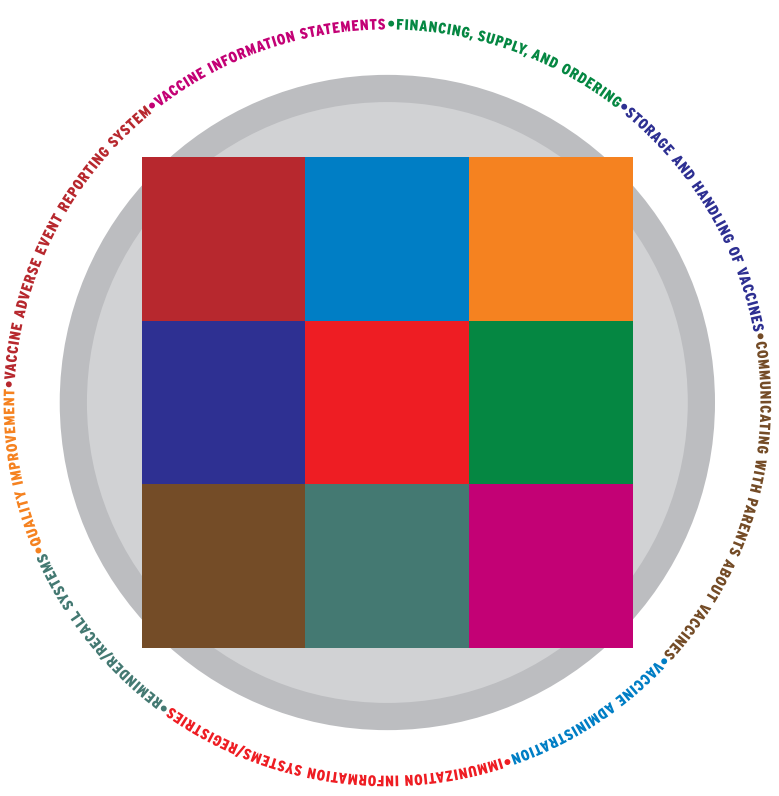
Immunization Training Guide & Practice Procedure Manual

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



Childhood Immunization Support Program
CISP

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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This manual is supported by the American Academy of Pediatrics Childhood Immunization Support Program, a grant from the Centers for Disease Control and Prevention, Cooperative Agreement Number U66/IP000400-02.

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Topics

Index of Acronyms, Vaccines, 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.

Financing, Supply, and Ordering

Introduction

Administering vaccines in pediatric practices is about providing a critical service to patients while reasonably covering overhead expenses and margin. Many practice administrators are forced to decide between staying in business and asking patients to obtain vaccines elsewhere, or risk going out of business by giving vaccines at a loss. 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 her 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 his 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. While 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. Further, 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. While 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 Management Online* Web site (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 adopted 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) and average wholesale price (AWP).

Average wholesale price 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 *Red Book*	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.

Average sales price 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.

Average sales price 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.

The AAP is currently evaluating options on facilitating access to updated AWP data. Because of vendor licensing agreements, there are restrictions on how AWP data can be exchanged (eg, posting lists of AWPs 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: 888/822-2749
- Merck: 800/734-6282
- MedImmune: 800/949-3789
- Wyeth: 800/666-7248

To obtain current ASP data, log on to 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 Member Center Private Payer Advocacy site at www.aap.org/securemoc/reimburse/VaccineAddendumtoPayerContracts.pdf.

More and more, however, the trend is to encourage 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 www.cdc.gov/vaccines/programs/vfc/cdc-vac-price-list.htm.

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, while a multicomponent vaccine, like 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, as 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

- Error by doctors or nurses in administration of vaccines
- Patients agreeing to a vaccine and then refusing 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 adopted from American Academy of Pediatrics PediaLink course, *Immunizations: Best Business Practices.*

Practices must pay special attention to wastage. While 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 x 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 the previously mentioned overhead costs. Please see the Commonly Administered Pediatric Vaccines/Toxoids coding table (www.aap.org/immunization/pediatricians/pdf/VaccineCodingTable.pdf) for a list of all *ICD-9-CM* and *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 wonderful resource at www.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.

Feel free to insert your practice's specific immunization schedule or 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.

Feel free to insert your state's Vaccines for Children (VFC) contact information, your order information, or 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 vaccine companies for prompt payment.
- Compare cost and payment. This may determine which vaccines you use.
- Determine the best way to order (eg, calling the representative, through purchasing groups).
- Which vaccines are available?

Key Facts

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

Tools and Resources

- Links for additional learning
  - Centers for Disease Control and Prevention
  - Chart of Vaccines in Delay or Shortage (www.cdc.gov/vaccines/vac-gen/shortages/default.htm)
    - Pediatric/VFC Vaccine Price List (www.cdc.gov/vaccines/programs/vfc/cdc-vac-price-list.htm)
  - *Practice Management Online* Vaccine Purchasing Groups (http://practice.aap.org/content.aspx?aid=2381&nodeID=3016)
- Documents you may include in your personalized manual (included on the following pages)
  - American Academy of Pediatrics
    - Commonly Administered Pediatric Vaccines/Toxoids table (www.aap.org/immunization/pediatricians/pdf/VaccineCodingTable.pdf)
    - *Red Book® Online* Vaccine Status Tables (http://aapredbook.aappublications.org/news/vaccstatus.pdf)
    - When Is it Appropriate to Report 99211 During Immunization Administration? (www.aap.org/immunization/pediatricians/pdf/AAPPositionPaper99211.pdf)
    - The Business Case for Pricing Immunization Administration (www.aap.org/immunization/pediatricians/pdf/TheBusinessCase.pdf)

Effective 01/01/2011

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The Business Case for Pricing Immunization Administration

One of the goals of the American Academy of Pediatrics (AAP), shared by the American Academy of Family Physicians (AAFP) and the Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) is to promote maximum immunization coverage for all infants, children, adolescents, and young adults. To achieve this goal, physicians must be paid for the full costs (direct and indirect) of vaccine product-related expenses and vaccine administration expenses as well as the margin for overall overhead expenses. Because the private physician practice is the backbone of the immunization delivery infrastructure, payers must recognize that a pediatric practice is really a business entity and must run on sound, generally accepted business principles to remain viable. Vaccines are among the top overhead expenses for the pediatric practice. Therefore, payments must ensure reimbursement for the total direct and indirect practice expenses and a margin for both the vaccine product and the vaccine administration office costs and the time spent counseling families on the indications for and potential side effects of each vaccine product.

Immunization Administration Expenses: ***This service is separately reportable from the vaccine product.***

Some payers mistakenly try to maintain that inadequate vaccine payments can be made up by nominal immunization administration fees. ***However, these are two separate expenses and both need to be appropriately covered by payers.***

Several studies published in the *Pediatrics* supplement, "Financing of Childhood and Adolescent Vaccines"[1], underscore the need for appropriate payment to cover the total costs for immunizations. In one study on variable costs for immunizations by pediatric practices in Colorado it was determined that the variable costs of vaccine administration exceeded reimbursement from some insurers and health plans.[2]

The Centers for Medicare and Medicaid Services (CMS) uses its Medicare Resource-Based Relative Value Scale (RBRVS), which assigns relative value units (RVUs) to services based on the resources utilized. The RVUs of a *Current Procedural Terminology* (CPT) code take into account the physician work, practice expenses, and professional insurance liability expenses associated with that service. For immunization administration, these components are detailed below.

1. Physician Work Component: The total value of physician work contained in the Medicare RBRVS physician fee schedule includes:

- Physician time required to perform the service
- Technical skill and physical effort
- Mental effort and judgment
- Psychological stress associated with the physician's concerns about the iatrogenic risk to the patient

2. Practice Expense Component: Medicare RBRVS uses both direct and indirect practice expenses to determine practice expense RVUs, including the resources used within the facility or physician's office (or patient's home) in providing the service. The practice expense component of the immunization administration fee includes: 1) clinical staff time (RN/LPN/MA blend, including time for vaccine registry input, refrigerator/freezer temperature log monitoring/documentation, and refrigerator/freezer alarm monitoring/documentation); 2) medical supplies (1 pair non-sterile gloves, 7 feet of exam table paper, 1 OSHA-compliant syringe with needle, 1 CDC information sheet, 2 alcohol swabs, 1 band-aid) and; 3) medical equipment (exam table, dedicated full size vaccine refrigerator with alarm/lock [commercial grade], and refrigerator/freezer vaccine temperature monitor/alarm).

3. Professional Liability Insurance Expense Component: The professional liability insurance RVUs assigned to

a code are based on CMS historic malpractice claims data.

These three components are combined to create total RVUs (see Table below).

2011 Medicare Relative Value Units for Immunization Administration

CPT code and description	Physician Work RVUs	Practice Expense RVUs (Non-Facility)	Professional Insurance Liability RVUs	Total RVUs (Non-Facility)	Total RVUs x 2011 Medicare conversion factor ($33.9764) = Medicare Amount (Non-Facility)
90460 Immunization administration through 18 years of age via any route of administration, with counseling by physician or other qualified health care professional; first vaccine/toxoid component *	0.17	0.50	0.01	0.68	$23.10
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/toxoid component *	0.15	0.18	0.01	0.34	$11.55
90471 Immunization administration, one injection **	0.17	0.50	0.01	0.68	$23.10
90472 Immunization administration, each additional injection**	0.15	0.18	0.01	0.34	$11.55
90473 Immunization administration by intranasal/oral route, first administration**	0.17	0.50	0.01	0.68	$23.10
90474 Immunization administration by intranasal/oral route, each additional vaccine **	0.15	0.18	0.01	0.34	$11.55

** CPT codes 90460 and 90461 are reported for patients under 19 years of age and when counseling is performed on the patient by the physician or other qualified health care professional. It should also be noted that the following codes are reported per vaccine component rather than per injection/administration and make no distinction between routes of administration (i.e., injectable versus oral/intranasal).*
***These codes are reported for older patients (i.e., those 19 years and older) or if there is no counseling performed on the patient or the healthcare professional counseling does not meet state requirements for an "other qualified healthcare professional". It should also be noted that the following codes are reported per injection/administration and allow distinction between routes of administration (i.e., injectable versus oral/intranasal).*

As a separately reported service, payments for immunization administration need to adequately cover those costs to the practice which are separate from the direct and indirect costs associated with the vaccine product. Insurers understand business principles including the concept of return on investment and expect it in their business. There is no reason physicians should accept carrier refusal to pay separately and adequately for the vaccine product ***and*** the administration/counseling. Viable businesses pass on their increased costs to their purchasers to maintain profitability. The pediatric practice has a legitimate business case to make for separate and adequate payment for vaccines and immunization administration and carriers need to provide adequate payments to cover the total direct and indirect expenses for both the vaccine product and the administration.

Pediatric practices are the public health infrastructure for the nation's childhood immunization program. It is imperative to incentivize pediatricians to participate in immunization efforts by appropriate payment for immunization administration.

References

1. Financing of Childhood and Adolescent Vaccines; Pediatrics Supplement 2009 Available at: http://pediatrics.aappublications.org/content/vol124/Supplement_5/)
2. Judith E. Glazner, MS, Brenda Beaty, MSPH and Stephen Berman, MD
Cost of Vaccine Administration Among Pediatric Practices Pediatrics 2009; 124:S492-S498 Available at: http://pediatrics.aappublications.org/cgi/content/abstract/124/Supplement_5/S492

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 vaccine/toxoid component
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/toxoid component
	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]

Effective 01/01/2011

Commonly Administered Pediatric Vaccines/Toxoids

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
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, tetanus toxoid conjugate (MenCY-Hib), 4-dose schedule, when administered to children 2-15 months of age, for intramuscular use	GlaxoSmithKline	MenHibrix™	V06.8	2
90645	Hemophilus influenza B vaccine (Hib), HbOC conjugate, 4 dose, for intramuscular use	Wyeth	HibTITER®	V03.81	1
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	sanofi pasteur	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	sanofi pasteur Novatis GlaxoSmithKline	Fluzone No Preservative® Fluvirin® FLUARIX™	V04.81	1
90657	Influenza virus vaccine, split virus, 6–35 months dosage, for intramuscular use	sanofi pasteur	Fluzone®	V04.81	1
90658	Influenza virus vaccine, split virus, 3 years and older dosage, for intramuscular use	sanofi pasteur Novartis	Fluzone® Fluvirin®	V04.81	1
90660	Influenza virus vaccine, live, intranasal use	MedImmune	FluMist®	V04.81	1
90661	Influenza virus vaccine, derived from cell cultures, subunit, preservative and antibiotic free, for intramuscular use			V04.81	1
90670	Pneumococcal conjugate vaccine, 13 valent, for intramuscular use	Wyeth	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

Red Book® Online: Vaccine Status Table*

Table 1: Status of Recently Submitted, Licensed, and Recommended Vaccines
Click on disease names for current Red Book® recommendations.
General Recommendations on Immunization from ACIP - cdc.gov/mmwr/preview/mmwrhtml/rr6002a1.htm

Vaccine	Manufacturer	BLA submitted to FDA	BLA age indications**	FDA licensure	Status of AAP/CDC recommendations***
Hib (Hiberix®)	GlaxoSmithKline (GSK)	Mar-2009	Booster dose in children 15 months through 4 years of age	Licensed 19-Aug-09	CDC: cdc.gov/mmwr/preview/mmwrhtml/mm5836a5.htm
HPV4 (GARDASIL®)	Merck	Dec-2005	Females 9 through 26 years of age	Licensed 8-Jun-06	CDC: cdc.gov/mmwr/preview/mmwrhtml/rr56e312a1.htm CDC: cdc.gov/mmwr/preview/mmwrhtml/mm5920a5.htm
		sBLA	Males 9 through 26 years of age	Licensed 16-Oct-09	
		sBLA	Prevention of anal cancer in males and females nine through 26 years of age	Licensed 22-Dec-10	Pending review
HPV2 (Cervarix™)	GlaxoSmithKline (GSK)	Mar-2007	Females 10 through 25 years of age	Licensed 16-Oct-09	CDC: cdc.gov/mmwr/preview/mmwrhtml/mm5920a4.htm
Influenza vaccines - TIV	varies	n/a	See recommendations	varies	AAP: aappolicy.aappublications.org/cgi/content/full/pediatrics;126/4/816 CDC: cdc.gov/mmwr/preview/mmwrhtml/rr59e0729a1.htm CDC Seasonal: cdc.gov/flu *Red Book Online* Influenza Resource Page: aapredbook.org/flu
Influenza – LAIV-T (FluMist®)	MedImmune	sBLA	24 months through 49 years of age	Licensed 19-Sep-07	
		sBLA	Quadrivalent vaccine for B strains	To be reviewed	
Influenza – Intradermal (Fluzone®)	sanofi pasteur	New administration route	18 through 64 years of age	Licensed 9-May-11	Pending review
MCV4 (Menactra®)	sanofi pasteur	Dec-2003	11 through 55 years of age	Licensed 14-Jan-05	AAP: aappolicy.aappublications.org/cgi/content/full/pediatrics;116/2/496 CDC Menactra: cdc.gov/mmwr/preview/mmwrhtml/rr5407a1.htm CDC Menveo: cdc.gov/mmwr/preview/mmwrhtml/mm5909a5.htm CDC Update: cdc.gov/mmwr/preview/mmwrhtml/mm6030a3.htm Recommendations for children at prolonged risk: see Table 3. Recommendations pending for children under 2 years of age.
			2 through 10 years of age	Licensed 17-Oct-07	
			9 through 23 months of age	Licensed 22-Apr-11	
MCV4 (Menveo™)	Novartis	Apr-2010	11 through 55 years of age	Licensed 19-Feb-10	
			2 through 10 years of age	Licensed 28-Jan-11	
MenCY-Hib (MenHibrix™)	GlaxoSmithKline (GSK)	2009	2, 4, 6 and 12 months of age	To be reviewed	Pending FDA licensure
MMRV (ProQuad®)	Merck	Aug-2004	Same as for MMR for dose 1 or dose 2: 12 months through 12 years of age	Licensed 6-Sep-05	AAP: aappolicy.aappublications.org/cgi/content/full/pediatrics;120/1/221 CDC: cdc.gov/mmwr/preview/mmwrhtml/mm5447a4.htm CDC: cdc.gov/mmwr/preview/mmwrhtml/rr5903a1.htm
PCV13 (Prevnar 13®)	Wyeth	Mar-2009	2 months through 71 months of age	Licensed 25-Feb-10	AAP: aappolicy.aappublications.org/cgi/content/full/pediatrics;126/1/186 CDC: cdc.gov/mmwr/preview/mmwrhtml/mm5909a2.htm CDC: cdc.gov/mmwr/preview/mmwrhtml/rr5911a1.htm Recommendations for adults: see Table 3.
Rotavirus (ROTATEQ®)	Merck	Apr-2005	2, 4, and 6 months of age	Licensed 3-Feb-06	AAP: aappolicy.aappublications.org/cgi/content/full/pediatrics;123/5/1412 CDC: cdc.gov/mmwr/preview/mmwrhtml/rr5802a1.htm Recommendations for contraindication for SCID: see Table 3.
Rotavirus (ROTARIX®)	GlaxoSmithKline (GSK)	Jun-2007	2 and 4 months of age	Licensed 3-Apr-08	
Tdap (ADACEL™)	sanofi pasteur	Aug-2004	11 through 64 years of age	Licensed 10-Jun-05	AAP: aappolicy.aappublications.org/cgi/content/full/pediatrics;117/3/965 CDC Adolescent: cdc.gov/mmwr/preview/mmwrhtml/rr5503a1.htm CDC Update: cdc.gov/mmwr/preview/mmwrhtml/mm6001a4.htm CDC Pregnancy: cdc.gov/mmwr/preview/mmwrhtml/rr5704a1.htm ACIP Provisional: cdc.gov/vaccines/recs/provisional/downloads/pregnant-Tdap-use.pdf CDC Adacel for health care personnel: cdc.gov/mmwr/preview/mmwrhtml/rr5517a1.htm
Tdap (BOOSTRIX®)	GlaxoSmithKline (GSK)	Jul-2004	10 through 18 years of age	Licensed 3-May-05	
		sBLA	19 through 64 years of age	Licensed 4-Dec-08	CDC: cdc.gov/mmwr/preview/mmwrhtml/mm5814a5.htm
		sBLA	Greater than or equal to 65 years of age	Licensed 8-Jul-11	Pending review

Table Updated: 8/11/11

Table available on Red Book Online: www.aapredbook.org/news/vaccstatus.dtl
Current Recommended Immunization Schedules: 0-6 Years | 7-18 Years | Catch-up Schedule | Adult
Vaccine supply shortages may result in changes to recommendations. Please consult cdc.gov/vaccines/vac-gen/shortages/default.htm

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 = Pnemococcal 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: Status of Older Vaccine Licensure and Recommendations					
Vaccine	**Manufacturer**	**BLA submitted to FDA**	**BLA age indications****	**FDA licensure**	**Status of AAP/CDC recommendations*****
DTaP-IPV (KINRIX)	GlaxoSmithKline (GSK)	Jun-2007	4 through 6 years of age	Licensed 24-Jun-08	CDC: cdc.gov/mmwr/preview/mmwrhtml/mm5739a4.htm
DTaP-IPV/Hib (PENTACEL™)	sanofi pasteur	Jul-2005	2, 4, 6, and 15 through 18 months of age	Licensed 20-Jun-08	CDC: cdc.gov/mmwr/preview/mmwrhtml/mm5739a5.htm
Hepatitis A (VAQTA®)	Merck	sBLA	Greater than or equal to 12 months of age	Licensed 11-Aug-05	AAP: aappolicy.aappublications.org/cgi/content/full/pediatrics;120/1/189 CDC: cdc.gov/mmwr/preview/mmwrhtml/rr5507a1.htm CDC for post-exposure and for international travelers: cdc.gov/mmwr/preview/mmwrhtml/mm5641a3.htm
Hepatitis A (HAVRIX®)	GlaxoSmithKline (GSK)	sBLA	Greater than or equal to 12 months of age	Licensed 17-Oct-05	
Varicella virus second dose (Varivax®)	Merck	sBLA: second dose	12 months to 12 years of age (3 month minimum interval)	Licensed 5-Apr-05	AAP: aappolicy.aappublications.org/cgi/content/full/pediatrics;120/1/221 CDC: cdc.gov/mmwr/preview/mmwrhtml/rr5604a1.htm

Table Updated: 8/11/11

Table 3: Status of Recommendations for Vaccine Use in Special Circumstances or in Adults, or Changes in Recommended Vaccine Use			
Vaccine	**Indications****	**Date of Recommendation**	**Web site**
Anthrax AVA	People at risk of or already exposed to *Bacillus anthracis* spores	July 2010	CDC: cdc.gov/mmwr/preview/mmwrhtml/rr5906a1.htm
Hepatitis A and Hepatitis B (TWINRIX®)	Greater than or equal to 18 years of age: 0, 7, and 21 through 30 days; 12 month booster	Mar 2007	CDC: cdc.gov/mmwr/preview/mmwrhtml/mm5640a5.htm
Hepatitis A	International adoptees	Sep 2009	CDC: cdc.gov/mmwr/preview/mmwrhtml/mm5836a4.htm
Herpes zoster vaccine (ZOSTAVAX®)	Greater than or equal to 60 years of age	May 2006	CDC: cdc.gov/mmwr/preview/mmwrhtml/rr57e0515a1.htm
	50 through 59 years of age	Mar 2011	Pending review
Influenza (Afluria)	Greater than or equal to 9 years of age	Aug 2010	CDC: cdc.gov/mmwr/preview/mmwrhtml/mm5931a4.htm
Influenza, high dose	65 years of age and older	Apr 2010	CDC: cdc.gov/mmwr/preview/mmwrhtml/mm5916a2.htm
Japanese Encephalitis (IXIARO)	Greater than or equal to 17 years of age	Mar 2010	CDC: cdc.gov/mmwr/preview/mmwrhtml/rr5901a1.htm May 2011 Update: cdc.gov/mmwr/preview/mmwrhtml/mm6020a6.htm
	Booster dose	Feb 2011	CDC: cdc.gov/mmwr/preview/mmwrhtml/mm6020a5.htm
MCV4 (Menactra)	2 through 55 years of age, reimmunize people at prolonged risk of meningococcal disease	Sep 2009 Jan 2011	AAP: aapnews.aappublications.org/cgi/reprint/28/12/14-a.pdf CDC: cdc.gov/mmwr/preview/mmwrhtml/mm5648a4.htm CDC: cdc.gov/mmwr/preview/mmwrhtml/mm5717a4.htm CDC: cdc.gov/mmwr/preview/mmwrhtml/mm5837a4.htm CDC Update: cdc.gov/mmwr/preview/mmwrhtml/mm6003a3.htm
MCV4 (Menveo)	2 through 55 years of age, reimmunize people at prolonged risk of meningococcal disease	Jan 2011	
MMR	Evidence of immunity requirement for healthcare personnel	Jun 2009	ACIP Provisional: cdc.gov/vaccines/recs/provisional/downloads/mmr-evidence-immunity-Aug2009-508.pdf
PPSV23	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
PCV13	Greater than or equal to 50 years of age	To be reviewed	Pending FDA licensure
Polio	Final dose administered on or after 4th birthday and at least 6 months following previous dose	Aug 2009	CDC: cdc.gov/mmwr/preview/mmwrhtml/mm5830a3.htm
Rabies HDCV or PCECV	4-dose vaccination regimen for postexposure prophylaxis	Mar 2010	CDC: cdc.gov/mmwr/preview/mmwrhtml/rr5902a1.htm
RV5 and RV1	Addition of severe combined immune deficiency as a contraindication for administration of rotavirus vaccine	Feb 2010	CDC: cdc.gov/mmwr/preview/mmwrhtml/mm5922a3.htm
Tdap	All healthcare personnel	Apr 2011	ACIP: cdc.gov/vaccines/recs/provisional/downloads/use-of-Tdap-in-hcp.pdf
Yellow Fever	Persons greater than or equal to 9 months of age traveling to or living in areas at risk for yellow fever transmission in South America and Africa.	Oct 2009	CDC: cdc.gov/mmwr/preview/mmwrhtml/rr5907a1.htm

Table Updated: 8/11/11

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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	*ICD-9-CM*
99211-25 (E/M service)	**786.2** (*cough*)
90657 (influenza vaccine)	**V04.81** (*need for prophylactic vaccination and inoculation against certain viral diseases; influenza*)
90471 (immunization administration)	**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 98.7ºF 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	*ICD-9-CM*
90707 (MMR vaccine)	**V06.4** (*need for prophylactic vaccination and inoculation against combinations of diseases; measles-mumps-rubella [MMR])*
90471 (immunization administration)	**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	*ICD-9-CM*
99211-25 (E/M service)	**V67.59** (*follow-up examination; following other treatment; other*)
90744 (hepatitis B vaccine)	**V05.3** (*need for other prophylactic vaccination and inoculation against single diseases; viral hepatitis*)
90471 (immunization administration)	**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 98.7ºF and she appears well. The risk and potential side affects 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.

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.

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.

Please feel free to 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, or 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 vaccine on arrival, immediately place vaccine in recommended storage, then contact the manufacturer's quality control office or state health department for guidance.

The following vaccines should be refrigerated immediately on arrival and must be maintained between 35°F and 46°F (2°C–8°C). They should not be frozen or exposed to freezing temperatures.

- Diphtheria and tetanus, pediatric (DT), or tetanus and diphtheria toxoid, adult (Td)
- Diphtheria, tetanus, pertussis combinations (DTaP, DTaP-Hib, DTaP-IPV, DTaP-IPV-Hib, DTaP-Hep B-IPV, Tdap)
- *Haemophilus influenzae* type b (Hib)
- Hepatitis (Hep A, Hep B, Hep A-Hep B, Hep B-Hib)
- Human papillomavirus (HPV)
- Inactivated poliovirus (IPV)
- Live attenuated influenza (LAIV) (nasal spray)
- Meningococcal conjugate (MCV)
- Meningococcal polysaccharide (MPSV) (requires diluent)
- Pneumococcal conjugate (PCV)
- Pneumococcal polysaccharide (PPSV)
- Rotavirus (requires diluents)
- Trivalent inactivated influenza (TIV)

The following vaccines have different requirements:

- Measles, mumps, rubella (MMR)
  - Must be shipped with refrigerant or dry ice, and temperature of 50°F or lower must be maintained.
  - Diluent must not be frozen. Measles, mumps, rubella may be stored in the refrigerator between 35°F and 46°F or stored in the freezer. *Must be protected from the light*.
  - Diluent may be stored in refrigerator or at room temperature (68°F–77°F).
- Varicella (chickenpox)
  - Must arrive frozen (dry ice should still be present in package).
  - Must be stored in freezer immediately on arrival (5°F [-15°C] or lower) in a refrigerator or freezer with a separate external door.
  - Diluent may be stored in the refrigerator or at room temperature (68°F–77°F).
- Zoster (shingles)
  - Must arrive frozen (dry ice should still be present in package).
  - Must be stored in freezer immediately on arrival (5°F [-15°C] or lower) in a refrigerator or freezer with a separate external door.
  - Diluent should not be shipped in container with dry ice.
  - Diluent can be stored in refrigerator or at room temperature (68°F–77°F). Diluent should *not* be frozen.

In most cases the vaccine should be administered shortly after withdrawal from vial. Multi-dose vials should be immediately returned to the refrigerator once the dosage has been withdrawn from the vial. Multi-dose vials can then be used until expiration date unless contaminated.

Special Instructions for Shelf Life After Opening

1. Measles, mumps, rubella multi-dose vials must be reconstituted just prior to use. Vial may be refrigerated, but discard if additional doses are not used within 8 hours after reconstitution.
2. Meningococcal polysaccharide multi-dose 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. Dosing tube should not be returned to the refrigerator once 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.
7. Check the label for special indications on additional vaccines.

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 35°F and 46°F (2°C–7.7°C). Freezers should measure 5°F (-15°C) or lower. Monthly temperature logs should be maintained a minimum of 3 years, unless state regulations require a longer period. If temperature falls outside of the requirements, store under proper conditions immediately and call the manufacturer to determine if 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 up before they expire. Electronic systems can be used to monitor vaccine inventory.

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

Additional Instructions/Notes

- Rotate stock so that earliest dated vaccines are used first.
- No food or drinks can be stored in the vaccine freezer or refrigerator.
- Freezer must have a separate external door. Dormitory-type refrigerators are not allowed.
- A minimum of 2 employees need to be designated in charge of handling and storage.
- Vaccines should be stored in the middle of the freezer and refrigerator, not in the door.
- 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 thermometer should always be kept in the refrigerator and freezer.
- Containers of water should be kept in the refrigerator to help maintain cold temperatures.
- Ice packs should be stored in the freezer to help maintain cold temperatures.
- A "Do Not Unplug" sign must be posted by the outlet to the freezer and refrigerator.
- The state health department should be contacted for instructions on how to dispose of expired vaccines.
- Varicella and zoster vaccines will lose potency if stored in a temperature warmer than 5°F (-15°C).
- A backup plan should be developed in case of power outages or equipment failure.

Key Facts

- Refrigerator should measure between 35°F and 46°F (2°C–7.7°C).
- Freezer should measure 5°F (-15°C) or lower.
- Temperatures of the refrigerator and freezer should be checked at least twice each day and documented on a temperature log.

Tools and Resources

- Links for additional learning
  - Immunization Action Coalition (www.immunize.org)
  - Centers for Disease Control and Prevention (www.cdc.gov/vaccines)
- Documents you may include in your personalized manual (included on the following pages)
  - Immunization Action Coalition
    - Checklist for Safe Vaccine Storage and Handling (www.immunize.org/catg.d/p3035.pdf)
    - Don't Be Guilty of These Errors in Vaccine Storage and Handling (www.immunize.org/catg.d/p3036.pdf)
    - Emergency Response Worksheet (www.immunize.org/catg.d/p3051.pdf)
    - Temperature logs
      - Celsius freezer (www.immunize.org/catg.d/p3038c.pdf)
      - Celsius refrigerator (www.immunize.org/catg.d/p3037c.pdf)
      - Fahrenheit freezer (www.immunize.org/catg.d/p3038f.pdf)
      - Fahrenheit refrigerator (www.immunize.org/catg.d/p3037f.pdf)

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

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 units(s) in the event of a power failure or other unforseen 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 (+/-1ºC [+/-2ºF]) 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 35–46ºF (2–8ºC), and we aim for 40ºF (5ºC).

(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.

Technical content reviewed by the Centers for Disease Control and Prevention, July 2011.

www.immunize.org/catg.d/p3035.pdf • Item #P3035 (7/11)

(**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 (+/-1ºC [+/-2ºF]) with vaccines in the freezer.

YES NO 15. We maintain the average temperature in the freezer at +5ºF (-15ºC), preferably colder but no colder than -58ºF (-50ºC).

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!

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 refrigertor 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 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.

*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.

Technical content reviewed by the Centers for Disease Control and Prevention, April 2011.

www.immunize.org/catg.d/p3036.pdf • Item #P3036 (4/11)

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

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)

Temperature Log for Freezer — Celsius

Month/Year:_____ **Days 1–15**

Completing this temperature log: Check the temperature in the freezer compartment of your vaccine storage unit at least twice each working day. Place an "X" in the box that corresponds with the temperature, the time of the temperature reading, 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 warmer than -15°C: this represents an unacceptable temperature range. You must **take action!**

Take Action!

If temperature is too warm (above -15°C):

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 potency of the vaccine(s) has been affected: (_____) _____.
4. **Document the action taken** on the reverse side of this log.

Staff Initials																														
Day of Month	1		2		3		4		5		6		7		8		9		10		11		12		13		14		15	
Room Temp.																														
Exact Time																														
	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm

***Write any unacceptable temps (above -15°C) on these lines. Then take action!**

Danger! Temperatures above -15°C are too warm! **Write any unacceptable temperature on the lines above* and call your state or local health department immediately!**

Acceptable Temperatures																														
	-15°C																													
	-16°C																													
	-17°C																													
	-18°C																													
	-19°C																													
	-20°C																													
	-21°C																													
	-22°C																													
	-23°C to -40°C and colder†																													

†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.

See back for "Vaccine Storage Troubleshooting Record"

Adapted with appreciation from California Department of Public Health

Technical content reviewed by the Centers for Disease Control and Prevention, August 2011.

www.immunize.org/catg.d/p3038C.pdf • Item #P3038C (8/11)

Distributed by the Immunization Action Coalition • (651) 647-9009 • www.immunize.org • www.vaccineinformation.org • admin@immunize.org

Vaccine Storage Troubleshooting Record

Date	Time	Storage Unit Temp	Room Temp	Problem	Action Taken	Results	Staff Initials

Temperature Log for Freezer — Celsius

Month/Year:_____ **Days 16–31**

Completing this temperature log: Check the temperature in the freezer compartment of your vaccine storage unit at least twice each working day. Place an "X" in the box that corresponds with the temperature, the time of the temperature reading, 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 warmer than -15°C: this represents an unacceptable temperature range. You must **take action!**

Take Action!

If temperature is too warm (above -15°C):

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 potency of the vaccine(s) has been affected: (_____) _____.
4. **Document the action taken** on the reverse side of this log.

Staff Initials																															
Day of Month	**16**		**17**		**18**		**19**		**20**		**21**		**22**		**23**		**24**		**25**		**26**		**27**		**28**		**29**		**30**		**31**	
Room Temp.																															
Exact Time																															
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***Write any unacceptable temps (above -15°C) on these lines. Then take action!**

_____ _____

Danger! Temperatures above -15°C are too warm! **Write any unacceptable temperature on the lines above* and call your state or local health department immediately!**

Acceptable Temperatures																															
-15°C																															
-16°C																															
-17°C																															
-18°C																															
-19°C																															
-20°C																															
-21°C																															
-22°C																															
-23°C to -40°C and colder†																															

†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.

See back for "Vaccine Storage Troubleshooting Record"

Adapted with appreciation from California Department of Public Health

Technical content reviewed by the Centers for Disease Control and Prevention, August 2011.

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Vaccine Storage Troubleshooting Record

Date	Time	Storage Unit Temp	Room Temp	Problem	Action Taken	Results	Staff Initials

Temperature Log for Refrigerator — Celsius

Month/Year:_____ **Days 1–15**

Completing this temperature log: Check the temperature in the refrigerator compartment of your vaccine storage unit at least twice each working day. Place an "X" in the box that corresponds with the temperature, the time of the temperature reading, 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 warmer than 8°C or colder than 2°C: this represents an unacceptable temperature range. You must **take action!**

Take Action!

If temperature is too warm (above 8°C) or too cold (below 2°C):

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 potency of the vaccine(s) has been affected: (_____) _____.
4. **Document the action taken** on the reverse side of this log.

Staff Initials																													
Day of Month	1		2		3		4		5		6		7		8		9		10		11		12		13		14		15	
Room Temp.																													
Exact Time																													
	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm

***Write any unacceptable temps (above 8°C or below 2°C) on these lines. Then take action!** ___

Danger! Temperatures above 8°C are too warm! **Write any unacceptable temperature on the lines above* and call your state or local health department immediately!**

Acceptable Temperatures																													
8°C																													
7°C																													
6°C																													
5°C																													
4°C																													
3°C																													
2°C																													

Danger! Temperatures below 2°C are too cold! **Write any unacceptable temperature on the lines above* and call your state or local health department immediately!**

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Vaccine Storage Troubleshooting Record

Date	Time	Storage Unit Temp	Room Temp	Problem	Action Taken	Results	Staff Initials

C° Temperature Log for Refrigerator — Celsius

Month/Year:_____ **Days 16–31**

Completing this temperature log: Check the temperature in the freezer compartment of your vaccine storage unit at least twice each working day. Place an "X" in the box that corresponds with the temperature, the time of the temperature reading, 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 warmer than 8°C or colder than 2°C: this represents an unacceptable temperature range. You must **take action!**

Take Action!

If temperature is too warm (above 8°C) or too cold (below 2°C):

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 potency of the vaccine(s) has been affected: (_____) _____.
4. **Document the action taken** on the reverse side of this log.

Staff Initials																															
Day of Month	**16**		**17**		**18**		**19**		**20**		**21**		**22**		**23**		**24**		**25**		**26**		**27**		**28**		**29**		**30**		**31**	
Room Temp.																															
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***Write any unacceptable temps (above 8°C or below 2°C) on these lines. Then take action!**

_____ _____

Danger! Temperatures above 8°C are too warm! **Write any unacceptable temperature on the lines above* and call your state or local health department immediately!**

Acceptable Temperatures																															
8°C																															
7°C																															
6°C																															
5°C																															
4°C																															
3°C																															
2°C																															

Danger! Temperatures below 2°C are too cold! **Write any unacceptable temperature on the lines above* and call your state or local health department immediately!**

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Vaccine Storage Troubleshooting Record

Date	Time	Storage Unit Temp	Room Temp	Problem	Action Taken	Results	Staff Initials

F° Temperature Log for Freezer — Fahrenheit

Month/Year:_____ **Days 1–15**

Completing this temperature log: Check the temperature in the freezer compartment of your vaccine storage unit at least twice each working day. Place an "X" in the box that corresponds with the temperature, the time of the temperature reading, 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 warmer than 5°: this represents an unacceptable temperature range. You must **take action!**

Take Action!

If temperature is too warm (above 5°F):

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 potency of the vaccine(s) has been affected: (_____) _____.
4. **Document the action taken** on the reverse side of this log.

Staff Initials																														
Day of Month	1		2		3		4		5		6		7		8		9		10		11		12		13		14		15	
Room Temp.																														
Exact Time																														
	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm

***Write any unacceptable temps (above 5°F) on these lines. Then take action!**

_____ _____

Danger! Temperatures above 5°F are too warm! **Write any unacceptable temperature on the lines above* and call your state or local health department immediately!**

Acceptable Temperatures																														
5°F																														
4°F																														
3°F																														
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1°F																														
0°F																														
-1°F																														
-2°F																														
-3°F																														
-4°F																														
-5°F to -30°F and colder†																														

†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.

See back for "Vaccine Storage Troubleshooting Record"

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Vaccine Storage Troubleshooting Record

Date	Time	Storage Unit Temp	Room Temp	Problem	Action Taken	Results	Staff Initials

F° Temperature Log for Freezer — Fahrenheit

Month/Year:_____ **Days 16–31**

Completing this temperature log: Check the temperature in the freezer compartment of your vaccine storage unit at least twice each working day. Place an "X" in the box that corresponds with the temperature, the time of the temperature reading, 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 warmer than 5°: this represents an unacceptable temperature range. You must **take action!**

Take Action!

If temperature is too warm (above 5°F):

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 potency of the vaccine(s) has been affected: (_____) _____.
4. **Document the action taken** on the reverse side of this log.

Staff Initials																														
Day of Month	16		17		18		19		20		21		22		23		24		25		26		27		28		29		30		31	
Room Temp.																														
Exact Time																														
	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm

***Write any unacceptable temps (above 5°F) on these lines. Then take action!**

_____ _____

Danger! Temperatures above 5°F are too warm! **Write any unacceptable temperature on the lines above* and call your state or local health department immediately!**

Acceptable Temperatures																														
5°F																														
4°F																														
3°F																														
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0°F																														
-1°F																														
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Vaccine Storage Troubleshooting Record

Date	Time	Storage Unit Temp	Room Temp	Problem	Action Taken	Results	Staff Initials

F° Temperature Log for Refrigerator — Fahrenheit

Month/Year:_____ **Days 1–15**

Completing this temperature log: Check the temperature in the refrigerator compartment of your vaccine storage unit at least twice each working day. Place an "X" in the box that corresponds with the temperature, the time of the temperature reading, 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 warmer than 46°F or colder than 35°F: this represents an unacceptable temperature range. You must **take action!**

Take Action!

If temperature is too warm (above 46°F) or too cold (below 35°F):

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 potency of the vaccine(s) has been affected: (_____) _____.
4. **Document the action taken** on the reverse side of this log.

Staff Initials																														
Day of Month	1		2		3		4		5		6		7		8		9		10		11		12		13		14		15	
Room Temp.																														
Exact Time																														
	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm

***Write any unacceptable temps (above 46°F or below 35°F) on these lines. Then take action!** _____

Danger! Temperatures above 46°F are too warm! **Write any unacceptable temperature on the lines above* and call your state or local health department immediately!**

Acceptable Temperatures																														
46°F																														
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41°F																														
40°F																														
39°F																														
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37°F																														
36°F																														
35°F																														

Danger! Temperatures below 35°F are too cold! **Write any unacceptable temperature on the lines above* and call your state or local health department immediately!**

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Date	Time	Storage Unit Temp	Room Temp	Problem	Action Taken	Results	Staff Initials

F° Temperature Log for Refrigerator — Fahrenheit

Month/Year:_____ **Days 16–31**

Completing this temperature log: Check the temperature in the freezer compartment of your vaccine storage unit at least twice each working day. Place an "X" in the box that corresponds with the temperature, the time of the temperature reading, 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 warmer than 46°F or colder than 35°F: this represents an unacceptable temperature range. You must **take action!**

Take Action!

If temperature is too warm (above 46°F) or too cold (below 35°F):

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 potency of the vaccine(s) has been affected: (_____) _____.
4. **Document the action taken** on the reverse side of this log.

Staff Initials																														
Day of Month	16		17		18		19		20		21		22		23		24		25		26		27		28		29		30		31	
Room Temp.																														
Exact Time																														
	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm

***Write any unacceptable temps (above 46°F or below 35°F) on these lines. Then take action!**

Danger! Temperatures above 46°F are too warm! **Write any unacceptable temperature on the lines above* and call your state or local health department immediately!**

Acceptable Temperatures																														
46°F																														
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41°F																														
40°F																														
39°F																														
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37°F																														
36°F																														
35°F																														

Danger! Temperatures below 35°F are too cold! **Write any unacceptable temperature on the lines above* and call your state or local health department immediately!**

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Vaccine Storage Troubleshooting Record

Date	Time	Storage Unit Temp	Room Temp	Problem	Action Taken	Results	Staff Initials

Communicating With Parents About Vaccines

Introduction

All health care professionals providing care to newborns, infants, and children 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. Others want a nonstandard schedule to be followed, particular ingredients to be avoided, or single vaccines only to be provided.

The following section presents resources to help health care professionals address common concerns of parents. It also includes resources for parents that answer common questions. The federal requirements for providing Centers for Disease Control and Prevention (CDC) Vaccine Information Statements (VISs) are listed in a separate section of this guide. A sample 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.

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.

About Communicating With Parents

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

The effectiveness of these vaccines and earlier vaccines that decreased illnesses like diphtheria, tetanus, polio, and measles, mumps, and rubella (MMR) has led some parents to believe that vaccines are no longer necessary or that not all vaccines are 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.

Health care professionals can address concerns, asking parents what questions they have about each vaccine being refused. Vaccine Information Statements 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. There may be vaccines that are acceptable. Those vaccines can be given. Opportunities to have other vaccines can be presented at other visits.

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.

Addressing Common Concerns

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

Too Many/Too Soon

Vaccines are given to newborns and infants during the time at which they are most at risk of the illnesses protected against by vaccines. A baby is born with some protection against disease provided by mother's antibodies transferred during pregnancy, such as measles and chickenpox. These vaccines are given at 1 year, when maternal antibody has declined and the child's immune system can make antibodies. Babies are not protected against hepatitis B, diphtheria, whooping cough, polio, tetanus, or *H influenzae*. These infections can be fatal or cause lifelong impairment like liver damage, cardiac disease, and hearing loss. These vaccines are given to babies in series of small doses to build up immunity when they are most susceptible to these illnesses. Numerous studies are done to make sure 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; they are exposed to many more antigens on a daily basis than the number given in vaccines. Exposure to antigens occurs every time a baby eats, puts a toy in her mouth, or plays on the floor.

Alternative Schedules

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 has 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 susceptible to the diseases. Alternative schedules have not been tested for effectiveness and safety.

Too New

Human papillomavirus vaccine was approved for use for girls and young women aged 9 to 26 years in 2006 after clinical trials in thousands of females in different countries. In the trials it was found to be effective and safe in protecting against strains of the virus that can lead to cervical cancer. The CDC and Food and Drug Administration (FDA) monitor all vaccines in use, including HPV. They have found that some patients faint after they have received the vaccine. The FDA has added that information to the prescribing information for the vaccine, and the CDC has added this information to its educational material for parents. Physicians may have vaccine recipients wait in the office for 15 minutes after the vaccine is administered.

Pneumococcal vaccine (Prevnar 13) was introduced in February 2010. It includes 6 more strains of pneumococcus than the previous pneumococcal vaccine introduced in 2000. It provides more protection against a germ that causes meningitis, pneumonia, bloodstream infections, and ear infections. It is approved for use in infants and toddlers and older children at high risk of pneumococcal infection. The vaccine has been studied and found to have a safety profile like that of the vaccine that covers 7 strains. It is being monitored as it is being used.

Rotavirus vaccine was approved for use in infants 6 to 32 weeks old in 2006. Clinical trials of rotavirus vaccines have been conducted in tens of thousands of patients, and millions of infants have received them. Their safety record is good. They prevent illness with severe vomiting and diarrhea that leads to hospitalizations for dehydration in the United States and to death in other parts of the world.

Vaccine Ingredients

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 like MMR or chickenpox. Some of the antigens are killed, and some are live. Live virus vaccines are MMR and chickenpox vaccines.

Aluminum salts or gels are the only adjuvant used in some vaccines in the United States. An *adjuvant* is an addition to a vaccine that helps increase the body's immune response to the antigen in the vaccine. They 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. It is removed at the end of the vaccine manufacturing process, leaving an amount so small that it does not have any effect. Many scientific studies have shown that there is no link between thimerosal and autism. However, because of this concern, thimerosal was removed from most childhood vaccines in 2001. Rates of autism have actually increased since thimerosal was removed from vaccines. It is 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

No scientific studies show 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 research has been found to be biased and fraudulent. 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 shown that there is no relationship between the vaccine and autism.

Scientific studies about a link between thimerosal and autism have been completed with thousands and thousands of children. These studies have demonstrated that there is not a link between thimerosal and autism. During the past decade, with thimerosal removed from most childhood vaccines, the rate of autism has continued to rise.

Resources used to verify these statements were found through www.immunize.org, www.cdc.gov, and www.fda.gov.

Key Facts

- Vaccine Information Statements need to be provided to a parent or legal representative every time a vaccine is given. They are available from the CDC and Immunization Action Coalition Web sites. They are also available from state departments of community health. 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.
- 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.

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 (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)
    - 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)
    - Vaccine Safety - Hot Topics (www.chop.edu/service/vaccine-education-center/hot-topics)
  - *Pediatrics*
    - "On-time Vaccine Receipt in the First Year Does Not Adversely Affect Neuropsychological Outcomes" (http://pediatrics.aappublications.org/content/125/6/1134.full) (log-in required)
    - "The Problem With Dr Bob's Alternative Vaccine Schedule" (http://pediatrics.aappublications.org/content/123/1/e164.full) (log-in required)
  - ShotByShot.org: Why Use A Story? (http://shotbyshot.org/use-a-story)

- Documents you may include in your personalized manual (included on the following pages)
  - American Academy of Pediatrics
    - Documenting Parental Refusal to Have Their Children Vaccinated (www.aap.org/immunization/pediatricians/pdf/RefusaltoVaccinate.pdf)
    - Questions and Answers about Vaccine Ingredients (www.aap.org/immunization/families/faq/Vaccineingredients.pdf)
    - Strategies for Pediatricians: Addressing Common Concerns of Vaccine-Hesitant Parents (www.aap.org/immunization/pediatricians/pdf/Vaccine-Hesitant%20Parent_Final.pdf)
    - Talking with Parents about Vaccines for Infants (with US Department of Health and Human Services, CDC, and American Academy of Family Physicians) (www.cdc.gov/vaccines/spec-grps/hcp/downloads/talk-infants-bw-office.pdf)
  - Immunization Action Coalition
    - MMR vaccine does not cause autism (www.immunize.org/catg.d/p4026.pdf)

American Academy of Pediatrics
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Documenting Parental Refusal to Have Their Children Vaccinated

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. Within a 12-month period, 85% of pediatricians report encountering a parent who refused or delayed one or more vaccines and 54% report encountering a parent who refused all vaccines. Even though scientific data solidly support the fact that vaccines are safe and effective, concern over harmful side effects, often taken out of context in the media and on unmonitored and biased Web sites, cause substantial and often unrealistic fears.

All parents and patients should be informed about the risks and benefits of preventive and therapeutic procedures, including vaccination. In the case of vaccination, federal law mandates this discussion. Despite doctors' and nurses' best efforts to explain the importance of vaccines and to address parental concerns about vaccine safety, some families will refuse vaccination for their children. Others will ultimately accept some or all vaccinations after repeated discussions during which the provider has listened to the parents concerns and addressed them in a non-condescending manner. The use of this or a similar form demonstrates the importance you place on appropriate immunizations, focuses the 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 the parent's reason for refusing one or more vaccines, and maintaining a supportive relationship with the family are all part of a good risk management strategy. The American Academy of Pediatrics (AAP) encourages documentation of the healthcare provider's discussion with a parent about the serious risks of what could happen to their unimmunized or under-immunized child. Provide the parents the appropriate Vaccine Information Statement (VIS) for each vaccine and answer their questions. For parents who refuse one or more recommended immunizations, document your conversation, the provision of the VIS(s), and have the parent sign the vaccine refusal form and keep the form in the patient's medical record. 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 fever of unknown origin.

This form may be used as a template for such documentation but should not be considered a legal document and should not substitute for legal advice from a qualified attorney.

This form may be duplicated **or changed** to suit your needs and your patients' needs.

The 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 will be available on the AAP Web site (www.aap.org/bookstore), the Section on Infectious Diseases Web site (http://www.aap.org/sections/infectdis/index.cfm), and the Web site for the Academy's Childhood Immunization Support Program (www.cispimmunize.org/).

Sincerely,

/s/
Meg Fisher, MD, FAAP
Chairperson
AAP Section on Infectious Diseases

/s/
Ed Rothstein, MD, FAAP
AAP Section on Infectious Diseases

Refusal to Vaccinate

Child's Name: _____ Child's ID # _____

Parent's/Guardian's Name: _____

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

Recommended		Declined
☐	Hepatitis B vaccine	☐
☐	Diphtheria, tetanus, acellular pertussis (DTaP or Tdap) vaccine	☐
☐	Diphtheria tetanus (DT or Td) vaccine	☐
☐	*Haemophilus influenzae* type b (Hib) vaccine	☐
☐	Pneumococcal conjugate or polysaccharide vaccine	☐
☐	Inactivated poliovirus (IPV) vaccine	☐
☐	Measles-mumps-rubella (MMR) vaccine.	☐
☐	Varicella (chickenpox) vaccine	☐
☐	Influenza (flu) vaccine	☐
☐	Meningococcal conjugate or polysaccharide vaccine	☐
☐	Hepatitis A vaccine	☐
☐	Rotavirus vaccine	☐
☐	Human papillomavirus vaccine	☐
☐	Other	☐

I have read the Vaccine Information Statement from the Centers for Disease Control and Prevention explaining the vaccine(s) and the disease(s) it prevents. I have had the opportunity to discuss this with my child's doctor or nurse, who has answered all of my questions regarding the recommended vaccine(s). I understand the following:

- The **purpose** of and the need for the recommended vaccine(s)
- The **risks and benefits** of the recommended vaccine(s)
- If my child does not receive the vaccine(s) according to the medically accepted schedule, **the consequences** may include:
  - Contracting the illness the vaccine should 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
  - Requiring my child to stay out of child care or school during disease outbreaks
- My child's doctor or nurse, 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 which my child might come into contact.

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 anytime in the future.

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

Parent/Guardian Signature _____ Date _____

Witness _____ Date _____

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

Parent's initials _____ Date _____ Parent's initials _____ Date _____

Parent's initials _____ Date _____ Parent's initials _____ Date _____

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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's Childhood Immunization Support Program (CISP)**
   Information for providers and parents.
   www.cispimmunize.org
2. **The Immunization Education Program (IEP) of the Pennsylvania Chapter of the American Academy of Pediatrics**
   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.
   http://www.paiep.org/
3. **The 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. Their "Unprotected People Reports" are case reports, personal testimonies, and newspaper and journal articles about people who have suffered or died from vaccine-preventable diseases.
   http://www.immunize.org/reports/
4. **Centers for Disease Control and Prevention (CDC) National Immunization Program**
   Information about vaccine safety, including Parents' Guide to Childhood Immunizations.
   http://www.cdc.gov/vaccines/hcp.htm
5. **National Network of Immunization Information (NNii)**
   Includes the NNii Resource Kit – Communicating with Patients about Immunizations. A guide to help answer patients' questions and provide the facts about immunizations.
   www.immunizationinfo.org
6. **Vaccine Education Center at Children's Hospital of Philadelphia**
   Information for parents includes Common Concerns About Vaccines, Are Vaccines Safe, and A Look at Each Vaccine.
   www.vaccine.chop.edu
7. **Institute for Vaccine Safety, Johns Hopkins University**
   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
8. **The Canadian Coalition for Immunization Awareness and Promotion (CCIAP)**
   CCIAP aims to meet the goal of eliminating vaccine-preventable disease through education, promotion, advocacy, and media relations. It includes resources for parents and providers, including "How to advise parents unsure about immunization" by Scott A. Halperin, MD.
   http://immunize.cpha.ca/en/default.aspx

Journal Articles

1. Ball LK**,** Evans G**,** Bostrom A. Risky business: challenges in vaccine risk communication. *Pediatrics*. 1998;101:453-458. Available at: http://www.pediatrics.org/cgi/content/full/101/3/453 (subscription needed)
2. Dias M, Marcuse EK. When parents resist immunizations. *Contemp Pediatr*. 2000;17:75-86
3. Offit PA, Jew RK. Addressing parents' concerns: do vaccines contain harmful preservatives, adjuvants, additives, or residuals? *Pediatrics*. 2003;112:1394-1397
4. Offit PA, Quarles J, Gerber MA, et al. Addressing parents' concerns: do multiple vaccines overwhelm or weaken the infant's immune system? *Pediatrics*. 2002;109:124-129
5. Diekema DS, and American Academy of Pediatrics, Committee on Bioethics. Responding to parental refusals of immunization of children. *Pediatrics*. 2005;115:1428-1431

Books

1. Offit PA, Bell LM. *Vaccines: What Every Parent Should Know*. New York, NY: IDG Books; 1999
2. Humiston SG, Good C. *Vaccinating Your Child: Questions and Answers for the Concerned Parent*. Atlanta, GA: Peachtree Publishers; 2000
3. Fisher MC. *Immunizations and Infectious Diseases: An Informed Parent's Guide*. Elk Grove Village, IL: American Academy of Pediatrics; 2005
4. Marshall GS,.*The Vaccine Handbook: A Practical Guide for Clinicians*. 2nd ed. West Islip, NY: Professional Communications, Inc.; 2008.
5. Myers, MG and Pineda D. *Do Vaccines Cause That? A Guide for Evaluating Vaccine Safety Concerns.* Immunizations for Public Health. 2008

Reliable Immunization Resources for Parents

Web sites

1. **AAP's Childhood Immunization Support Program (CISP)**
   Information for providers and parents.
   www.cispimmunize.org

2. **Why Should I Immunize My Child?**
   A description of the individual diseases and the benefits expected from vaccination.
   www.cispimmunize.org/fam/why.html

3. **The Immunization Education Program (IEP) of the Pennsylvania Chapter of the American Academy of Pediatrics**
   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.
   http://www.paiep.org/

4. **Centers for Disease Control and Prevention National Immunization Program**
   Information about vaccine safety, including Parents' Guide to Childhood Immunizations
   http://www.cdc.gov/vaccines/spec-grps/parents.htm

5. **National Network of Immunization Information (NNii)**
   Includes the NNii Resource Kit – Communicating with Patients about Immunizations. A guide to help answer patients' questions and provide the facts about immunizations.
   www.immunizationinfo.org

6. **Vaccine Education Center at Children's Hospital of Philadelphia**
   Information for parents includes Common Concerns About Vaccines, Are Vaccines Safe, and A Look at Each Vaccine.
   www.vaccine.chop.edu

7. **Institute for Vaccine Safety, Johns Hopkins University**
   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

8. **The Canadian Coalition for Immunization Awareness and Promotion (CCIAP)**
   CCIAP aims to meet the goal of eliminating vaccine-preventable disease through education, promotion, advocacy, and media relations. It includes resources for parents and providers, including "How to advise parents unsure about immunization" by Scott A. Halperin, MD.
   http://immunize.cpha.ca/en/default.aspx

9. **Vaccinate Your Baby**
   The 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. Offit PA, Bell LM. *Vaccines: What Every Parent Should Know*. New York, NY: IDG Books; 1999
2. Humiston SG, Good C. *Vaccinating Your Child: Questions and Answers for the Concerned Parent*. Atlanta, GA: Peachtree Publishers; 2000
3. Fisher MC. *Immunizations and Infectious Diseases: An Informed Parent's Guide*. Elk Grove Village, IL: American Academy of Pediatrics; 2005
4. Myers, MG and Pineda D. *Do Vaccines Cause That? A Guide for Evaluating Vaccine Safety Concerns.* Immunizations for Public Health. 2008

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 vaccine contain weakened live viruses.
- **Inactivated (or killed) viruses.** These viruses cannot cause even a mild form of the disease, but the body still recognizes the virus and creates an immune response to protect itself. The polio, hepatitis A, influenza and rabies vaccines contain inactivated viruses.
- **Partial viruses.** These are made up of the specific part of the dead virus that will prompt a protective immune response. Some vaccines are made this way including the hepatitis B and HPV vaccine.
- **Partial bacteria.** These vaccines work in two ways. First, the Hib, pneumococcal and meningococcal vaccines are made using part of the sugar coating (or polysaccharide) of the bacteria. The vaccine creates immunity against this sugar coating, providing protection against the bacteria. Second, vaccines against diphtheria, tetanus and pertussis (whooping cough) are made by inactivating the protein in the bacteria that causes harm.

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. Why are these other ingredients in vaccines? Are they safe?
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. Polyethylene glycol (a chemical used in antifreeze and personal care products like skin creams and toothpaste) is used in vaccines and is safe. It is used to inactivate the influenza virus in some influenza vaccines. It is also used to purify other vaccines.

Q. Do vaccines contain mercury?
A: Thimerosal, a mercury-based preservative, was removed from most childhood vaccines in 2001. It is still present in some influenza vaccines. Thimerosal is still used in the manufacture of some vaccines to prevent contamination. The thimerosal is removed at the end of the manufacturing process. In some cases, a tiny amount of thimerosal remains. The remaining amount is so small, that it is not possible for it to have any effect. Valid scientific studies have shown there is no link between thimerosal and autism. In fact, autism rates have actually increased since thimerosal was removed from childhood vaccines. The American Academy of Pediatrics (AAP), the American Medical Association (AMA), the CDC, and the Institute of Medicine (IOM) agree that science does not support a link between thimerosal in vaccines and autism. For the IOM report, go to http://www.iom.edu/CMS/3793/4705/4717.aspx.

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.

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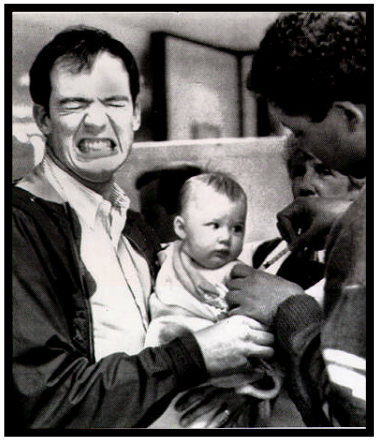
STRATEGIES FOR PEDIATRICIANS: ADDRESSING COMMON CONCERNS OF VACCINE-HESITANT PARENTS



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://www.aap.org/immunization/families/faq/FAQ_Safety.pdf.

I. 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 (eg, 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]

II. 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]

Some specific concerns of parents and information targeted to those concerns are listed below:

A. 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://www.aap.org/immunization/families/faq/Vaccineschedule.pdf.

B. 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:

- Offit 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://www.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.

C. 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.

D. 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://www.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.

E. 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://www.aap.org/immunization/pediatricians/influenzaguidance.html.

F. 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.

III. 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.

- To determine parental concerns, ask the following questions:[8]
  1) *Do you have any cultural, religious, or personal belief regarding immunization?*
  2) *Has your child or any child you know has a serious adverse event after an immunization?*
  3) *Do you have any vaccine safety concerns?*
  4) *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.[3]
- 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.

Additional Resources:

- **AAP Refusal to Vaccinate Form.** Available at: http://www.aap.org/immunization/pediatricians/pdf/RefusaltoVaccinate.pdf.
- AAP Manual**,** "**Medical Liability for Pediatricians**" Available at: http://tinyurl.com/5esgmc.
- AAP Policy Statement: ***Responding to Parental Refusals of Immunization of Children*** Available at: http://aappolicy.aappublications.org/cgi/reprint/pediatrics;115/5/1428.pdf.
- Centers for Disease Control and Prevention (CDC). **Providers' Guide: Helping Parents Who Question Vaccines.** Available at: http://www.cdc.gov/vaccines/pubs/providers-guide-parents-questioning-vacc.htm.
- 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.

American Academy of Pediatrics

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Childhood Immunization Support Program

CISP

You may encounter parents who participate in alternative methods of health care, including chiropractic. The following article offers insight about 7 possible arguments that these parents may have regarding vaccination:

Campbell JB, Busse JW, Injeyan HS. Chiropractors and vaccination: a historical perspective. *Pediatrics.* 2000; 105:43. http://www.aap.org/immunization/pediatricians/pdf/chiropractors.pdf(*Reproduced with Permission of Pediatrics. Volume 105, Page e43, Copyright 2000)*

Last updated October 2009

Talking with Parents about Vaccines for Infants

Physicians, nurses, 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 healthcare provider, you remain parents' most trusted source of information about vaccines, and 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 when raised
- Proven communication strategies and tips for having a successful vaccine conversation with parents

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

What You May Hear From Parents

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

Questions about whether vaccines cause autism

Parents may encounter poorly designed and conducted studies, misleading summaries of well-conducted studies, or anecdotes made to look like science—claiming that vaccines cause autism. Many rigorous studies show that there is no link between MMR vaccine or thimerosal and autism. Visit www.cdc.gov/vaccines/hcp 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 www.cdc.gov/vaccines/hcp 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 (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.

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

"There's no proven danger, 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. Remember, any time you delay a vaccine, you leave your baby vulnerable to disease. It's really best to stay on schedule."

Questions about the number of vaccines and vaccine ingredients

Some parents may have a general concern that there are too many vaccines. AAP's fact sheet *The Childhood Immunization Schedule: Why Is It Like That?* (www.cispimmunize.org/pro/pdf/Vaccineschedule.pdf) 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. The AAP's *Questions and Answers about Vaccine Ingredients* (www.cispimmunize.org/pro/pdf/Vaccineingredients.pdf) can help you counter myths that have circulated about vaccine ingredients. Finally, 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 full protection. 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.

"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 so many serious diseases with vaccines."

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 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.

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, let them know that you want to hear their questions.

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.

Don't be offended, and don't offend.

Some parents may come to you with a long list of questions or information from a variety of sources. Don't interpret this as a lack of respect for you or a lack of intelligence on the part of the parent. 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.
Never state that vaccines are risk-free and always discuss honestly the known side effects caused by vaccines. But don't forget to remind parents that the diseases vaccines prevent can return. 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 OK.

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* (www.cdc.gov/vaccines/hcp), 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 healthcare 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 (www.cispimmunize.org/pro/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 **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

   Retracted

   ★ 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

   ★ "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).

Technical content reviewed by the Centers for Disease Control and Prevention, November 2008.

www.immunize.org/catg.d/p4026.pdf • Item #P4026 (11/08)

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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.* Makela 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

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, while 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 are knowledgeable and have been well trained prior to 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 age and size of 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 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.

About Vaccine Administration

Infection control is very important, and hand washing is the single most important way to prevent spread of infection. Health care professionals should wash hands between each patient and prior to vaccine preparation. 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 his hands.

Vaccine Information Statements, produced by the CDC, contain information about the benefits and risks of vaccines. By federal law, all vaccine providers must give patients, parents, or legal guardians the appropriate VIS whenever a 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 route, size of 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 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 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 are just some examples of vaccines that require reconstitution.

The CDC does not advise drawing up syringes prior to a vaccine being ordered. 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. Pre-filling syringes with vaccine may cause waste of valuable and costly vaccines if they are not used within the manufacturer's time limit guidelines.

When administering multiple vaccines, never mix them in the same syringe. If administering more than one vaccine to the same limb, injection sites should be 1" to 2" apart so 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 the correct length to reach the muscle mass and not seep into SQ tissue. A chart in Tools and Resources on the next page describes doses, routes, sites, and needle sizes. This chart can also be located on the CDC and Immunization Action Coalition Web sites. For newborns, a 5/8" needle should be used in the vastus lateralis muscle of the upper thigh. For infants up to age 1 year, a 1" needle should be used in the same location. For toddlers, children, and adults, length varies based on injection site (vastus lateralis or deltoid) and weight of the patient (5/8"–1 1/2" length). For SQ injections, needle length should be 5/8".

When administering IM injections, the needle should be inserted at a 90° angle, and quickly. It is not necessary to aspirate after needle insertion. Subcutaneous 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" apart. (See charts on how to administer IM and SQ injections included in Tools and Resources on the next page.)

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.

Key Facts

- Hand washing is critical prior to preparing or administering immunizations.
- Always check expiration date before drawing up the vaccine.
- Vaccine Information Statements must be provided to parents or guardians prior to immunization.
- Reconstitute vaccines according to manufacturer 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 including 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
- Documents you may include in your personalized manual (included on the following pages)
  - Immunization Action Coalition
    - Administering Vaccines: Dose, Route, Site, and Needle Size (www.immunize.org/catg.d/p3085.pdf)
    - How to Administer IM and SC Vaccine Injections to Adults (www.immunize.org/catg.d/p2020A.pdf)
    - How to Administer Intramuscular (IM) Vaccine Injections and How to Administer Subcutaneous (SQ) Vaccine Injections (www.immunize.org/catg.d/p2020.pdf)
    - Vaccines with Diluents: How to Use Them (www.immunize.org/catg.d/p3040.pdf)

Administering Vaccines: Dose, Route, Site, and Needle Size

Vaccines	Dose	Route
Diphtheria, Tetanus, Pertussis (DTaP, DT, Tdap, Td)	0.5 mL	IM
***Haemophilus influenzae* type b (Hib)**	0.5 mL	IM
Hepatitis A (HepA)	≤18 yrs: 0.5 mL ≥19 yrs: 1.0 mL	IM
Hepatitis B (HepB) **Persons 11–15 yrs may be given Recombivax HB® (Merck) 1.0 mL adult formulation on a 2-dose schedule.*	≤19 yrs: 0.5 mL* ≥20 yrs: 1.0 mL	IM
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 ≥3 yrs: 0.5 mL	IM
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)	2.0 mL	Oral
Varicella (Var)	0.5 mL	SC
Zoster (Zos)	0.65 mL	SC
Combination Vaccines		
DTaP+HepB+IPV (Pediarix®) **DTaP+Hib+IPV (Pentacel®)** **DTaP+Hib (Trihibit®)** **DTaP+IPV (Kinrix®)** **Hib+HepB (Comvax®)**	0.5 mL	IM
MMR+Var (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.

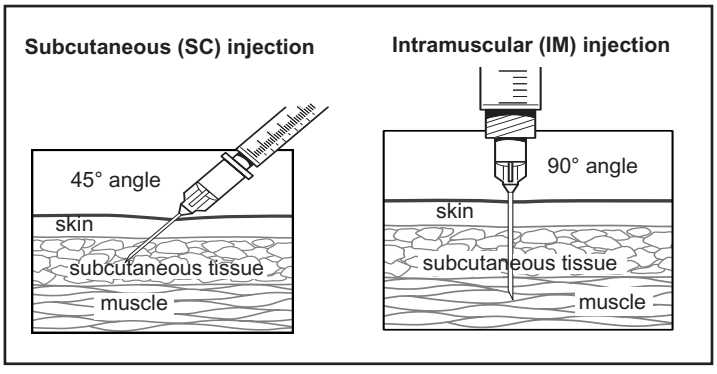
Age	Needle Length	Injection Site
Infants (1–12 mos)	⅝"	Fatty tissue over anterolateral thigh muscle
Children 12 mos or older, adolescents, and adults	⅝"	Fatty tissue over anterolateral thigh muscle or fatty tissue over triceps

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 (1st 28 days)	⅝"*	Anterolateral thigh muscle
Infants (1–12 mos)	1"	Anterolateral thigh muscle
Toddlers (1–2 yrs)	1–1¼" ⅝–1"*	Anterolateral thigh muscle or deltoid muscle of arm
Children & teens (3–18 years)	⅝–1"* 1"–1¼"	Deltoid muscle of arm or anterolateral thigh muscle
Adults 19 yrs or older		
Male or female less than 130 lbs	⅝–1"*	Deltoid muscle of arm
Female 130–200 lbs Male 130–260 lbs	1–1½"	Deltoid muscle of arm
Female 200+ lbs Male 260+ lbs	1½"	Deltoid muscle of arm

**A ⅝" needle may be used only if the skin is stretched tight, subcutaneous tissue is not bunched, and 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.

Technical content reviewed by the Centers for Disease Control and Prevention, February 2009.

www.immunize.org/catg.d/p3085.pdf • Item #P3085 (2/09)

How to Administer IM and SC Vaccine Injections to Adults

Intramuscular (IM) Injections

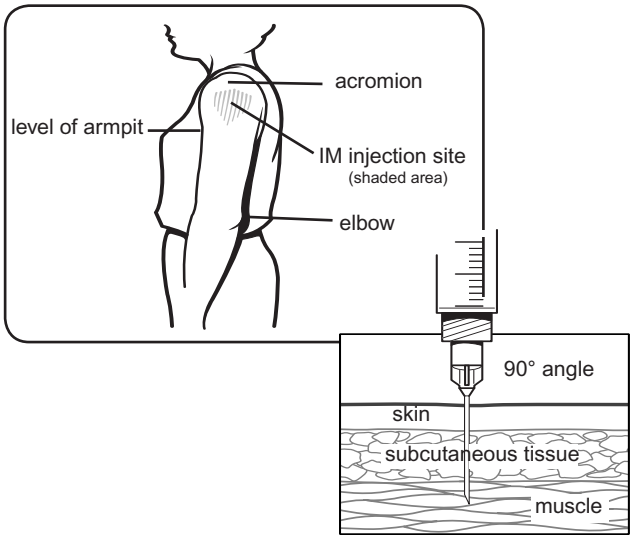
Administer these vaccines via IM route:
Tetanus, diphtheria (Td), or with pertussis (Tdap); hepatitis A; hepatitis B; human papillomavirus (HPV); trivalent inactivated influenza (TIV); and quadrivalent meningococcal conjugate (MCV4). Administer polio (IPV) and pneumococcal polysaccharide vaccine (PPSV23) 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 ⅝" needle is sufficient in adults weighing <130 lbs (<60 kg); 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 >200 lbs (>90 kg) or men weighing >260 lbs (>118 kg). A ⅝" (16mm) needle may be used only if the skin is stretched tight, the subcutaneous tissue is not bunched, and injection is made at a 90-degree angle.

Subcutaneous (SC) Injections

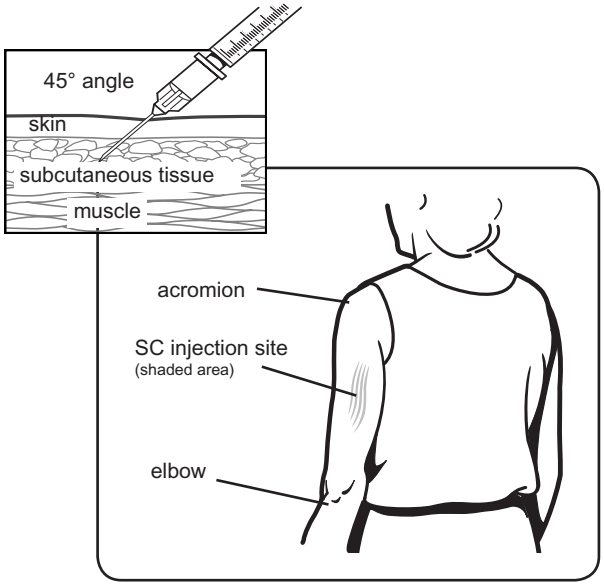
Administer these vaccines via SC route:
MMR, varicella, meningococcal polysaccharide (MPSV4), and zoster (shingles). Administer polio (IPV) and pneumococcal polysaccharide vaccine (PPSV23) either SC or IM.

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

Technical content reviewed by the Centers for Disease Control and Prevention, November 2010.

www.immunize.org/catg.d/p2020A.pdf • Item #P2020A (11/10)

How to Administer Intramuscular (IM) Vaccine Injections

Administer these vaccines by the intramuscular (IM) route: Diphtheria-tetanus (DT, Td) with pertussis (DTaP, Tdap); *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
Newborn (0–28 days)	Anterolateral thigh muscle	⅝"* (22–25 gauge)
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	⅝–1"* (22–25 gauge)
Children (3–18 years)	Deltoid muscle (upper arm)	⅝–1"* (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 ⅝" needle may be used only if the skin is stretched tight, the subcutaneous tissue is not bunched, and injection is made at a 90° angle.

†A ⅝" needle is sufficient in adults weighing <130 lbs (<60 kg); 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 >200 lbs (>90 kg) or men weighing >260 lbs (>118 kg).

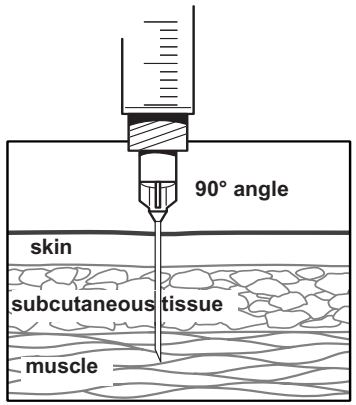
Needle insertion

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

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

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

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

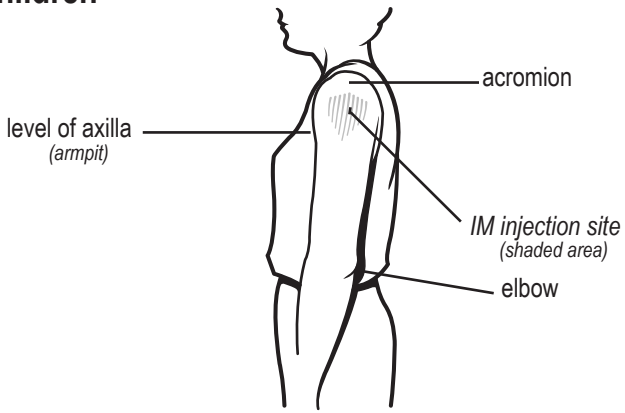


¶CDC. "ACIP General Recommendations on Immunization" at www.immunize.org/acip

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.

Technical content reviewed by the Centers for Disease Control and Prevention, November 2010.

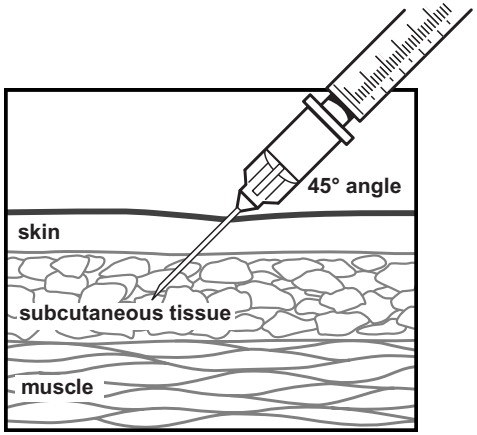
www.immunize.org/catg.d/p2020.pdf • Item #P2020 (11/10)

Immunization Action Coalition • 1573 Selby Ave. • St. Paul, MN 55104 • (651) 647-9009 • www.immunize.org • www.vaccineinformation.org • admin@immunize.org

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.

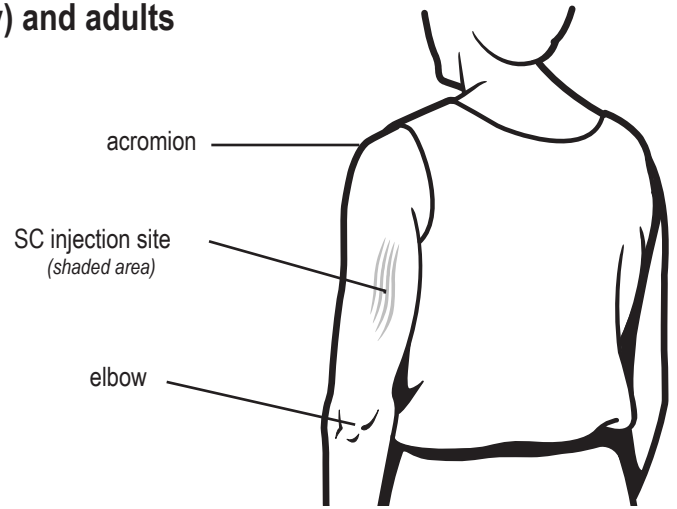
Patient age	Injection site	Needle size	Needle insertion
Birth to 12 mos.	Fatty tissue over the anterolateral thigh muscle	⅝" needle, 23–25 gauge	Pinch up on subcutaneous (SC) tissue to prevent injection into muscle. Insert needle at 45° angle to the skin. (Before administering an injection of vaccine, it is not necessary to aspirate, i.e., to pull back on the syringe plunger after needle insertion.*) Multiple injections given in the same extremity should be separated by a minimum of 1". *CDC. "ACIP General Recommendations on Immunization" at www.immunize.org/acip
12 mos. and older	Fatty tissue over anterolateral thigh or fatty tissue over triceps	⅝" 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.

Technical content reviewed by the Centers for Disease Control and Prevention, November 2010.

www.immunize.org/catg.d/p2020.pdf • Item #P2020 (11/10)

Immunization Action Coalition • 1573 Selby Ave. • St. Paul, MN 55104 • (651) 647-9009 • www.immunize.org • www.vaccineinformation.org • admin@immunize.org

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	ActHIB	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	Imovax	Sterile water	Immediately	Refrigerator
M-M-R II (MMR)	Merck	MMR	Sterile water	8 hrs	Refrigerator or room temp
Menomune (MPSV4)	sanofi pasteur	MPSV4	Distilled water	30 min (single-dose vial) 35 days (multi-dose vial)	Refrigerator
Menveo (MCV4)	Novartis	MenA	MenCWY	8 hrs	Refrigerator
Pentacel (DTaP-IPV/Hib)	sanofi pasteur	ActHIB	DTaP-IPV	Immediately†	Refrigerator
ProQuad (MMRV)	Merck	MMRV	Sterile water	30 min	Refrigerator or room temp
RabAvert (RAB_{PCECV})	Novartis	RabAvert	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-VAX	0.9% sodium chloride	60 min	Refrigerator or room temp
Zostavax (ZOS)	Merck	ZOS	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:

1. 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 multi-dose vial will require a new needle and syringe for each dose of vaccine to be administered. For Rotarix, see the package insert.‡
2. Before reconstituting, check labels on both the lyophilized vaccine vial and the diluent to verify the following:
   - that they are the correct two products to mix together
   - that the diluent is the correct volume (especially for Menomune in the multi-dose vial)
   - that neither vaccine nor diluent has expired
3. Reconstitute (i.e., mix) vaccine ***just prior to use***‡ by
   - removing the protective caps and wiping each stopper with an alcohol swab
   - inserting needle of syringe into diluent vial and withdrawing entire contents
   - injecting diluent into lyophilized vaccine vial and rotating or agitating to thoroughly dissolve the lyophilized powder
4. Check the appearance of the reconstituted vaccine.
   - Reconstituted vaccine may be used if the color and appearance match the description on the package insert.
   - If there is discoloration, extraneous particulate matter, obvious lack of resuspension, or cannot be thoroughly mixed, mark the vial as "DO NOT USE," return it to proper storage conditions, and contact your state or local health department immunization program or the vaccine manufacturer.
5. If reconstituted vaccine is not used immediately or comes in a multi-dose 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.
† Within 30 minutes or less.
‡ Rotarix vaccine is administered by mouth using the applicator that contains the diluent. It is not administered as an injection.

Technical content reviewed by the Centers for Disease Control and Prevention, June 2011.

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. While 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 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.

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

Immunization information systems offer health care professionals an opportunity to provide easily accessible, extremely accurate, and completely up-to-date immunization information to patients, parents, and other health care professionals. As described by the Centers for Disease Control and Prevention (CDC), "[I]mmunization information systems…are confidential, computerized information systems that attempt to collect vaccination data about all children within a geographic area….[I]t can provide a single data source for all community immunization partners." The American Academy of Pediatrics is a strong supporter of IISs to advance immunization coverage, cost-effectiveness, physician payment, quality of care, and integration with electronic health records (see References on page 22).

There is good research to support the development and refinement of IISs. Every Child By Two states that 21% of children are over-immunized and more than 2 million children are under-immunized, leaving themselves and others at risk of vaccine-preventable diseases. Furthermore, as 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 Every Child By Two at www.ecbt.org/registries.)

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 13 minimum standards that an effective IIS should meet. The standards are as follows:

1. Electronically store data on all National Vaccine Advisory Committee (NVAC)-approved core data elements. (Please see next section for more information.)
2. Establish a registry record within 6 weeks of birth for each newborn in the catchment area.
3. Enable access to immunization information in the registry at the time of encounter.
4. Receive and process immunization information within 1 month of vaccine administration.
5. Protect the confidentiality of medical information.
6. Ensure the security of medical information.
7. Recover lost data (disaster recovery).
8. Exchange immunization records using Health Level Seven (HL7) standards. (Please see Tools and Resources on page 22 for more information.)
9. Automatically determine the immunization(s) needed, in compliance with current Advisory Committee on Immunization Practices recommendations, when an individual presents for a scheduled encounter.
10. Automatically identify individuals due or late for immunization(s) to enable the production of reminder/recall notifications.
11. Automatically produce immunization coverage reports by providers, age groups, and geographic areas.
12. Produce authorized immunization records.
13. Consolidate all immunization records from multiple providers, using duplication and edit-checking procedures to optimize accuracy and completeness.

While these are minimum standards, there are increased and ideal mechanisms to achieve greater success using IISs. Please visit the AIRA Web site for more information on functional standards (www.immregistries.org/know/standards.phtml).

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 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, patient's alias, address and phone number, social security number, and father's name, as well as vaccine provider and Vaccines for Children program eligibility.

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

How Do Immunization Information Systems Benefit Patients and Their Families?

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

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

How Do Immunization Information Systems Benefit Health Care Professionals?

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

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

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

The AIRA has great resources for health care professionals researching individual state IISs under its Registry Profiles page (www.immregistries.org/public.php/ImmRegs/regMain.php). This resource includes important contact information to enroll in your state's program.

Furthermore, the CDC has a wealth of information on its IIS States & Territories page (www.cdc.gov/vaccines/programs/iis/states-territories.htm). Specifically, it supplies information concerning IIS legislation throughout the country. Please visit the Survey of State Immunization Information System Legislation page (www.cdc.gov/vaccines/programs/iis/privacy/legsurv.htm).

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

Key Facts

- Immunization information systems or registries assist health care professionals and parents in keeping their patients and children completely and fully immunized through a centralized system.
- Immunization information systems 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. http://www.immregistries.org/know/standards.phtml. Accessed September 6, 2011

Tools and Resources

- Links for additional learning
  - Centers for Disease Control and Prevention (www.cdc.gov)
    - Immunization Information Systems (IIS) (www.cdc.gov/vaccines/programs/iis/default.htm)
    - *Implementation Guide for Immunization Data Transactions using Version 2.3.1 of the Health Level Seven (HL7) Standard Protocol* (www.cdc.gov/vaccines/programs/iis/stds/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.
- Implement a reminder/recall system if one is not in place at his practice.
- Manage or update current reminder/recall systems at her practice.

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.

About Reminder/Recall Systems

Good immunization practices in pediatric offices are important, as they are the most common place for a child to receive 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 one routine vaccination, and many adolescents are not protected against 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 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 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, 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 use varied record-keeping 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 Immunization Reminder/Recall Systems fact sheet.
- One size does not fit all. Successful reminder/recall 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 Systems Suggestions

Chart Reminders

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.

Mail/Telephone Reminders

Staff phone the patient or send a postcard or letter reminding the patient that a vaccination is due and offer the opportunity to schedule an appointment.

Computerized Immunization Reminders

A list of possible reminders to appear on a patient's record can be printed. Software can be programmed to determine the dates that certain preventive procedures are due or past due and print reminder messages, usually overnight, for patients with visits scheduled for the next day.

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.

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.

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 the use of patient health records.

Please feel free to use this text box to add an additional method that your practice currently uses or may want to implement, or 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

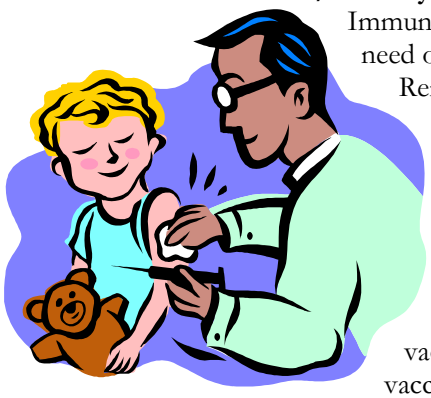
The role of office staff is to overcome the immunization information gap and ensure that children are vaccinated on time. There are many ways to assist the health care professional in this task.

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 (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/15_ImmuRemi_E10L.pdf)
- Document you may include in your personalized manual (included on the following pages)
  - American Academy of Pediatrics: Immunization Reminder/Recall Systems (www.aap.org/immunization/pediatricians/pdf/ReminderRecall.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 will am I doing at vaccinating my patients?" To know for certain, contact the local state health department to request and 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.

Childhood Immunization Support Program
CISP

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.

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 www.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 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.

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 their 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 there was a shortage when he was due for it and 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.

This text box can be used to add other NVAC standards with your own examples of how they can be met or other notes you wish to add.

Key Facts

- The NVAC Standards for Child and Adolescent Immunization Practices 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 (www.aap.org/immunization/pediatricians/nvacstandards.html)
  - National Vaccine Advisory Committee: The Standards for Pediatric Immunization Practice (www.hhs.gov/nvpo/nvac/standar.html)
  - *Pediatrics:* "Standards for Child and Adolescent Immunization Practices" (http://pediatrics.aappublications.org/content/112/4/958.full.pdf) (log-in required)

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 post-surveillance of an immunization.
- Know how to report an adverse event to VAERS.

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.

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 can report an adverse event to the system, eg, patient, doctor, vaccine manufacturer, health departments. 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 following 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 Vaccine Adverse Event Reporting System 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
  - Centers for Disease Control and Prevention: Vaccine Adverse Event Reporting System (VAERS) (www.cdc.gov/vaccinesafety/Activities/vaers.html)
  - Centers for Disease Control and Prevention and FDA: VAERS (http://vaers.hhs.gov)
  - Food and Drug Administration: Vaccine Adverse Events (www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ReportaProblem/VaccineAdverseEvents/default.htm)

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 prior to 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 ahead of time (eg, at a prior visit), or instruct them to download the VIS to read ahead of time (in the case, you may still want to provide a hard copy 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, lot number, and expiration date

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.

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 made available for every dose of vaccine administered.

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 prior to administration of the vaccine.
- Providers must give it each time vaccine is given (not just with the first dose).
- Providers must record certain information in the patient's permanent medical record.

Altering Vaccine Information Statements

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

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

Key Facts

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

Tools and Resources

- Links for additional learning
  - Centers for Disease Control and Prevention (www.cdc.gov)
    - Fact Sheet for Vaccine Information Statements (www.cdc.gov/vaccines/pubs/vis/vis-facts.htm)
    - Vaccine Information Statements (www.cdc.gov/vaccines/pubs/vis/default.htm)
  - Immunization Action Coalition (www.immunize.org)
    - Vaccine Information Statements (www.immunize.org/vis)
- Document you may include in your personalized manual (included on the following pages)
  - Immunization Action Coalition
    - It's federal law! (www.immunize.org/catg.d/p2027.pdf)

It's federal law!

You must give your patients current Vaccine Information Statements (VISs)

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.

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

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 August 2011, the most recent versions of the VISs are as follows:

DTaP/DT 5/17/07
Hepatitis A 3/21/06
Hepatitis B 7/18/07
Hib 12/16/98
HPV (H. papillomavirus) .....
Cervarix 5/3/11
Gardasil 5/3/11
Influenza (inactive).....7/26/11
Influenza (live) 7/26/11
Japanese encephalitis....3/1/10
Meningococcal 1/28/08
MMR.....3/13/08
MMRV.....5/21/10
PCV13 .....4/16/10
PPSV 10/6/09
Polio 1/1/00
Rabies 10/6/09
Rotavirus 12/6/10
Shingles 10/6/09
Td/Tdap 11/18/08
Typhoid.....5/19/04
Varicella (chickenpox) ...3/13/08
Yellow fever 3/30/11
Multi-vaccine VIS 9/18/08
(for 6 vaccines given to infants/children: DTaP, IPV, Hib, Hep B, PCV, RV)

Technical content reviewed by the Centers for Disease Control and Prevention, August 2011.

www.immunize.org/catg.d/p2027.pdf • Item #P2027 (8/11)

Immunization Action Coalition • 1573 Selby Ave. • St. Paul, MN 55104 • (651) 647-9009 • www.immunize.org • www.vaccineinformation.org

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/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.

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 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, pneumococcal (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

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 English-language VISs to all patients (even if the patient's first language is not English)**

For patients who don't read or speak English, the law requires that providers ensure all patients (parent/legal representatives) receive the appropriate VIS, regardless of their ability to read English. If available, provide a translation of the VIS in the patient's language as well.

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.

www.immunize.org/catg.d/p2027.pdf • Item #P2027 (8/11)