

California Pharmacist Immunization Protocol

Authorizing Prescriber Statement for Vaccination

Pharmacists in the state of California meeting the Qualifications of Persons Administering Vaccines as described below, acting as delegates for _____, MD according to and in compliance with Article 3 of the Business and Professional Code 4052.(a).(4).(C) and B&P code 4052.(a).(5).(A).(iii) of the California Pharmacy Scope of Practice section, will independently determine the need for and administer vaccinations and epinephrine as outlined in the following protocol. Licensed intern pharmacists meeting qualifications 1,2 and 3 below, under the supervision of a pharmacist meeting all of the qualifications below, may administer vaccines pursuant to this protocol.

Qualifications of Persons Administering Vaccine

1. CPR certified (BLS) – American Red Cross or American Heart Association or equivalent
2. Certificate of completion of an appropriate immunization program (see Appendix A)
3. Completion of an appropriate blood borne pathogen and universal precautions program
4. Pharmacy liability insurance that covers the administration of immunization either implied or explicit
5. California licensed pharmacist

Vaccine(s) to be administered (see Appendix B)

- Seasonal and H1N1 Influenza (IM and Intranasal)
- Pneumococcal (PPV23 adult)

Policies

1. A standard form will be used to document immunizations and the pharmacy will maintain a patient record of administration, including, but not limited to, patient name, date, vaccine given (manufacturer, lot #, and expiration date), and signature of person administering vaccine (Appendix C)
2. The screening form contained in this protocol will be maintained as documentation (Appendix C)
3. The current Vaccine Information Statement for each vaccine will be discussed and given to each patient
4. Written informed consent will be obtained for each patient prior to vaccination (Appendix C)
5. The pharmacist will notify the patient's primary care provider of immunization when contact information is available (see Appendix D for a sample form).
6. All supplies needed for vaccination and vaccine adverse event management as detailed in this protocol will be available and not expired.
7. Authorizing prescriber will be periodically notified of vaccinated patients at their discretion

Emergencies

Authorize use of the Pharmacy Procedure and Standing Orders for Management of Allergic or Anaphylactic Reactions for emergencies (Appendix F)

Physician Authorization:

Physician Name: _____ Affiliation (Clinic): _____
Phone: _____ Fax: _____ Pager/Mobile: _____
Physician CA license number: _____

Date

<Physician name and degree>

This authorization will be in effect unless rescinded earlier in writing by either party. Any changes in the protocol must be agreed upon by both parties.

Appendix A. Immunization Training

Certificate of completion of an appropriate immunization-training program that includes the *current guidelines and recommendations of the Advisory Committee on Immunization Practices* and uses the core curriculum of the CDC (Epidemiology and Prevention of Vaccine-Preventable Diseases). An appropriate training program shall include, at a minimum, instruction on how to:

- A. Identify persons eligible for vaccination based on current ACIP guidelines. Factors taken into consideration will include age, vaccination status (e.g., persons previously unvaccinated or due for vaccination according to the recommended schedule), or the presence of a medical condition that puts them at high risk, etc.
- B. Screen patients for contraindications and precautions to vaccination (e.g. severe illness, previous allergic reaction, egg allergy, etc.).
- C. Provide adequate information to patients or their guardians regarding the risks for and benefits of a vaccine and documenting the delivery of that information. (i.e. Distribution/discussion of Vaccination Information Statements as required by law).
- D. Assess anatomic location and administer vaccines
 - i. Intranasal
 - ii. Intramuscular (deltoid)
 - iii. Subcutaneous (fatty tissue over triceps)
- E. Monitor patients for adverse events.
- F. Manage anaphylactic and other reactions according to protocol
- G. Report adverse outcomes to the Vaccine Adverse Events Reporting System (VAERS).
- H. Record administration of a vaccine(s)
- I. Provide documentation of vaccine administration to patients and whenever possible, their primary-care providers.
- J. Follow Universal Precautions and Infection Control and pertinent OSHA regulations (i.e. for Blood Borne Pathogens).

Appendix B. Criteria for Patients to Receive Vaccine

Procedures for Administering Seasonal and Influenza A (H1N1) 2009 Monovalent Vaccines

Purpose: To reduce morbidity and mortality from seasonal influenza by vaccinating all children, adolescents and adults who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

Procedure:

1. Identify children, adolescents and adults in need of influenza vaccination based on meeting any of the following criteria:

- a. Age 6 months through 18 years and age 50 years or older
- b. Age 19 years and older with any of the following conditions: chronic pulmonary (including asthma), cardiovascular (excluding hypertension), renal, hepatic, cognitive, neurologic/neuromuscular, hematologic, or metabolic (e.g., diabetes) disorders; immunosuppression, including that caused by medications or HIV; long-term aspirin therapy (applies to a child or adolescent age 6 months through 18 years)
- c. Being pregnant during the influenza season
- d. Residence in a nursing home or other chronic-care facility that houses persons of any age who have chronic medical conditions
- e. All healthcare personnel
- f. All adults, children, and teens who are household contacts, caregivers, or workplace contacts of persons listed in category 1.b. above, or of children age 0–59 months, or of adults age 50 years or older.
- g. Want to reduce the risk of becoming ill with influenza or of transmitting it to others
- h. For H1N1 vaccine, ACIP target groups are:
 1. pregnant women
 2. persons who live with or provide care for infants aged <6 months (e.g., parents, siblings, and daycare providers)
 3. health-care and emergency medical services personnel
 4. persons aged 6 months--24 years
 5. persons aged 25--64 years who have medical conditions that put them at higher risk for influenza-related complications

2. Screen all patients for contraindications and precautions to influenza vaccine:

a. **Contraindications:** serious reaction (e.g., anaphylaxis) after ingesting eggs or after receiving a previous dose of influenza vaccine or an influenza vaccine component. For a list of vaccine components, go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf. Do not give live attenuated influenza vaccine (LAIV; nasal spray) to pregnant women; children younger than age 2 years; children age 2 through 4 years who have experienced wheezing or asthma within the past 12 months, based on a healthcare provider's statement; or anyone with any of the conditions described in 1.b. above.

b. **Precautions:** moderate or severe acute illness with or without fever; history of Guillain-Barré syndrome within 6 weeks of a previous influenza vaccination; for LAIV only, close contact with an immunosuppressed person when the person requires protective isolation.

3. Provide all patients (or, in the case of a minor, their parent or legal representative) with a copy of the most current federal Vaccine Information Statement (VIS). You must document in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient (parent/legal representative). Provide non-English speaking patients with a copy of the VIS in their native language, if available and preferred; these can be found at www.immunize.org/vis.

4. Administer injectable trivalent inactivated vaccine (TIV) intramuscularly in the deltoid muscle. Use a 22–25 g needle. Choose needle length appropriate to the patient's age and body mass: 3 yrs and older: 1–1½". Give 0.5 mL for all age 3 years and older. (Note: A 5/8" needle may be used for patients weighing less than 130 lbs (<60kg) for injection in the deltoid muscle *only* if the skin is stretched tight, subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle.) Alternatively, healthy people age 2 years and older may be given 0.2 mL of intranasal LAIV; 0.1 mL is sprayed into

each nostril while the patient is in an upright position. Children age 6 months through 8 years who are receiving influenza vaccine for the first time, or whose first-time influenza vaccination was in the preceding season and who received only one dose, should receive a second dose at least 4 weeks after the first dose.

5. Document each patient's vaccine administration information and follow up in the following places:
 - a. **Pharmacy Record:** Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. If vaccine was not given, record the reason(s) for non- receipt of the vaccine (e.g., medical contraindication, patient refusal). Communicate vaccination information to the patient's primary care provider, if known
 - b. **Personal immunization record card:** Record the date of vaccination and the name/location of the administering clinic.
6. Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications.
7. Report all adverse reactions to influenza vaccine to the federal Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov or (800) 822-7967. VAERS report forms are available at www.vaers.hhs.gov.

Above procedures based upon:

Technical content reviewed by the Centers for Disease Control and Prevention, September 2009.
Immunization Action Coalition • 1573 Selby Ave. • St. Paul, MN 55104 • (651) 647-9009 •
www.immunize.org • www.vaccineinformation.org

Procedures for Administering Pneumococcal Vaccine to Adults

Purpose: To reduce morbidity and mortality from pneumococcal disease by vaccinating all adults who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

Procedure

1. Identify adults in need of vaccination with pneumococcal polysaccharide vaccine (PPSV) based on the following criteria:
 - a. Age 65 years or older with no or unknown history of prior receipt of PPSV
 - b. Age 64 years or younger with no or unknown history of prior receipt of PPSV and any of the following conditions:
 - i. cigarette smoker
 - ii. chronic cardiovascular disease (e.g., congestive heart failure, cardiomyopathies)
 - iii. chronic pulmonary disease (e.g., chronic obstructive pulmonary disease, emphysema, asthma)
 - iv. diabetes, alcoholism, chronic liver disease (cirrhosis), or cerebrospinal fluid leaks
 - v. functional or anatomic asplenia (e.g., sickle cell disease, splenectomy)
 - vi. immunocompromising condition (e.g., HIV infection, congenital immunodeficiency, hematologic and solid tumors)
 - vii. immunosuppressive therapy (e.g., alkylating agents, antimetabolites, long-term systemic corticosteroids, radiation therapy)
 - viii. organ or bone marrow transplantation
 - ix. chronic renal failure or nephrotic syndrome
 - x. candidate for or recipient of cochlear implant
2. Identify adults in need of a second (and final) dose of PPSV if five or more years have elapsed since the previous dose of PPSV and the patient meets one of the following criteria:
 - a. Age 65 years or older and received prior PPSV vaccination before age 65 years
 - b. At highest risk for serious pneumococcal infection or likely to have a rapid decline in pneumococcal antibody levels (i.e., categories v. -ix. above)
3. Screen all patients for contraindications and precautions to PPSV vaccine:
 - a. **Contraindication:** a history of a serious reaction (e.g., anaphylaxis) after a previous dose of PPSV or to a vaccine component. For a list of vaccine components, go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf.
 - b. **Precaution:** moderate or severe acute illness with or without fever
4. Provide all patients with a copy of the most current federal Vaccine Information Statement (VIS). Although not required by federal law, it is prudent to document in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient. Provide non-English speaking patients with a copy of the VIS in their native language, if available; these can be found at www.immunize.org/vis.
5. Administer 0.5 mL PPSV vaccine either intramuscularly (22–25g, 1–1½" needle) in the deltoid muscle or subcutaneously (23–25g, 1-1/2" needle) in the posterolateral fat of the upper arm.
6. Document each patient's vaccine administration information and follow up in the following places:
 - a. **Pharmacy Record:** Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. If vaccine was not given, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal). Communicate vaccination information to the patient's primary care provider, if known

b. Personal immunization record card: Record the date of vaccination and the name/location of the administering clinic.

7. Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications.

8. Report all adverse reactions to PPSV to the federal Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov or by calling (800) 822-7967. VAERS report forms are available at www.vaers.hhs.gov.

Based upon:

www.immunize.org/catg.d/p3075.pdf • Item #P3075 (2/09)

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www.immunize.org • www.vaccineinformation.org

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

Appendix C. Screening, VAR, Consent Form

Appendix C

Appendix D

Medical Management of Vaccine Reactions in Children and Teens

All vaccines have the potential to cause an adverse reaction. To minimize adverse reactions, patients should be carefully screened for precautions and contraindications before vaccine is administered. Even with careful screening, reactions can occur. These reactions can vary from trivial and inconvenient (e.g., soreness, itching) to severe and life threatening (e.g., anaphylaxis). If reactions occur, staff should be prepared with procedures for their management. The table below describes procedures to follow if various reactions occur.

Reaction	Symptoms	Management
Localized	Soreness, redness, itching, or swelling at the injection site	Apply a cold compress to the injection site. Consider giving an analgesic (pain reliever) or antipruritic (anti-itch) medication.
	Slight bleeding	Apply an adhesive compress over the injection site.
	Continuous bleeding	Place thick layer of gauze pads over site and maintain direct and firm pressure; raise the bleeding injection site (e.g., arm) above the level of the patient's heart.
Psychological fright and syncope (fainting)	Fright before injection is given	Have patient sit or lie down for the vaccination.
	Extreme paleness, sweating, coldness of the hands and feet, nausea, light-headedness, dizziness, weakness, or visual disturbances	Have patient lie flat or sit with head between knees for several minutes. Loosen any tight clothing and maintain an open airway. Apply cool, damp cloths to patient's face and neck.
	Fall, without loss of consciousness	Examine the patient to determine if injury is present before attempting to move the patient. Place patient flat on back with feet elevated.
	Loss of consciousness	Check the patient to determine if injury is present before attempting to move the patient. Place patient flat on back with feet elevated. Call 911 if patient does not recover immediately.
Anaphylaxis	Sudden or gradual onset of generalized itching, erythema (redness), or urticaria (hives); angioedema (swelling of the lips, face, or throat); severe bronchospasm (wheezing); shortness of breath; shock; abdominal cramping; or cardiovascular collapse	See "Emergency Medical Protocol for Management of Anaphylactic Reactions in Children and Teens" on the next page for detailed steps to follow in treating anaphylaxis.

Supplies Needed

- Aqueous epinephrine 1:1000 dilution, in ampules, vials of solution, or prefilled syringes, including epinephrine auto-injectors (e.g., EpiPen). If EpiPens are to be stocked, both EpiPen Jr. (0.15 mg) and adult EpiPens (0.30 mg) should be available.
- Diphenhydramine (Benadryl) injectable (50 mg/mL solution) and oral (12.5 mg/5 mL suspension) and 25 mg or 50 mg capsules or tablets
- Syringes: 1–3 cc, 22–25g, 1", 1½", and 2" needles for epinephrine and diphenhydramine (Benadryl)
- Pediatric & adult airways (small, medium, and large)
- Sphygmomanometer (child, adult & extra-large cuffs) and stethoscope
- Pediatric & adult size pocket masks with one-way valve
- Alcohol swabs
- Tongue depressors
- Flashlight with extra batteries (for examination of mouth and throat)
- Wrist watch
- Tourniquet
- Cell phone or access to an on-site phone

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Emergency Medical Protocol for Management of Anaphylactic Reactions in Children and Teens

Signs and Symptoms of Anaphylactic Reaction

Sudden or gradual onset of generalized itching, erythema (redness), or urticaria (hives); angioedema (swelling of the lips, face, or throat); bronchospasm (wheezing); shortness of breath; shock; abdominal cramping; or cardiovascular collapse.

Treatment in Children and Teens

- If itching and swelling are confined to the injection site where the vaccination was given, observe patient closely for the development of generalized symptoms.
- If symptoms are generalized, activate the emergency medical system (EMS; e.g., call 911) and notify the on-call physician. This should be done by a second person, while the primary nurse assesses the airway, breathing, circulation, and level of consciousness of the patient.
- Administer aqueous epinephrine 1:1000 dilution (i.e., 1 mg/mL) intramuscularly; the standard dose is 0.01 mg/kg body weight, up to 0.3 mg maximum single dose in children and 0.5 mg maximum in adolescents (see chart below).
- In addition, for anaphylaxis, administer diphenhydramine either orally or by intramuscular injection; the standard dose is 1 mg/kg body weight, up to 30 mg maximum dose in children and 100 mg maximum dose in adolescents (see chart below).
- Monitor the patient closely until EMS arrives. Perform cardiopulmonary resuscitation (CPR), if necessary, and maintain airway. Keep patient in supine position (flat on back) unless he or she is having breathing difficulty. If breathing is difficult, patient's head may be elevated, provided blood pressure is adequate to prevent loss of consciousness. If blood pressure is low, elevate legs. Monitor blood pressure and pulse every 5 minutes.
- If EMS has not arrived and symptoms are still present, repeat dose of epinephrine every 10–20 minutes for up to 3 doses, depending on patient's response.
- Record all vital signs, medications administered to the patient, including the time, dosage, response, and the name of the medical personnel who administered the medication, and other relevant clinical information.
- Notify the patient's primary care physician.

Suggested Dosing of Epinephrine and Diphenhydramine

Age Group Dose	Weight * in kg	Weight (lbs)* in lbs	Epinephrine Dose 1 mg/mL injectable (1:1000 dilution) intramuscular	Diphenhydramine (Benadryl) 12.5 mg/5 mL liquid 25 and 50 mg capsules or tabs 50 mg/mL injectable
1–6 mos	4–7 kg	9–15 lbs	0.05 mg (0.05 ml)	5 mg
7–18 mos	7–11 kg	15–24 lbs	0.1 mg (0.1 ml)	10 mg
19–36 mos	11–14 kg	24–31 lbs	0.15 mg (0.15 ml)	15 mg
37–48 mos	14–17 kg	31–37 lbs	0.15 mg (0.15 ml)	20 mg
49–59 mos	17–19 kg	37–42 lbs	0.2 mg (0.2 ml)	
5–7 yrs	19–23 kg	42–51 lbs	0.2 mg (0.2 ml)	30 mg
8–10 yrs	23–35 kg	51–77 lbs	0.3 mg (0.3 ml)	
11–12 yrs	35–45 kg	77–99 lbs	0.4 mg (0.4 ml)	40 mg
13 yrs & older	45+ kg	99+ lbs	0.5 mg (0.5 ml)	50–100 mg

*Dosing by body weight is preferred.

Sources: American Academy of Pediatrics. Passive Immunization. In: Pickering LK, ed. *Red Book: 2006 Report of the Committee on Infectious Diseases*. 27th ed. Elk Grove Village, IL: American Academy of Pediatrics; 2006: 64–66.
American Pharmacists Association, Grabenstein, JD, *Pharmacy-Based Immunization Delivery*, 2002.

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www.immunize.org/catg.d/p3082a.pdf • Item #P3082a (8/06)

Medical Management of Vaccine Reactions in Adult Patients

All vaccines have the potential to cause an adverse reaction. In order to minimize adverse reactions, patients should be carefully screened for precautions and contraindications before vaccine is administered. Even with careful screening, reactions may occur. These reactions can vary from trivial and inconvenient (e.g., soreness, itching) to severe and life threatening (e.g., anaphylaxis). If reactions occur, staff should be prepared with procedures for their management. The table below describes procedures to follow if various reactions occur.

Reaction	Symptoms	Management
Localized	Soreness, redness, itching, or swelling at the injection site	Apply a cold compress to the injection site. Consider giving an analgesic (pain reliever) or antipruritic (anti-itch) medication.
	Slight bleeding	Apply an adhesive compress over the injection site.
	Continuous bleeding	Place thick layer of gauze pads over site and maintain direct and firm pressure; raise the bleeding injection site (e.g., arm) above the level of the patient's heart.
Psychological fright and syncope (fainting)	Fright before injection is given	Have patient sit or lie down for the vaccination.
	Extreme paleness, sweating, coldness of the hands and feet, nausea, light-headedness, dizziness, weakness, or visual disturbances	Have patient lie flat or sit with head between knees for several minutes. Loosen any tight clothing and maintain an open airway. Apply cool, damp cloths to patient's face and neck.
	Fall, without loss of consciousness	Examine the patient to determine if injury is present before attempting to move the patient. Place patient flat on back with feet elevated.
	Loss of consciousness	Check the patient to determine if injury is present before attempting to move the patient. Place patient flat on back with feet elevated. Call 911 if patient does not recover immediately.
Anaphylaxis	Sudden or gradual onset of generalized itching, erythema (redness), or urticaria (hives); angioedema (swelling of the lips, face, or throat); severe bronchospasm (wheezing); shortness of breath; shock; abdominal cramping; or cardiovascular collapse.	See "Emergency Medical Protocol for Management of Anaphylactic Reactions in Adults" on the next page for detailed steps to follow in treating anaphylaxis.

(continued on page 2)

Emergency Medical Protocol for Management of Anaphylactic Reactions in Adults

Supplies Needed

- | | |
|---|--|
| <ul style="list-style-type: none"> <input type="checkbox"/> Aqueous epinephrine 1:1000 (i.e., 1 mg/mL) dilution, in ampules, vials of solution, or prefilled syringes, including epinephrine autoinjectors (e.g., EpiPen). If EpiPens are stocked, at least three adult EpiPens (0.30 mg) should be available. <input type="checkbox"/> Diphenhydramine (Benadryl) injectable (50 mg/mL solution) and 25 mg or 50 mg capsules or tablets and syrup (12.5 mg/5 mL suspension) <input type="checkbox"/> Syringes: 1–3 cc, 22–25g, 1", 1½", and 2" needles for epinephrine and diphenhydramine (Benadryl) <input type="checkbox"/> Wristwatch with second hand | <ul style="list-style-type: none"> <input type="checkbox"/> Adult airways (small, medium, and large) <input type="checkbox"/> Sphygmomanometer (adult and extra-large cuffs) and stethoscope <input type="checkbox"/> Adult size pocket mask with one-way valve <input type="checkbox"/> Alcohol swabs <input type="checkbox"/> Tourniquet <input type="checkbox"/> Tongue depressors <input type="checkbox"/> Flashlight with extra batteries (for examination of the mouth and throat) <input type="checkbox"/> Cell phone or access to an on-site phone |
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Signs and Symptoms of Anaphylactic Reaction

Sudden or gradual onset of generalized itching, erythema (redness), or urticaria (hives); angioedema (swelling of the lips, face, or throat); bronchospasm (wheezing); shortness of breath; shock; abdominal cramping; or cardiovascular collapse.

Treatment in Adults

- a. If itching and swelling are confined to the injection site where the vaccination was given, observe patient closely for the development of generalized symptoms.
- b. If symptoms are generalized, activate the emergency medical system (EMS; e.g., call 911) and notify the on-call physician. This should be done by a second person, while the primary nurse assesses the airway, breathing, circulation, and level of consciousness of the patient.
- c. Administer aqueous epinephrine 1:1000 dilution intramuscularly, 0.01 mL/kg/dose (adult dose ranges from 0.3 mL to 0.5 mL, with maximum single dose of 0.5 mL).
- d. In addition, for systemic anaphylaxis, administer diphenhydramine either orally or by intramuscular injection; the standard dose is 1–2 mg/kg, up to 100 mg maximum single dose.
- e. Monitor the patient closely until EMS arrives. Perform cardiopulmonary resuscitation (CPR), if necessary, and maintain airway. Keep patient in supine position (flat on back) unless he or she is having breathing difficulty. If breathing is difficult, patient's head may be elevated, provided blood pressure is adequate to prevent loss of consciousness. If blood pressure is low, elevate legs. Monitor blood pressure and pulse every 5 minutes.
- f. If EMS has not arrived and symptoms are still present, repeat dose of epinephrine every 10–20 minutes for up to 3 doses, depending on patient's response.
- g. Record all vital signs, medications administered to the patient, including the time, dosage, response, and the name of the medical personnel who administered the medication, and other relevant clinical information.
- h. Notify the patient's primary care physician.

Sources: 1. American Academy of Pediatrics. Passive Immunization. In: Pickering LK, ed. *Red Book: 2006 Report of the Committee on Infectious Diseases*. 27th ed. Elk Grove Village, IL: American Academy of Pediatrics; 2006:64–66.
 2. American Pharmacists Association, Grabenstein, JD, *Pharmacy-Based Immunization Delivery*, 2002.
 3. *Got Your Shots? A Providers Guide to Immunizations in Minnesota*, Second Edition, Minnesota Department of Health, 2001:80-82.