have to invest a lot of time or money to develop a successful reminder/recall system. By evaluating their resources and needs, physicians can implement a simple, effective system suited to their practice. For more information about reminder/recall systems, visit: <http://www.thecommunityguide.org/vaccines/universally/clientreminder.html>.

Chart Reminders: Chart reminders can be as simple as a colorful sticker on the chart or can be a comprehensive checklist of preventive services including vaccinations. Reminders to physicians should be prominently placed in the chart. Reminders that require some type of acknowledgment (such as a checkmark) are more effective. **Advantages:** Inexpensive, efficient (reviewing health maintenance inventories with patients on average requires less than 4 minutes with the patients and quickly becomes part of the physician's routine). **Disadvantages:** 1) Only reaches patients with scheduled office visits, 2) chart reminders may be more effective in managed care organizations as compared with fee-for-service practices since cost to the patient may be a barrier to vaccination in a fee-for-service practice.

Standing Orders: A standing order is a written order stipulating that all persons meeting certain criteria (i.e., age) should be vaccinated, thus eliminating the need for individual physician's orders for each patient. **Advantages:** Easy to implement. **Disadvantages:** Only reaches patients already contacting the health care system.

Mail/Telephone Reminders: Staff phone the patient or send a postcard/letter reminding the patient that a vaccination is due and offer the opportunity for the patient to schedule an appointment. **Advantages:** 1) Phone contact can help to ensure that the message is understood and provides the opportunity to schedule an appointment, 2) reaches patients who may otherwise not have scheduled visits, 3) easy to implement, requiring minimal staff time. **Disadvantages:** 1) Relies on patient to schedule and keep appointments, 2) not useful in practices with high patient turnover or with a population that changes residences frequently, 3) may need bilingual reminders, generating the list of patients who should receive reminders may be difficult in some practices (e.g., for those without computerized records), 4) if baseline vaccination rates are high, the incremental increase in vaccination rate attained may not be worth the time and effort invested.

Expanding Clinic Hours: Expanding access can include: 1) reducing the distance from the setting to patients, 2) increasing, or making more convenient, the hours during which vaccination services are provided, 3) delivering vaccinations in settings previously not used, and/or 4) reducing administrative barriers to vaccination (e.g., "drop-in" clinics or "express lane" vaccination services). This group of strategies has been very effective in increasing immunization rates when combined with other strategies, such as patient reminder/recall, less clearly so when used alone. **Advantages:** Efficient, may help increase access to care among lower income and other disadvantaged persons. **Disadvantages:** Increased staff time and expense, new clients may lack records, or recall, of previous immunizations.

Computerized Immunization Reminders: The computer can print a list of possible reminders that appear on a patient's record. The software can be programmed to determine the dates that certain preventive procedures are due or past due and then print computer-generated reminder messages, usually overnight, for patients with visits scheduled for the next day. **Advantages:** effective, inexpensive once computerized system is in place, efficient. **Disadvantages:** 1) Only reaches patients with office visits, 2) may be less effective in fee-for-service practices since cost to the patient may be a barrier to vaccination in a fee-for-service practice.

Card file: A 3x5 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.

Phone lists: Phone lists can be used to follow-up with patients who have future immunizations or have missed appointments. By tracking patients whose immunizations are 6 months away and contacting them as their appointment nears, physicians show parents they are aware of their children's needs.

Clinical Assessment Software Application (CASA): The CASA is a database developed by the Centers for Disease Control and Prevention (CDC) to help immunization providers assess immunization rates in their offices. This database can help physicians determine the immunization status of children at critical age markers and antigen-specific levels, as well as the percentage of children who drop out of the vaccination schedule and miss opportunities for immunization. The CASA also produces reports and provides programmatic feedback, and programs are available from the National Immunization Program at <http://www.cdc.gov/vaccines/programs/cocasa/default.htm>.

Local or state health departments: Using a modem to link to the local health department registry allows staff to check or update immunization records daily. This ensures that there are no missed opportunities at any location.

Multiple systems: It might be necessary to use several systems. For example, office personnel can ask parents to address reminder postcards. These postcards can be sent prior to the next appointment, and patients who fail to show up can be placed in an "alert" file and called to set up a new appointment. Additional reminder/recall systems include: performance feedback, patient education, and using patient health records. For more information on these and other reminder/recall systems visit www.aap.org/immunization or www.cdc.gov/vaccines.



Immunization coverage rates for adolescents are much lower than they are for younger children. To help your practice increase immunization coverage in adolescents, consider implementing one or more of the strategies below.

1. Patient Reminder-Recall

Immunization reminder-recall systems are cost-effective methods to identify and notify families whose children are due soon for immunizations (reminder) or are already behind (recall). Reminder and recall systems are powerful ways to ensure optimal vaccination rates. Staff must first pull a list containing names and contact information of patients who are due or overdue for immunizations prior to attempting contact. Many state immunization information systems (IIS) and electronic health records (EHRs) can run such reports easily – if immunization records and family contact information is updated at every visit. Building those practices into patient flow is key.

Methods to remind or recall families include:

- **Phone calls by office staff**
Calls placed by office staff tend to be more effective than auto-dialer calls, but often cost more.
- **Auto-dialers**
Auto-dialers automatically dial phone numbers and either play a recorded message or connect the call to a live person. Such systems also can be used for appointment reminders.
- **Mail reminder cards or letters (snail mail)**
Again, your IIS or EHR may print these for you. Another approach is to have the family fill out the reminder card for the next visit (e.g., dose 2 or 3 of HPV vaccine) when in your office.
- **Text messages**
You may want to get families to opt-in for text messages during a visit so your office can send text message reminders to both parents and adolescents. While parents/guardians need to consent for the vaccine, it is useful to include adolescents in the discussion of their own care.
- **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.

For more information, visit: <http://www2.aap.org/immunization/pediatricians/pdf/ReminderRecall.pdf>

The following is a list of some auto-dialer vendors. Please note that the AAP cannot endorse or recommend specific products or brands. This is only meant to aid you in your selection.

| Auto-dialer | Website |
|-------------|---|
| Call-em-all | https://www.call-em-all.com/ |
| Call Fire | http://www.callfire.com |
| Televox | http://www.televox.com/appointment-reminders/ |
| Voicent | http://www.voicent.com/autodialers.php |



2. Provider Prompts or Standing Orders

Provider prompts usually consist of electronic prompts in EHRs or notes in charts. Now, most EHR provider prompts are automatic pop-up alerts that notify the viewer that the patient is due/overdue for an immunization(s). Other EHR provider prompts may show up as a “to-do” task, even if the patient is not scheduled that day for an appointment. Many EHRs have provider prompts pre-installed that can be customized in the office.

Standing orders for immunizations include office policies, procedures, and orders to provide recommended immunizations to patients. For example, a standing order might be in place to instruct health care personnel (as allowed by the state) to give a specific vaccine to all patients for whom the vaccine is recommended based on the harmonized immunization schedule. Standing orders should include procedures for vaccinating eligible patients and contraindications. To access sample standing orders for vaccines, visit: <http://www.immunize.org/standing-orders/>.

3. Strong Provider Recommendation

Studies have shown that parents trust their pediatrician’s guidance¹. Be sure to give a strong recommendation for all vaccines on the current immunization schedule. It is important to state that you recommend all vaccines on the schedule and not merely mention that they are available. For example, some providers may shy away from discussing the HPV vaccine. It is especially important to strongly recommend HPV vaccine, as parents often have more questions about it.

4. Include All Recommended Vaccinations at Every Visit

It is important to vaccinate whenever possible, because you don’t know when a patient will be back in your office. Use sick-child and chronic care visits as a time to immunize. Be sure to check what vaccinations, if any, are due every time a patient is in the office. Always screen for contraindications. Most vaccines can be given even if the child has a mild illness.²

5. Provider Feedback

Providers change their behavior (e.g., clinical practices) based on feedback that they are different from those of their peers. Consider running an immunization rate report through your EHR or perform a chart audit to determine the percentage of your patients that are up-to-date on immunizations. Benchmark this data against yourself annually. You can also benchmark this data against the national and state (or city) data from the National Immunization Survey.

¹ Freed GL, Clark SJ, Butchart AT, Singer DC, and Davis MM. Sources and Perceived Credibility of Vaccine-Safety Information for Parents. 2011. *Pediatrics*, 127, 1, Supplement 107-112.

² CDC. Chart of Contraindications and Precautions to Commonly Used Vaccines. 2011. Accessed on April 12, 2013 at: <http://www.cdc.gov/vaccines/recs/vac-admin/contraindications-vacc.htm>.



6. Find an Immunization Champion in Your Practice

An immunization champion can serve as a steward and advocate of immunizations in your practice. This role can be filled by any clinical provider. Being the immunization champion should be written into that job description and that provider should have time devoted to perform those tasks. Offices should cross-train staff and appoint a different person to fill-in and complete these duties in case the immunization champion is unavailable. It is also suggested, if the immunization champion is not a physician, that a physician provides oversight to the immunization champion. Since a physician is more likely to have a financial stake in the practice, he/she may ensure that vaccine-related tasks are handled appropriately.

7. Educate Patients and Their Parents

Educate parents and patients about each recommended vaccine and the disease it prevents. Let parents know that vaccines are safe and effective, and that not vaccinating could put their children at risk for very serious diseases. Take every opportunity to educate parents and patients. Let them know at each visit what vaccines they can expect at their next health supervision appointment and provide handouts on these vaccines and diseases. This allows parents time to consider their questions, find answers, and discuss their most serious concerns with their pediatrician. For more resources on communicating with parents, visit:

AAP Risk Communication Videos:

<http://www2.aap.org/immunization/pediatricians/riskcommunicationvideos.html>

AAP Adolescent Immunization: Common Concerns Addressed

<http://www2.aap.org/immunization/families/faq/AdolescentIZCommonConcerns.pdf>

AAP Communication with Families Web page:

<http://www2.aap.org/immunization/pediatricians/communicating.html>

CDC Provider Resources for Immunization Conversations with Parents

<http://www.cdc.gov/vaccines/hcp/patient-ed/conversations/index.html>

8. Address Costs

Vaccinations can be costly, and some families may believe they cannot afford to immunize their children. The Affordable Care Act (ACA) now requires insurance companies to cover the costs of receiving all recommended vaccines, which includes those for teens. If an insurance plan has been unchanged since March 23, 2010, it may be “grandfathered” and may not have to abide by all of the new rules under the ACA. If this is the case, the insurance plan may require your patient’s family to pay co-insurance (a portion of the vaccination cost) or to meet their deductible before paying for vaccination. Speak with parents about options for paying this portion of vaccine costs.



If a patient does not have health insurance, has Medicaid, has insurance that does not cover vaccines, or is American Indian or Alaskan Native, he/she qualifies to receive vaccines at no cost through the Vaccines for Children (VFC) Program. If you are not a VFC provider, consider becoming one by contacting your state VFC office. Contact information is available at:

<http://www.cdc.gov/vaccines/programs/vfc/contacts.html>. In the meantime, suggest that eligible children receive vaccines at the local health department. Direct parents to learn more about the VFC program at <http://www.cdc.gov/vaccines/programs/vfc/parents/qa-detailed.html>.

9. Hold Vaccine Clinics at Hours that are Convenient for Families

Holding vaccination clinics with special hours (evening or Saturday) at your practice allows for more opportunities for busy adolescents and their parents to access vaccination services. This has been proven to work especially well for influenza vaccine. While other recommended vaccines, such as Tdap, HPV, and meningococcal should be given during the 11 or 12 year old well-child care visit - when parents will be given the opportunity to discuss the vaccines - shorter vaccination visits for subsequent doses of HPV and influenza may be more convenient.

More Resources for Your Pediatric Practice

AAP Immunization Practice Management page

<http://www2.aap.org/immunization/pediatricians/practicemanagement.html>

AAP Immunization Adolescents page

<http://www2.aap.org/immunization/pediatricians/adolescents.html>

AAP Immunization Quality Improvement page

<http://www2.aap.org/immunization/pediatricians/qualityimprovement.html>

MANUAL REMINDER RECALL SYSTEM

Objectives: To facilitate timely administration of immunizations in accordance with the public health laws of the State of Florida.

Materials: 3"x5" index cards
3"x5" index card file(s) or box(es)
3"x5" monthly index card guides (3 sets – Jan-Dec)

(5"x8" may be substituted)

A. SET-UP OF THE SYSTEM

1. Review child's (birth – 35 months of age) immunizations records for age-appropriate immunizations.
2. Create a 3x5 index card for each child who needs additional immunizations that includes:
 - a) Child's name, address (street and mailing), phone number
 - b) Date next immunization is due in upper right corner of card
3. As new patients are added to the practice, evaluate their status and create a recall card as needed.
4. File the cards alphabetically by the month the next immunizations are due.

B. OPERATING THE SYSTEM

1. At the beginning of each month, work the cards of children who need shots that month. They can be reminded when they are due their next immunization by:
 - a) Calling the parent and making an appointment.
 - b) Sending a card and asking the parent to call for an appointment.
2. A note should be made on the card after each contact or attempted contact.
3. If a child moves away from the practice, inactivate the card by noting the circumstances on the card and filing it with the chart.
4. Keep the card in the current month until the child comes in for their next immunizations or they are inactivated.
5. When the child comes in and gets immunized, change the due date for the next immunization on the card's corner and re-file in the new month.
6. If the child has not come in for immunizations, continue to call or write until either the child comes in or is inactivated. Circumstances for

inactivation should be noted on the card, and the card should be filed with the child's chart.

7. At the beginning of the next month, start at number 1, above. In addition, continue to work any children who still need immunizations from the previous month(s).



Immunization Reminder/Recall Systems

This document may be a helpful resource for providers who are interested in setting up a reminder/recall system and need more information about autodialer, mail, or web-based reminder/recall programs.

What is Reminder/Recall?

Reminder/recall involves identifying patients who are due (reminder) or overdue (recall) for immunizations and contacting them to schedule an appointment. There are many different types of systems and ways to do reminder/recall. Some clinics may want to use an autodialer program and others may want to run a list and have their own staff label and send postcards or call patients. Choosing a reminder/recall system involves looking at:

- Your clinic's immunization workflow.
- Amount of staff time and resources available.
- Cost of reminder/recall system.

Using the Washington State Immunization Information System for Reminder/Recall

You can use the Washington State Immunization Information System to create reminder/recall reports showing which patients are due or overdue for immunizations. The system can generate this report in several different formats, including:

- Patient phone lists
- Mailing labels or postcards
- Letters or mail merge letters
- Autodialer files
- Emails – need to have parent/patient's email address entered on the patient's demographic page.

Contact the Help Desk at 800-325-5599 if you have questions or need assistance running reminder/recall reports.

Autodialers

What is an autodialer?

Autodialers automatically dial phone numbers and either play a recorded message or connect the call to a live person. You must pull a list of patient names and phone numbers who are due or overdue for immunizations in order to use an autodialer system. If you use an appointment reminder system, you may be able to send recorded immunization reminders to patients using this same system.

For people with disabilities, this document is available on request in other formats. To submit a request, please call 1-800-525-0127 (TDD/TTY call 711).

This list of autodialer programs is for your information only. We do not endorse specific vendors or products.

| Company | Highlighted Features | Cost Estimate | For More Information |
|--------------------|--|---|--|
| WellConnect | <ul style="list-style-type: none"> • Multiple delivery methods <ul style="list-style-type: none"> ○ Voice ○ Text • Customizable messages • Schedule messages to send right away, in the future, or recurring | Discuss reduced cost options with your Sanofi Pasteur representative. | www.call-em-all.com 877-226-3080 info@call-em-all.com |
| Televox | <ul style="list-style-type: none"> • Multiple delivery methods <ul style="list-style-type: none"> ○ Voice ○ Email ○ Text • Customizable messages • May work with clinic's scheduling/EMR systems • Secure message transmission | Contact company for more information. | www.televox.com 800-644-4266 info@televox.com |

Mail/Web-based Reminder/Recall Resources

Mail/web-based reminder/recall involves sending postcards or emails to patients who are due or overdue for immunizations. The list below contains examples of some mail and web-based programs offered by vaccine manufacturers.

| Company | Highlighted Features | Cost Estimate | For More Information |
|----------------------------------|---|--------------------------|---|
| Merck's Outreach Program | <ul style="list-style-type: none"> • Postage pre-paid postcards <ul style="list-style-type: none"> ○ Available in English & Spanish ○ Offer pediatric/adolescent & young adult postcards. • Can only use this program for vaccine series completion. • Tools are available to help track patient response to reminders. | No fee for this program. | www.vaccineoutreach.com 877-VAX-6646 Contact your Merck representative for additional details. |
| Pfizer's Postcard Program | <ul style="list-style-type: none"> • Postage pre-paid postcards. • Postcard reminders are only available for pneumococcal conjugate vaccine series completion. | No fee for this program. | 484-865-1117 Contact your Pfizer representative for additional details. |

For people with disabilities, this document is available on request in other formats. To submit a request, please call 1-800-525-0127 (TDD/TTY call 711).

| Company | Highlighted Features | Cost Estimate | For More Information |
|--------------|--|--------------------------|---|
| GSKReminders | <ul style="list-style-type: none"> • This is a web-based immunization reminder system for adult immunizations. • Patients “enroll” in this program directly to receive these reminders. • Multiple delivery methods: <ul style="list-style-type: none"> ○ Email ○ Text • Clinics can get wallet card reminders for patients. | No fee for this program. | www.gskreminders.com Contact your GSK representative for additional details. |

Reminder/Recall Resources

Reminder Recall Strategies in the Washington State Immunization Information System

www.doh.wa.gov/Portals/1/Documents/Pubs/348-266-ReminderRecallStrategies.pdf

American Academy of Pediatrics Immunization Reminder/Recall Systems

<http://www2.aap.org/immunization/pediatricians/pdf/ReminderRecall.pdf>

Cochrane Review: Does Reminding People to have Vaccinations Increase the Number of People who Receive Vaccinations?

<http://summaries.cochrane.org/CD003941/does-reminding-people-to-have-vaccinations-increase-the-number-of-people-who-receive-vaccinations>

For people with disabilities, this document is available on request in other formats. To submit a request, please call 1-800-525-0127 (TDD/TTY call 711).

DOH 348-310 April 2013



Quality Improvement

Introduction

The American Academy of Pediatrics (AAP) endorses the Standards for Child and Adolescent Immunization Practices of the National Vaccine Advisory Committee (NVAC), which was established in the US Department of Health and Human Services to advise the director of the National Immunization Program. The standards describe optimal immunization practices in 18 areas that practices can aim to meet to increase levels of immunization coverage for the children in their practices and communities. The most recent standards are accessible at <http://www2.aap.org/immunization/pediatricians/nvacstandards.html>. In endorsing these standards, the AAP points out that these are goals for practices to work toward. A few of the standards follow, with examples of ways they can be adopted in practice.

Learning Objectives

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

- Use the standards to assess his or her practice.
- Make plans to administer vaccines at another time if, and only if, there are true contraindications.
- Set goals for improvement to work on regularly.

Professional Policies

Medical practices administering vaccines will set policies for purchasing, storing, administering, and monitoring the immunization portion of the practice, following federal and state requirements. They will perform chart audits at regular intervals and use the data to plan improvements.

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 Quality Improvement

Following 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

Example:

Joe is a 4-year-old boy who has come for a well-child examination to prepare for entry into a Head Start program. He is very excited even though he knows he is going to have to get shots. His mother is concerned that her insurance plan will not cover the vaccines he needs. She knows that he is due for diphtheria, tetanus, and acellular pertussis (DTaP); inactivated poliovirus (IPV); measles, mumps, and rubella (MMR); and varicella vaccines. Office staff confirm that the family qualifies for use of vaccines from the state Vaccines for Children program. Joe's immunizations are covered at his primary care physician's office. He does not need to be referred to another site to obtain them.

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

Example:

Evan is a 4-year-old boy whose parents have brought him in for a well-child examination for preschool entry. They know that he is due for DTaP, IPV, MMR, and varicella vaccines. Both parents have come because they remember how hard it was for Evan's 6-year-old brother to have the shots. At check-in they learn that Evan needs another *Haemophilus influenzae* type b vaccine dose because he did not receive it when he was due for it as a result of a shortage but it is now in supply. There is also a new version of the pneumococcal vaccine that covers 13 strains instead of 7 and is given up to 59 months of age. Evan's parents ask if it is safe to give so many vaccines at one time. They can be reassured that it is safe and given advice on how to make Evan comfortable afterward.

Standard #9: Up-to-date, Written Vaccination Protocols Are Accessible at All Locations Where Vaccines Are Administered

Example:

During the influenza vaccine season, Mayville Pediatrics does not have enough 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 delegate giving vaccines to medical assistants. They have regular reviews of immunization technique and written screening tools to assess patients' eligibility for the vaccine. They have protocols that delegate the responsibility to give vaccines under the supervision of physicians in accordance with their state laws.

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.

Example:

Olivia is a 12-year-old girl. She has recently stopped seeing her pediatrician for well-child visits and has not received any of her adolescent vaccines (tetanus and diphtheria toxoids and acellular pertussis [Tdap], human papillomavirus [HPV], meningococcal [MCV4], and influenza). Bayside Pediatrics sent her parents a letter requesting that they bring her in for a well-child care check and the recommended vaccinations. One week later, a phone call is placed to her home, and a message is left for her parents. One month after the initial letter was sent, a second letter is sent to Olivia's parents with the same request. A week later, Bayside Pediatrics staff are preparing to make a second phone call to Olivia's parents when they call in to schedule an appointment.

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.

Example:

Lucas is a 14-year-old boy who is at Mountainview Medical Group for a sports physical. A medical assistant alerts the pediatrician that this child has not yet received his HPV vaccine. The pediatrician makes a strong recommendation for the vaccine. When the parents express uncertainty about the vaccine, the pediatrician explains that the vaccine can prevent certain cancers and warts from developing in their son. The pediatrician also explains that children do not have to be sexually active to receive the vaccine and that it is most effective when administered at the recommended age range, before the child begins having sex.

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 can work to meet to include quality improvement in their daily practice.
- The standards describe goals to make vaccines readily available, given at appropriate times, with reliable record keeping and transmission of information to the state immunization registry.

Tools and Resources

- Links for additional learning:
 - American Academy of Pediatrics: NVAC Standards of Excellence: A Series in Support of the National Vaccine Advisory Committee Standards for Child and Adolescent Immunization Practices (www2.aap.org/immunization/pediatricians/nvacstandards.html)
 - *Pediatrics*: "Standards for Child and Adolescent Immunization Practices" ([http://pediatrics.aappublications.org/content/112/4/958.full.pdf; login required](http://pediatrics.aappublications.org/content/112/4/958.full.pdf;login%20required))
 - National Vaccine Advisory Committee: The Standards for Pediatric Immunization Practice (www.hhs.gov/nvpo/nvac/standar.html)



Vaccine Adverse Event Reporting System

Introduction

Even after an extensive and exhaustive process of verifying that an immunization is effective and safe, the safety of that immunization is scrutinized and tracked for years through the Vaccine Adverse Event Reporting System (VAERS). Promoted by the Centers for Disease Control and Prevention (CDC) and the 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” (<http://vaers.hhs.gov>).

Learning Objectives

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

- Discuss the reasons for postsurveillance of an immunization.
- Know 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.

About the Vaccine Adverse Event Reporting System

According to <http://vaers.hhs.gov>, the primary objectives of VAERS are 5-fold.

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.

Anyone (eg, patient, doctor, vaccine manufacturer, health departments) can report an adverse event to the system. Any medical event that occurs after a vaccine administration should be reported, even if the reporter cannot be sure that 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 limitations to the system. The most common are overreporting and underreporting. For example, shortly after a new vaccine is brought to the market, reports to the system typically dramatically increase for that vaccine. Also, if there are media reports of a specific adverse event after a vaccine, reports with that adverse event increase. 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 statistics.

In the end, the system works. No vaccine can be 100% studied and found safe, even after the initial licensing phase; VAERS increases the likelihood that concerns will be found. For example, the first-generation rotavirus vaccine was found to impose an increased risk of intussusceptions onto those patients who received it. Because of the quick and appropriate response enabled by VAERS, that vaccine was pulled from the market, protecting the public.

Vaccine Safety Datalink

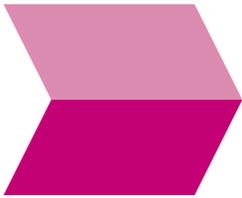
The Vaccine Safety Datalink (VSD) project began in 1990 to monitor vaccine safety and address gaps in scientific knowledge about rare and serious adverse events after immunization. It is a collaborative effort among the CDC and 8 managed care organizations (MCOs). The VSD project is made up of linked databases that use administrative data sources at each of the 8 MCOs. Each site collects data on vaccination, including type and date of administration, medical outcomes, birth data, and census data. This project allows for planned immunization safety studies as well as timely investigations of hypotheses that develop from review of medical literature, reports to VAERS (www.cdc.gov/vaccinesafety/Activities/VAERS.html), changes in immunization schedules, or introduction of new vaccines.

Key Facts

- Immunizations are tracked for adverse events after licensing through VAERS.
- Anyone with a concern about an adverse immunization event can report to VAERS.
- The VAERS does not define causality between the immunization and adverse event.
- Patterns in reports to VAERS can be studied and investigated through the VSD.

Tools and Resources

- Links for additional learning:
 - CDC and FDA: VAERS (<http://vaers.hhs.gov>)
 - FDA: Vaccine Adverse Events (www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ReportaProblem/VaccineAdverseEvents/default.htm)
 - CDC: Vaccine Adverse Event Reporting System (VAERS) (www.cdc.gov/vaccinesafety/Activities/vaers.html)



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 vaccine administration.

Learning Objectives

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

- Understand 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 that 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 that 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 the following:
 - Edition date of the VIS (found on the back in either lower corner)
 - Date the VIS was provided
 - Name, address, and title of the 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 to the recipient's parent or legal representative with each dose of vaccines.
- 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:

- CDC
(www.cdc.gov)
 - Fact Sheet for Vaccine Information Statements
(www.cdc.gov/vaccines/pubs/vis/vis-facts.htm)
 - Vaccine Information Statements
(www.cdc.gov/vaccines/pubs/vis/default.htm)
- Immunization Action Coalition
(www.immunize.org)
 - Vaccine Information Statements (VIS)
(www.immunize.org/vis)
- **Document you may include in your personalized manual (included below):**
 - IAC
 - 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)

To obtain current VISs in more than 30 languages, visit the Immunization Action Coalition's website at www.immunize.org/vis

As healthcare professionals understand, the risks of serious consequences following vaccination are many hundreds or thousands of times less likely than the risks associated with the diseases that the vaccines protect against. Most adverse reactions from vaccines are mild and self-limited. Serious complications are rare, but they can have a devastating effect on the recipient, family members, and the providers involved with the care of the patient. We must continue the efforts to make vaccines as safe as possible.

Equally important is the need to furnish vaccine recipients (or the parents/legal representatives of minors) with objective information on vaccine safety and the diseases that the vaccines protect against, so that they are actively involved in making decisions affecting their health or the health of their children. When people are not informed about vaccine adverse events, even common, mild events, they can lose their trust in healthcare providers and vaccines. Vaccine Information Statements (VISs) provide a standardized way to present objective information about vaccine benefits and adverse events.

What are VISs?

VISs are developed by the staff of the Centers for Disease Control and Prevention (CDC) and undergo intense scrutiny by panels of experts for accuracy. Each VIS provides information to properly inform the adult vaccine recipient or the minor child's parent or legal representative about the risks and benefits of each vaccine. VISs are not meant to replace interactions with healthcare providers, who should answer

questions and address concerns that the recipient or the parent/legal representative may have.

Use of the VIS is mandatory!

Before a healthcare provider vaccinates a child or an adult with a dose of any vaccine containing 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) vaccine, the provider is required by the National Childhood Vaccine Injury Act (NCVIA) to provide a copy of the VIS to either the adult recipient or to the child's parent/legal representative.

How to get VISs

All available VISs can be downloaded from the website of the Immunization Action Coalition at www.immunize.org/vis or from CDC's website at www.cdc.gov/vaccines/pubs/vis/default.htm. Ready-to-copy versions may also be available from your state or local health department.

You can find VISs in more than 30 languages on the Immunization Action Coalition website at www.immunize.org/vis. To find VISs in alternative formats (e.g., audio, web-video), go to: www.immunize.org/vis/vis_sources.asp

Most current versions of VISs

As of May 9, 2013, the most recent versions of the VISs are as follows:

| | | | |
|----------------------|----------|---------------------------|----------|
| Adenovirus | 7/14/11 | Meningococcal..... | 10/14/11 |
| Anthrax | 3/10/10 | Multi-vaccine | 11/16/12 |
| Chickenpox..... | 3/13/08 | PCV13 | 2/27/13 |
| DTaP..... | 5/17/07 | PPSV | 10/6/09 |
| Hib | 12/16/98 | Polio | 11/8/11 |
| Hepatitis A | 10/25/11 | Rabies | 10/6/09 |
| Hepatitis B | 2/2/12 | Rotavirus..... | 12/6/10 |
| HPV-Cervarix | 5/3/11 | Shingles | 10/6/09 |
| HPV-Gardasil | 2/22/12 | Td/Tdap (use for Td).... | 1/24/12 |
| Influenza..... | 7/2/12 | Tdap (use for Tdap) | 5/9/13 |
| Japanese enceph..... | 12/7/11 | Typhoid | 5/29/12 |
| MMR..... | 4/20/12 | Yellow fever | 3/30/11 |
| MMRV..... | 5/21/10 | | |

According to CDC, every time one of these vaccines is given — regardless of what combination vaccine it is given in — regardless of whether it is given by a public health clinic or a private provider — regardless of how the vaccine was purchased — and regardless of the age of the recipient — the appropriate VIS must be given out prior to the vaccination.

Source: www.cdc.gov/vaccines/pubs/vis/vis-facts.htm

Top 10 Facts about VISs

Fact 1 It's federal law!

Federal law requires that VISs must be used for the following vaccines when vaccinating patients of ALL ages:

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

According to CDC, every time one of these vaccines is given — regardless of what combination vaccine it is given in — regardless of whether it is given by a public health clinic or a private provider — regardless of how the vaccine was purchased — and regardless of the age of the recipient — the appropriate VIS must be given out prior to the vaccination. There are also VISs for vaccines not covered by NCVIA: anthrax, Japanese encephalitis, pneumococcal polysaccharide, rabies, shingles, smallpox, typhoid, and yellow fever. CDC recommends the use of VISs whenever these vaccines are given. The VIS must always be used if vaccine was purchased under CDC contract.

Fact 2 VISs are required for both public and private sectors

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

Fact 3 VIS must be provided *before* vaccine is administered to the patient

The VIS provides information about the disease and the vaccine and should be given to the patient before 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 the VIS right before administering vaccines.

Fact 4 You must provide a current VIS for each dose of vaccine

The most current VIS must be provided before each dose of vaccine is given, including vaccines given as a series of doses. If five doses of a single vaccine are required, the patient (parent/legal representative) must have the opportunity to read the information on the VIS before each dose is given.

Fact 5 You must provide VISs for combination vaccines too

There is a VIS available for MMRV (ProQuad). An alternative VIS — the multi-vaccine VIS — is an option to providing single-vaccine VISs when administering one or more of these routine birth-through-6-month vaccines: DTaP, hepatitis B, Hib, pneumo-

coccal (PCV), polio (IPV), or rotavirus (RV). The multi-vaccine VIS can also be used when giving combination vaccines (e.g., Pediarix, Pentacel, Comvax) or when giving two or more routine vaccines at other pediatric visits (e.g., 12–15 months, 4–6 years). However, when giving combination vaccines for which no VIS exist (e.g., Twinrix), give out all relevant single VISs. For example, before administering Twinrix give your patient the VISs for both hepatitis A and hepatitis B vaccines.

Fact 6 VISs are available in other formats, including more than 30 languages

You may use laminated copies of VISs for patients and parents to read and return before leaving the clinic, but you must **also** offer the patient (parent/legal representative) a printed copy of the VIS to take home.

If they prefer to download the VIS onto a mobile device, direct them to CDC's VIS Mobile Downloads web page: www.cdc.gov/vaccines/Pubs/vis/vis-downloads.htm

To download VISs in other languages, visit www.immunize.org/vis

By using the VISs with your patients, you are helping to develop a better educated patient population and you are doing the right thing.

Fact 7 Federal law does not require signed consent in order for a person to be vaccinated

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

Fact 8 To verify that a VIS was given, providers must record in the patient's chart (or permanent office log or file) the following information:

- The published date of the VIS
- The date the VIS is given to the patient
- Name, address (office address), and title of the person who administers the vaccine
- The date the vaccine is administered
- The vaccine manufacturer and lot number of each dose administered

Fact 9 VISs should not be altered before giving them to patients

Providers should not change a VIS or write their own VISs. It is permissible to add a practice's name, address, or phone number to an existing VIS. Providers are encouraged to supplement the VIS with additional patient-education materials.

Fact 10 Provide VISs to all patients

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. If available, provide a translation of the VIS in the patient's language.

Translations of VISs in more than 30 languages are available from IAC. Go to www.immunize.org/vis for VISs in multiple languages as well as in other formats.