Disclosure: Session B4

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CDC did not accept commercial support for this continuing education activity.
Using Clinical Decision Support to Avoid and Detect Administration Errors

Eric Larson
Northrop Grumman contractor to CDC
Takeaways from Today

- Overview of CDSi
- Definition of an Administration Error
- Avoiding Administration Errors
- Detecting Administration Errors
- Impact of CDSi Resources
OVERVIEW OF CDSI
CDSi

- CDSi= Clinical Decision Support for Immunization
- CDC created and managed set of resources
- Designed to map ACIP recommendations into IT-friendly resources
- Goal = Consistent implementations aligned with ACIP recommendations
Before CDSi

ACIP Recommendations and Clarifications

System A
System B
System C

System A Recommendation
System B Recommendation
System C Recommendation

Individual Interpretation And Implementation
With CDSi

ACIP Recommendations and Clarifications

CDSiResources

Workgroup Interpretation and Documentation

Individual Implementation

Consistent System Recommendations
CDSiResources

- The CDSi project focuses on documenting ACIP recommendations and test cases.

- The CDC does not have or maintain a CDS engine.
ADMINISTRATION ERRORS IN CDSI
What is an Administration Error in CDSi?

Does the dose need to be repeated?
AVOIDING ADMINISTRATION ERRORS
CDSi- Forecasting

- Presentation to a Clinician on when the next doses should be administered
- Uses previous doses administered to calculate when the next doses should be administered
- Only recommends “best practice”
Forecasting Example

- **Dose 4 of DTaP is Recommended at**
  - 15-18 months of age AND
  - 6 months after Dose 3

- **Dose 4 of DTaP does not have to be repeated if**
  - On or after 12 months of age AND
  - 4 months after Dose 3
DETECTING ADMINISTRATION ERRORS
CDSi- Evaluation

- Measure administered doses against published and clarified absolute minimums
  - Doses not meeting defined absolute minimums must be repeated

- Evaluation Includes
  - Ages
  - Intervals
  - Products
  - Live Virus Conflicts
  - Expired Doses
  - Inadvertent Administrations
Evaluation Example

- Dose 4 of DTaP is Recommended at
  - 15-18 months of age AND
  - 6 months after Dose 3

- Dose 4 of DTaP does not have to be repeated if
  - On or after 12 months of age AND
  - 4 months after Dose 3
The Grey Area (Dose 4 DTaP)

BEFORE
• 12 Months of Age
• 4 Months from Dose 3

BETWEEN
• 12-15 Months of Age
• 4-6 Months from Dose 3

ON OR AFTER
• 15-18 Months of Age
• 6 Months from Dose 3
IMPACT OF CDSI RESOURCES
Impact of CDSiResources

What type of impact have the resource had in terms of the ease of use in developing and maintaining CDS logic?

Impact levels are high across each resource

*Somewhat Negative Impact and Very Negative Impact = 0%
Questions

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CDC Project Lead

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Informatics Specialist

https://www.cdc.gov/vaccines/programs/iis/cdsi.html  
Or Google “CDC CDSI”

For more information please contact Centers for Disease Control and Prevention

1600 Clifton Road NE, Atlanta, GA 30333  
Telephone, 1-800-CDGINFO (2324636)/TTY: 4888-232-6348  
E-mail: cdcinfo@cdc.gov  
Web: www.cdc.gov
NIPINFO Data Analysis of Vaccine Administration Errors: August 2013–October 2017

National Immunization Conference

Lauren M. Hughes, MPH, CPH
ORISE Fellow

Communication and Education Branch (CEB)
Immunization Services Division (ISD)
Overview of Presentation

- What is NIPINFO?
- Review of NIPINFO Data
- How does NIPINFO address vaccine administration errors?
What is NIPINFO?
What is NIPINFO?

- NIPINFO is an e-mail service provided by Communication and Education Branch (CEB) staff members
  - Multidisciplinary primary staff and medical officers
- CEB staff answers an average of 30–35 immunization-related questions per day from health care providers and the public
- NIPINFO usually answers within 24 hours
- NIPINFO requires individual staff to answer or refer each inquiry
Workflow of NIPINFO E-mails

- E-mails from CDC-INFO (50%)
- E-mails Directly to NIPINFO (50%)

NIPINFO E-mails Drafted and Reviewed -> NIPINFO E-mails Sent (36,466) -> Subject Lines are Recoded and Archived

Sent to Subject Matter Expert (If needed)
NIPINFO Subject Line Coding

- Primary (Vaccine)
- Secondary (Subject of the e-mail)
- Inquiry Source
  - GP-general public
  - PRPUB-public provider (e.g., public health nurse)
  - PRPRIV-private provider (e.g., private practice physician)
  - PRUNK-provider unknown (e.g., identifies self as a health care provider but does not state where they practice)
  - OTHER- anyone else (e.g., academic, media)
NIPINFO Subject Line Coding

- Difficulty Score
  - 1- Easy (knows answer already or can quickly find answer)
  - 2- Moderate (requires search or interpretation)
  - 3- Difficult (very complicated or requires a subject matter expert [SME])

- Example: Pneumo Error PRPUB 3
  - Question is about an administration error involving pneumococcal vaccine, source is a public provider, and SME involvement was required.
NIPINFO Primary Topics (n=36,466)
August 2013–October 2017

- Multiple
- Influenza
- Misc
- TDAP/TD
- Pneumo
- Mening
- MMR
- HepB
- Zoster
- HPV
- Varicella
- DTAP/DT
- Polio
- HepA
- Typhoid
- Notimm
- Rotavirus
- Twinrix
- Hib
NIPINFO Secondary Topics (n=36,466)
August 2013–October 2017
NIPINFO Inquiry Source (n=36,466)
August 2013–October 2017

<table>
<thead>
<tr>
<th>Providers</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>GP</td>
<td>6599</td>
</tr>
<tr>
<td>OTHER</td>
<td>1500</td>
</tr>
<tr>
<td>PRPRIV</td>
<td>13775</td>
</tr>
<tr>
<td>PRPUB</td>
<td>8772</td>
</tr>
<tr>
<td>PRUNK</td>
<td>5820</td>
</tr>
</tbody>
</table>
Vaccine Administration Errors-Vaccines (n=2,724) August 2013–October 2017
Vaccine Administration Errors by Month (n=2,724)
August 2013–October 2017
Vaccine Administration Errors-Sources (n=2,724)
August 2013–October 2017

![Bar chart showing vaccine administration errors by source.](chart.png)
Limitations

- **NIPINFO is not a data collection tool**
  - Not designed to collect specific information

- **Subject line coding depends on the primary CEB staff on duty**
  - Coding can be subjective

- **Cannot code types of errors**
  - Only room for one code per topic
How does NIPINFO address vaccine administration errors?
How do we address vaccine administration errors?

Good afternoon NIPINFO,

I’m a nurse in a public health department and we received an e-mail that a doctor’s office had given a dose of DTaP to a healthy 11-year old child instead of their recommended dose of Tdap. They have already informed the parents of the error but what else should they do?

Thank you,
Provider X
Questions about vaccine administration errors

- Is this a vaccine administration error?
- Does this patient need to be revaccinated? If so, when?
- Will this vaccine administration error cause harm to the patient?
Dear Provider X,

Thank you for your question. The DTaP dose can be counted as valid (please see the CDC childhood immunization schedule, footnote 13). We would, however, consider this a vaccine administration error and recommend that you work with the office to determine how the error occurred and find ways of preventing this in the future. We also recommend that you report this error to VAERS at https://vaers.hhs.gov/.

Best regards,
NIPINFO
How does NIPINFO research answers?

- CDC childhood and adult Immunization schedules
- ACIP vaccine recommendations and guidelines
  - Vaccine specific-information
- ACIP General Best Practice Guidelines
  - Timing and spacing of vaccines
- Immunization Action Coalition “Ask the Experts”
  - Repository of frequently asked questions about immunizations, organized by vaccine type
Acknowledgements

• Thank you to:
  • Raymond Strikas, MD
  • Skip Wolfe, BA
  • JoEllen Wolicki, RN, BSN
  • NIPINFO staff
Have immunization questions?

- CDC-INFO: cdcinfo@cdc.gov
- NIPINFO: nipinfo@cdc.gov
Resources to Help Providers PREVENT Vaccination Errors

National Immunization Conference
May 15, 2018
Teresa Asper Anderson, DDS, MPH
Immunization Action Coalition
Background

• Healthcare professionals and members of the public can contact IAC by writing to admin@immunize.org.
• We answer ~200–300 such emails each month.
• It appears that more errors are being made (IZ schedule more complex, additional available products, “alternative schedules,” more recommended adult vaccines). In addition, some types of errors that might have gone undetected in the past are now caught by state immunization information systems.
From January 2015 through December 2017, IAC received questions about approximately 1,180 medical errors related to vaccination, including errors in vaccine storage and handling, administration, scheduling, and documentation.
### Types of Vaccine Administration Errors Communicated to IAC
January 2015–December 2017

<table>
<thead>
<tr>
<th>Error Type</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minimum interval violation</td>
<td>213</td>
</tr>
<tr>
<td>Wrong vaccine</td>
<td>173</td>
</tr>
<tr>
<td>Intended off-label use</td>
<td>149</td>
</tr>
<tr>
<td>Wrong dose</td>
<td>140</td>
</tr>
<tr>
<td>Minimum age violation</td>
<td>130</td>
</tr>
<tr>
<td>Double/extra dose</td>
<td>99</td>
</tr>
<tr>
<td>Expired vaccine administered</td>
<td>64</td>
</tr>
<tr>
<td>Wrong route</td>
<td>55</td>
</tr>
<tr>
<td>Wrong diluent or diluent only</td>
<td>54</td>
</tr>
<tr>
<td>Two live vaccines not 4 weeks apart</td>
<td>33</td>
</tr>
<tr>
<td>Inappropriate simultaneous admin</td>
<td>28</td>
</tr>
<tr>
<td>Vaccine mishandled (e.g., temp)</td>
<td>21</td>
</tr>
<tr>
<td>Wrong site</td>
<td>16</td>
</tr>
<tr>
<td>Wrong needle</td>
<td>5</td>
</tr>
</tbody>
</table>
Resources to help immunization providers AVOID errors

• Vaccine Storage and Handling
• Administration
• Scheduling
• Documentation
Storage & handling resources

www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf
Storage & handling resources

- CDC’s “You Call the Shots” web-based course on storage & handling [www.cdc.gov/vaccines/ed/youcalltheshots.html](http://www.cdc.gov/vaccines/ed/youcalltheshots.html)
- CDC video: *Keys to Storage and Handling Your Vaccine Supply* [www2.cdc.gov/vaccines/ed/shvideo](http://www2.cdc.gov/vaccines/ed/shvideo)
- CDC’s Vaccine Label Examples [www.cdc.gov/vaccines/hcp/admin/storage/guide/vaccine-storage-labels.pdf](http://www.cdc.gov/vaccines/hcp/admin/storage/guide/vaccine-storage-labels.pdf)
# Haemophilus influenzae type b-containing Vaccines

<table>
<thead>
<tr>
<th>Hib (ActHIB)</th>
<th>Hib (PedvaxHIB)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ages:</strong> 6 weeks through 4 years</td>
<td><strong>Ages:</strong> 6 weeks through 4 years</td>
</tr>
<tr>
<td><strong>Use for:</strong> Any dose in the series</td>
<td><strong>Use for:</strong> Any dose in the series</td>
</tr>
<tr>
<td><strong>Route:</strong> Intramuscular (IM) injection</td>
<td><strong>Route:</strong> Intramuscular (IM) injection</td>
</tr>
</tbody>
</table>

Reconstitute Hib powder ONLY with manufacturer-supplied 0.4% sodium chloride diluent

Beyond Use Time: If not used immediately after reconstitution, store at 2°C to 8°C (36°F to 46°F) and discard if not used within 24 hours. Should be shaken vigorously before injection.

**Vial stopper contains latex**

<table>
<thead>
<tr>
<th>Hib (Hiberix)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ages:</strong> 6 weeks through 4 years</td>
</tr>
<tr>
<td><strong>Use for:</strong> Any dose in the series</td>
</tr>
<tr>
<td><strong>Route:</strong> Intramuscular (IM) injection</td>
</tr>
</tbody>
</table>

Reconstitute Hib powder ONLY with manufacturer-supplied 0.9% sodium chloride diluent

Beyond Use Time: If not used immediately after reconstitution, store at 2°C to 8°C (36°F to 46°F) and discard if not used within 24 hours. Should be shaken vigorously before injection.
Storage & handling resources

- CDC’s *Temperature Monitoring Best Practices for Refrigerated Vaccines*
- CDC’s *Temperature Monitoring Best Practices for Frozen Vaccines*
- CDC’s *Storage Best Practices for Refrigerated Vaccines*
- CDC’s *Storage Best Practices for Frozen Vaccines*

Each available in Celsius and Fahrenheit
All available at www.cdc.gov/vaccines/hcp/admin/storage/index.html
Temperature Monitoring Best Practices for Refrigerated Vaccines—Fahrenheit (°F)

1. Store vaccines at ideal temperature: 40°F
   - Never freeze refrigerated vaccines!
   - Exceptions: MMR can be stored in refrigerator or freezer
   - Report out-of-range temperatures immediately!

2. Record daily temperatures
   - 3 steps, daily: Check and record min/max temperatures at the start of the workday.
   1. Min/Max: The coldest and warmest temperatures in the refrigerator since you last reset the thermometer.
   2. Reset: The button you push after you have recorded the min/max temperatures.
   3. Current temperature: Check current temperature each time you access vaccines in the refrigerator

3. Take action if out of range!
   - Take your time. Check and record temperatures accurately.
   - Make your mark! Initial the log when recording temperatures.
   - Leave it blank. If min/max temperatures were not recorded, leave the space blank!

Best Practices
- Contact your state or local health department immediately. Or for private vaccines, call the manufacturer directly.
- Tally the total amount of time the refrigerator temperature was out of range.

Storage Best Practices for Frozen Vaccines—Celsius (°C)

1. Unpack vaccines immediately
   - 1. Place the vaccines in trays or uncovered containers for proper air flow.
   - 2. Put vaccines that are first to expire in front.
   - 3. Keep vaccines in original boxes with lids closed to prevent exposure to light.
   - 4. Separate and label vaccines by type and public (VFC) or private.

2. Thermostat should be at the factory-set or midpoint temperature setting

3. Use vaccine storage best practices

DO
- Do make sure the freezer door is closed!
- Do use water bottles to help maintain consistent temperature.
- Do leave 2 to 3 inches between vaccine containers and freezer walls.
- Do post “Do Not Unplug” signs on freezer and by electrical outlet.

DON'T
- Don’t use dormitory-style refrigerator/freezer.
- Don’t use combo refrigerator/freezer unit.
- Don’t put food in freezer.
- Don’t store vaccines on shelves in freezer door.

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

Distributed by
Visit www.cdc.gov/vaccines/SafetHT
or contact your state health department for more information.
Storage & handling resources

- IAC's "Storage and Handling" print resources
  www.immunize.org/handouts/vaccine-storage-handling.asp

- IAC’s “Clinic Tools: Vaccine Storage and Handling”
  web page  www.immunize.org/clinic/storage-handling.asp

Print resources include:
Storage & handling resources

- Checklist for Safe Vaccine Storage and Handling
  www.immunize.org/catg.d/p3035.pdf
- Don’t Be Guilty of These Preventable Errors in Vaccine Storage and Handling!
  www.immunize.org/catg.d/p3036.pdf
- Emergency Response Worksheet
  www.immunize.org/catg.d/p3051.pdf
- Vaccines with Diluents: How to Use Them
  www.immunize.org/catg.d/p3040.pdf
- Temperature logs in Celsius and Fahrenheit for refrigerators and freezers
- And more...
# Vaccines with Diluents: How to Use Them

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

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

<table>
<thead>
<tr>
<th>Vaccine product name</th>
<th>Manufacturer</th>
<th>Lyophilized vaccine (powder)</th>
<th>Liquid diluent (may contain vaccine)</th>
<th>Time allowed between reconstitution and use, as stated in package insert</th>
</tr>
</thead>
<tbody>
<tr>
<td>ActiHIB (Hib)</td>
<td>Sanofi Pasteur</td>
<td>Hib</td>
<td>0.4% sodium chloride</td>
<td>24 hrs</td>
</tr>
<tr>
<td>Hiberix (Hib)</td>
<td>GlaxoSmithKline</td>
<td>Hib</td>
<td>0.9% sodium chloride</td>
<td>24 hrs</td>
</tr>
<tr>
<td>Imovax (RAB_vacc)</td>
<td>Sanofi Pasteur</td>
<td>Rabies virus</td>
<td>Sterile water</td>
<td>Immediately¹</td>
</tr>
<tr>
<td>M-M-R II (MMR)</td>
<td>Merck</td>
<td>MMR</td>
<td>Sterile water</td>
<td>8 hrs</td>
</tr>
<tr>
<td>Menveo (MenACWY)</td>
<td>GlaxoSmithKline</td>
<td>MenA</td>
<td>Sterile water</td>
<td>8 hrs</td>
</tr>
<tr>
<td>Pentacel (DTaP-IPV/Hib)</td>
<td>Sanofi Pasteur</td>
<td>Hib</td>
<td>DTaP-IPV</td>
<td>Immediately¹</td>
</tr>
<tr>
<td>ProQuad (MMRV)</td>
<td>Merck</td>
<td>MMRV</td>
<td>Sterile water</td>
<td>30 min</td>
</tr>
<tr>
<td>RabAvert (RAB_vacc)</td>
<td>GlaxoSmithKline</td>
<td>Rabies virus</td>
<td>Sterile water</td>
<td>Immediately¹</td>
</tr>
<tr>
<td>Rotarix (RV)</td>
<td>GlaxoSmithKline</td>
<td>RV1</td>
<td>Sterile water, calcium carbonate, and xanthan</td>
<td>24 hrs</td>
</tr>
<tr>
<td>Shingrix (RZV)</td>
<td>GlaxoSmithKline</td>
<td>RZV</td>
<td>AS01 adjuvant suspension</td>
<td>6 hours</td>
</tr>
<tr>
<td>Varivax (VAR)</td>
<td>Merck</td>
<td>VAR</td>
<td>Sterile water</td>
<td>30 min</td>
</tr>
<tr>
<td>YF-VAX (YF)</td>
<td>Sanofi Pasteur</td>
<td>YF</td>
<td>0.9% sodium chloride</td>
<td>60 min</td>
</tr>
<tr>
<td>Zostavax (LZV)</td>
<td>Merck</td>
<td>LZV</td>
<td>Sterile water</td>
<td>30 min</td>
</tr>
</tbody>
</table>

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

1. For single-dose vaccine products (exception is Rotarix), select a syringe and needle of proper length to be used for both reconstitution and administration of the vaccine. Following reconstitution, Menomune in a multidose vial will require a new needle and syringe for each dose of vaccine to be administered. For Rotarix, see the package insert².
2. Before reconstituting, check labels on both the lyophilized vaccine vial and the diluent to verify that:
   - they are the correct two products to mix together,
   - the diluent is the correct volume, and
   - neither the vaccine nor the diluent has expired.
3. Reconstitute (i.e., mix) vaccine just prior to use by:
   - removing the protective cap and wiping each stopper with an alcohol swab,
   - inserting needle of syringe into diluent vial and withdrawing entire contents, and
   - injecting diluted 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.
5. If reconstituted vaccine is not used immediately or comes in a multidose vial (i.e., multi-dose Menomune), be sure to:
   - clearly mark the vial with the date and time the vaccine was reconstituted,
   - maintain the product at 2°-8°C (36°-46°F), do not freeze, and
   - use only within the time indicated on chart above.

¹If the reconstituted vaccine is not used within this time period, it must be discarded.
²For purposes of this guidance, IMC defines "immediately" as within 30 minutes or less.
³Rotarix 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

IMMUNIZATION ACTION COALITION
Saint Paul, Minnesota • 651-647-9009 • www.immunize.org • www.vaccineinformation.org
www.immunize.org/catg.d/p3040.pdf • Item #P3040 (12/17)
Temperature Log for Freezer – Celsius

DAYS 1–15

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

<table>
<thead>
<tr>
<th>Day of Month</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
<th>11</th>
<th>12</th>
<th>13</th>
<th>14</th>
<th>15</th>
</tr>
</thead>
<tbody>
<tr>
<td>Staff Initials</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exact Time</td>
<td>AM</td>
<td>PM</td>
<td>AM</td>
<td>PM</td>
<td>AM</td>
<td>PM</td>
<td>AM</td>
<td>PM</td>
<td>AM</td>
<td>PM</td>
<td>AM</td>
<td>PM</td>
<td>AM</td>
<td>PM</td>
<td>AM</td>
</tr>
<tr>
<td>Min/Max Temp</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(since previous reading)</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Danger! Temperatures above -15°C are too warm! Write any out-of-range temps and room temp on the lines below and call your state or local health department immediately!

-15°C
-16°C
-17°C
-18°C
-19°C
-20°C
-21°C
-22°C
-50°C to -23°C

ACTION
Write any out-of-range temps (above -15°C or below -50°C) here.
Room Temperature

Take action if temp is out of range—too warm (above -15°C) or too cold (below -50°C).
1. Label exposed vaccine “do not use,” and store it under proper conditions as quickly as possible. Do not discard vaccines unless directed to by your state/local health department and/or the manufacturer(s).
2. Record the out-of-range temps and the room temp in the “Action” area on the bottom of the log.
3. Notify your vaccine coordinator, or call the immunization program at your state or local health department for guidance.
4. Document the action taken on the “Vaccine Storage Troubleshooting Record” on page 3.

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

Adapted with appreciation from California Department of Public Health
Technical content reviewed by the Centers for Disease Control and Prevention
www.immunize.org/catg.d/p3038C.pdf • Item #P3038C (8/16)
California’s VFC program has many helpful resources at www.eziz.org.
Resources to help immunization providers AVOID errors

- Vaccine Storage and Handling
- Administration
- Scheduling
- Documentation
Vaccine administration resources

- CDC’s “Vaccine Administration” web section
  www.cdc.gov/vaccines/hcp/admin/admin-protocols.html
- CDC’s “You Call the Shots” web-based course on vaccine administration
  www.cdc.gov/vaccines/ed/courses.html#elearn-vaccadmin
- CDC’s “Pink Book” chapter on vaccine administration
  www.cdc.gov/vaccines/pubs/pinkbook/vac-admin.html
Make sure vaccination is safe.

KNOW THE SITE. GET IT RIGHT!

When administering vaccine by an intramuscular (IM) injection to an adult:

**Use** the correct syringe and needle
- Vaccine may be administered using either a 1-ml, or 3-ml, syringe
- Use a 22 to 25 gauge needle
- Use the correct needle size based on your patient’s size

Injection site: Deltoide muscle of upper arm

<table>
<thead>
<tr>
<th>1 in (25 mm)</th>
<th>1.5 in (38 mm) OR 2 in (51 mm)</th>
<th>1.5 in (38 mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Men and women, less than 40 kg (90 lbs)</td>
<td>Men and women, 40-70 kg (90-154 lbs)</td>
<td>Men, greater than 70 kg (154 lbs)</td>
</tr>
<tr>
<td>Teen and women, 15-19 yrs, (59-120 lbs)</td>
<td>Teen and women, 15-19 yrs, (59-120 lbs)</td>
<td>Teen and women, 15-19 yrs, (59-120 lbs)</td>
</tr>
</tbody>
</table>

*Some experts recommend a 5/8-inch needle for men and women who weigh less than 60 kg (132 lbs).

**Identify** the injection site
- Locate the deltoide muscle of the upper arm
- Use anatomical landmarks to determine the injection site
- In adults, the midpoint of the deltoide is about 2 inches (or 2 to 3 fingers’ breadth) below the acromion process (bony prominence) and above the armpit in the middle of the upper arm

**Administer** the vaccine correctly
- Inject the vaccine into the middle and thickest part of the deltoide muscle
- Insert the needle at a 90° angle and inject all of the vaccine into the muscle tissue

**Always follow safe injection practices**
- Maintain aseptic technique
- Perform hand hygiene before preparing and administering vaccines
- Use a new needle and new syringe for each injection
- If using a single-dose vial (SDV) discard after use
- A SDV should be used for one patient only

Report any clinically significant adverse event after vaccination to the Vaccine Adverse Event Reporting System (VAERS) at vaers.hhs.gov

For additional information on proper vaccine administration, visit the CDC vaccine administration web page at: www.cdc.gov/vaccines/administration/procedures.html

Remember — you call the shots when it comes to proper vaccine administration.
Immunization Techniques: Best Practices with Infants, Children, and Adults

Purchase at www.immunize.org/dvd
Watch online at www.youtube.com/watch?v=JEMREaOrfRE
Vaccine administration resources

- IAC's “Administering Vaccines" print resources www.immunize.org/handouts/administering-vaccines.asp
- IAC’s “Clinic Tools: Administering Vaccines” web page www.immunize.org/clinic/administering-vaccines.asp

Print resources include:
Vaccine administration resources

- **Administering Vaccines: Dose, Route, Site, and Needle Size**
  www.immunize.org/catg.d/p3085.pdf
- **Don’t Be Guilty of These Preventable Errors in Vaccine Administration!**
  www.immunize.org/catg.d/p3033.pdf
- **Skills Checklist for Vaccine Administration**
  www.immunize.org/catg.d/p7010.pdf
- **How to Administer Intradermal, Intranasal, and Oral Vaccinations**
- **Hepatitis A and Hepatitis B Vaccines: Be Sure Your Patients Get the Correct Dose**
  www.immunize.org/catg.d/p2081.pdf
- And more...
Vaccine administration resources

http://eziz.org/resources/vaccine-admin-job-aids
Giving All the Doses Under 12 Months

- Needle Lengths:
  IM = 1 inch  SC = 5/8 inch
- IM injections are given in the infant’s thigh
- SC injections may be given in the arm or thigh
- Separate injection sites by 1-2 inches
- Using combination vaccines will decrease the number of injections
- May consider a 5/8 inch needle for IM injections only in newborns less than age 4 weeks

Pain Management:
- Administer vaccines likely to cause a greater local reaction (DTaP, PCV) into separate limbs
- Inject the most painful injections last (i.e., PCV)

www.aimtoolkit.org/docs/Giving_all_doses_under_12mths.pdf
Alliance for Immunization in Michigan toolkit: www.aimtoolkit.org
# Quick Reference to Combination and/or Reconstituted Vaccines: Childhood: Birth through 18 Years

Highlight Vaccines in Your Refrigerator/Freezer and Post

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Contains</th>
<th>Use for Ages</th>
<th>Use for Dose</th>
<th>Administration Tips</th>
</tr>
</thead>
</table>
| Pentacel SP | DTaP-IPV/Hib | 6 weeks through 4 years | 1, 2, 3, or 4 of DTaP, IPV, or Hib | - DTaP-IPV liquid (diluent) packaged with Hib vial  
- Draw up diluent; add to Hib vial; shake well  
- Administer within 30 minutes; give IM |
| Pediatrix GSK | DTaP-IPV-HepB | 6 weeks through 6 years | 1, 2, or 3 of DTaP or IPV; any dose of HepB | - Premixed  
- Shake well before administering; give IM |
| Kinrix GSK | DTaP-IPV | 4 through 6 years | 5th dose of DTaP; 4th (valid) dose of IPV\(^2\) | - Premixed  
- Shake well before administering; give IM |
| Quadracel SP | DTaP-IPV | 4 through 6 years | 5th dose of DTaP; 4th or 5th dose of IPV | - Premixed  
- Shake well before administering; give IM |
| ProQuad Merck | MMR, Var (MMRV) | If 1st dose: ages 12-47 months, use separate MMR and Var  
If 1st dose: ages 4-12 years, use MMRV  
If 2nd dose: ages 15 months-12 years, use MMRV | - Draw up supplied diluent  
- Add diluent to MMRV vial; shake well  
- Administer within 30 minutes; give SC |
| M-M-R II Merck | MMR | 12 months and older | 1 or 2 of MMR | - Draw up supplied diluent  
- Add diluent to MMR vial; shake well; give SC |
| AdoHIB SP | Hib | 6 weeks through 4 years | Any dose of Hib | - Draw up diluent packaged with Hib vial  
- Add diluent to Hib vial; shake well; give IM |
| Hiberix GSK | Hib | 6 weeks through 4 years | Any dose of Hib | - Draw up diluent supplied with Hib vial  
- Add diluent to Hib vial; shake well; give IM |
| Varivax Merck | Var | 12 months and older | 1 or 2 of Var | - Draw up diluent supplied with Varicella vial  
- Add diluent to Varicella vial; shake well  
- Administer within 30 minutes; give SC |
| Mencevo GSK | MenACWY | 2 months through 55 years | Any dose of MenACWY | - MenCYW liquid (diluent) packaged with MenA vial  
- Draw up MenCYW diluent; add to MenA vial  
- Invert; shake well; give IM |
| Rotarix GSK | RV1 (Rotavirus) | 6 weeks through 7 months | Any dose of RV | - GSK diluent packaged with vial  
- Shake diluent in pre-filled oral applicator  
- Add to RV1 vial; shake; withdraw; give orally |

\(^1\)Refer to the manufacturer's package insert for further details regarding reconstituting and/or administering these products.  
\(^2\)When used in combination with Pentacel (DTaP-IPV/Hib), Kinrix may be used for the 5th (4th valid) dose of the IPV series.

Avoid medication errors! Use only the diluent that is packaged or sent with each specific vaccine—don’t use any other liquid.

Michigan Department of Health and Human Services – Division of Immunization  
2/13/2018

Alliance for Immunization in Michigan toolkit: www.aimtoolkit.org
Resources to help immunization providers AVOID errors

- Vaccine Storage and Handling
- Administration
- Scheduling
- Documentation
A clinician’s best friend...

CDC’s “Recommended and Minimum Ages and Intervals Between Doses of Routinely Recommended Vaccines”

<table>
<thead>
<tr>
<th>Vaccine and dose number</th>
<th>Recommended age for this dose</th>
<th>Minimum age for this dose</th>
<th>Recommended interval to next dose</th>
<th>Minimum interval to next dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diphereria-tetanus-acellular pertussis (DTaP)-1</td>
<td>2 months</td>
<td>6 weeks</td>
<td>8 weeks</td>
<td>4 weeks</td>
</tr>
<tr>
<td>DTaP-2</td>
<td>4 months</td>
<td>10 weeks</td>
<td>8 weeks</td>
<td>4 weeks</td>
</tr>
<tr>
<td>DTaP-3</td>
<td>6 months</td>
<td>14 weeks</td>
<td>6-12 months</td>
<td>6 months</td>
</tr>
<tr>
<td>DTaP-4</td>
<td>15-18 months</td>
<td>15 months</td>
<td>3 years</td>
<td>6 months</td>
</tr>
<tr>
<td>DTaP-5</td>
<td>4-6 years</td>
<td>4 years</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Haemophilus influenzae type b (Hib)-1</td>
<td>2 months</td>
<td>6 weeks</td>
<td>8 weeks</td>
<td>4 weeks</td>
</tr>
<tr>
<td>Hib-2</td>
<td>4 months</td>
<td>10 weeks</td>
<td>8 weeks</td>
<td>4 weeks</td>
</tr>
<tr>
<td>Hib-3</td>
<td>6 months</td>
<td>14 weeks</td>
<td>6-9 months</td>
<td>8 weeks</td>
</tr>
<tr>
<td>Hib-4</td>
<td>12-15 months</td>
<td>12 months</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Hepatitis A (HepA)-1</td>
<td>12-23 months</td>
<td>12 months</td>
<td>6-18 months</td>
<td>6 months</td>
</tr>
<tr>
<td>HepA-2</td>
<td>≥18 months</td>
<td>18 months</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Hepatitis B (HepB)-1</td>
<td>Birth</td>
<td>Birth</td>
<td>4 weeks-4 months</td>
<td>8 weeks</td>
</tr>
<tr>
<td>HepB-2</td>
<td>1-2 months</td>
<td>4 weeks</td>
<td>8 weeks-17 months</td>
<td>8 weeks</td>
</tr>
<tr>
<td>HepB-3</td>
<td>6-18 months</td>
<td>24 weeks</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Herpes zoster (HZV)-1</td>
<td>≥50 years</td>
<td>50 years</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Human papillomavirus (HPV)-1</td>
<td>11-12 years</td>
<td>9 years</td>
<td>8 weeks</td>
<td>4 weeks</td>
</tr>
<tr>
<td>HPV-2</td>
<td>11-12 years (+ 2 months)</td>
<td>9 years</td>
<td>4 months</td>
<td>12 weeks</td>
</tr>
<tr>
<td>HPV-3,13</td>
<td>11-12 years (+ 6 months)</td>
<td>9 years</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Influenza, inactivated (ILV)-14</td>
<td>≥6 months</td>
<td>6 months</td>
<td>4 weeks</td>
<td>4 weeks</td>
</tr>
<tr>
<td>Influenza, live attenuated (LAIV)-14</td>
<td>2-49 years</td>
<td>2 years</td>
<td>4 weeks</td>
<td>4 weeks</td>
</tr>
<tr>
<td>Measles-mumps-rubella (MMR)-1</td>
<td>12-15 months</td>
<td>12 months</td>
<td>3-5 years</td>
<td>4 weeks</td>
</tr>
<tr>
<td>MMR-2</td>
<td>4-6 years</td>
<td>13 months</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Menicoccal conjugate (MenACWY)-2</td>
<td>11-12 years</td>
<td>6 weeks</td>
<td>4-5 years</td>
<td>8 weeks</td>
</tr>
<tr>
<td>MenACWY-2</td>
<td>16 years</td>
<td>11 years (+ 8 weeks)</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Meningococcal polysaccharide (MPSV4)-1</td>
<td>--</td>
<td>2 years</td>
<td>5 years</td>
<td>5 years</td>
</tr>
<tr>
<td>MPSV4-2</td>
<td>--</td>
<td>7 years</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Pneumococcal vaccine (PCV13)-1</td>
<td>2 months</td>
<td>6 weeks</td>
<td>8 weeks</td>
<td>4 weeks</td>
</tr>
<tr>
<td>PCV-2</td>
<td>4 months</td>
<td>10 weeks</td>
<td>8 weeks</td>
<td>4 weeks</td>
</tr>
<tr>
<td>PCV-3</td>
<td>6 months</td>
<td>14 weeks</td>
<td>6 weeks</td>
<td>8 weeks</td>
</tr>
<tr>
<td>PCV-4</td>
<td>12-15 months</td>
<td>12 months</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Pneumococcal polysaccharide (PPSV)-1</td>
<td>--</td>
<td>2 years</td>
<td>5 years</td>
<td>3 years</td>
</tr>
<tr>
<td>PPSV-2</td>
<td>--</td>
<td>7 years</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Poliovirus, Inactivated (IPV)-1</td>
<td>2 months</td>
<td>6 weeks</td>
<td>8 weeks</td>
<td>4 weeks</td>
</tr>
<tr>
<td>IPV-2</td>
<td>4 months</td>
<td>10 weeks</td>
<td>8-14 weeks</td>
<td>4 weeks</td>
</tr>
<tr>
<td>IPV-3</td>
<td>6-18 months</td>
<td>14 weeks</td>
<td>3-5 years</td>
<td>6 weeks</td>
</tr>
<tr>
<td>IPV-4</td>
<td>4-6 years</td>
<td>4 years</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Rotavirus (RV)-1</td>
<td>2 months</td>
<td>6 weeks</td>
<td>8 weeks</td>
<td>4 weeks</td>
</tr>
<tr>
<td>RV-2</td>
<td>4 months</td>
<td>10 weeks</td>
<td>8 weeks</td>
<td>4 weeks</td>
</tr>
<tr>
<td>RV-3</td>
<td>6 months</td>
<td>14 weeks</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Tetanus-diphtheria (Td)</td>
<td>11-12 years</td>
<td>7 years</td>
<td>10 years</td>
<td>5 years</td>
</tr>
<tr>
<td>Tetanus-diphtheria-acellular pertussis (Tdap)</td>
<td>≥11 years</td>
<td>7 years</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Varicella (Var)-1</td>
<td>12-15 months</td>
<td>12 months</td>
<td>3-5 years</td>
<td>12 weeks</td>
</tr>
<tr>
<td>Var-2</td>
<td>4-6 years</td>
<td>15 months</td>
<td>--</td>
<td>--</td>
</tr>
</tbody>
</table>
Vaccine scheduling resources

- IAC's “Vaccine Recommendations” print resources
  www.immunize.org/handouts/vaccine-recommendations.asp
- IAC’s “Clinic Tools: Scheduling Vaccines” web page
  www.immunize.org/clinic/scheduling-vaccines.asp
- IAC's “Standing Orders" web page
  www.immunize.org/standing-orders
- IAC’s *The Importance of Minimum Ages and Intervals in the Vaccine Schedule* slide set
  www.immunize.org/catg.d/s8025.pdf
### Summary of Recommendations for Child/Teen Immunization (Age birth through 18 years)

<table>
<thead>
<tr>
<th>Vaccine name and route</th>
<th>Schedule for routine vaccination and other guidelines (any vaccine can be given with another, unless otherwise noted)</th>
<th>Schedule for catch-up vaccination and related issues</th>
<th>Contraindications and precautions (mild illness is not a contraindication)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hepatitis B (HepB)</td>
<td>Give HepB dose #1 within 24hrs of birth to all medically stable infants weighing ≥2000g and born to HBsAg-negative mothers. Give dose #2 at age 1–2m and the final dose at age 16–18m (the last dose is the infant series should not be given earlier than age 24wks). After the birth dose, the series may be completed using 2 doses of single-antigen vaccine (ages 1–2m, 6–18m) or with 3 doses of Hib (ages 2m, 4m, 6m), which may result in giving a total of 4 doses of HepB vaccine. If mother is HBsAg-positive: Give HBIG and HepB dose #1 within 12hrs of birth; complete series by age 6m. If mother’s HBsAg status is unknown: Give HepB dose #1 within 12 hrs of birth. If low birth weight (less than 2000g), also give HBIG within 12hrs. For infants weighing 2000g or more whose mother is subsequently found to be HBsAg positive, give the infant HBIG; ASIP (no later than age 7d) and follow HepB immunization schedule for infants born to HBsAg-positive mothers. Vaccinate all other children and teens who have not completed a series of HepB vaccine.</td>
<td>Do not restart series, no matter how long since previous dose. Minimum intervals between doses: 4wks between #1 and #2, 2wks between #2 and #3, and at least 16wks between #1 and #3 (and give dose #1 no earlier than age 24wks).</td>
<td>Contraindication: Previous severe allergic reaction (e.g., anaphylaxis) to this vaccine or to any of its components, including hypersensitivity to yeast. Precaution: Moderate or severe acute illness, with or without fever. For infants who weigh less than 2000g, see ACP recommendation at <a href="http://www.cdc.gov/mmwr/PDF/rn5476.pdf">www.cdc.gov/mmwr/PDF/rn5476.pdf</a>.</td>
</tr>
<tr>
<td>DTPa, DT (Diphtheria, tetanus, acellular pertussis)</td>
<td>Give to children at ages 2m, 4m, 6m, 15–18m, and 4–6yrs. May give dose #1 as early as age 6wks. If dose #4 as early as age 12m if ≥6m have elapsed since #3. Do not give DTaP/DT to children age 7yrs and older. If possible, use the same DTaP product for all doses.</td>
<td>Dose #2 and #3 may be given 4wks after previous dose. Dose #4 may be given 6m after #3. If dose #4 is given before 4th birthday, wait at least 6m for #5 (age 4–6yrs). If dose #4 is given after 4th birthday, #5 is not needed.</td>
<td>Contraindications: Previous severe allergic reaction (e.g., anaphylaxis) to this vaccine or to any of its components, with or without fever. For all pertussis-containing vaccines: Encephalopathy not attributable to an identifiable cause, within 7d after DTaP/DTp/Dtp. Precaution: Moderate or severe acute illness. History of Arthus reaction following a prior dose of tetanus or diphtheria toxoid-containing vaccine (including MenACWY); defer vaccine until at least 10yrs have elapsed since the last tetanus toxoid-containing vaccine. Gullain-Barré syndrome (GBS) within 6wks after previous dose of tetanus toxoid-containing vaccine. For DTaP only: Any of these events following a previous dose of DTaP/DTp: 1) temperature of 105°F; 2) severe crying for 1hr or more within 48hrs; 3) collapse or shock-like state within 48hrs; 4) seizure within 3d. For all pertussis-containing vaccines. Progressive or unstable neurologic disorder, uncontrolled seizures, or progressive encephalopathy until a treatment regimen has been established and the condition has stabilized.</td>
</tr>
<tr>
<td>Td, Tdap (Tetanus, diphtheria, acellular pertussis)</td>
<td>For children and teens lacking previous Tdap: Give Tdap routinely at age 11–12yrs and vaccinate older teens on a catch-up basis; then boost every 10yrs with Td. Make special efforts to give Td to children and teens who are 1) in contact with infants younger than age 12m and 2) healthcare workers with direct patient contact. Give Tdap to pregnant adolescents during each pregnancy (preferred during the early part of gestational weeks 27 through 30wks), regardless of interval since prior Td or Tdap.</td>
<td>DTaP and DT should not be used for children age 7yrs and older; use Td and Tdap instead. Children ≤ age 7yrs or teens who are unvaccinated or behind schedule should complete a primary Td series (3 doses), with an interval of 1–2m between dose #1 and #2, and an interval of 6–12m between dose #2 and #3; substitute Tdap for any dose in the series, preferably as dose #1. Tdap should be given regardless of interval since previous Td.</td>
<td>This table is revised periodically. Visit IAC’s website at <a href="http://www.immunize.org/child/">www.immunize.org/child/</a> to make sure you have the most current version. Technical content reviewed by the Centers for Disease Control and Prevention.</td>
</tr>
</tbody>
</table>
# Summary of Recommendations for Adult Immunization (Age 19 years and older)

<table>
<thead>
<tr>
<th>Vaccine name and route</th>
<th>People for whom vaccination is recommended</th>
<th>Schedule for vaccination administration (any vaccine can be given with another unless otherwise noted)</th>
<th>Contraindications and precautions (mild illness is not a contraindication)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Influenza</strong></td>
<td></td>
<td></td>
<td><strong>Contraindications</strong></td>
</tr>
<tr>
<td>Inactivated Influenza vaccine (IV*)</td>
<td>For people through age 18 yrs, consult “Summary of Recommendations for Child/Teen Immunization” at <a href="http://www.immunize.org/catg.d/p2010.pdf">www.immunize.org/catg.d/p2010.pdf</a>.</td>
<td>• Give 1 dose every year in the fall or winter. Begin vaccination services as soon as vaccine is available and continue until the supply is depleted.</td>
<td>Previous severe allergic reaction (e.g., anaphylaxis) to this vaccine, to any of its components, including egg protein.</td>
</tr>
<tr>
<td></td>
<td>Vaccination is recommended for all adults.</td>
<td>• Contribute to give vaccine to unvaccinated adults throughout the influenza season (including when influenza activity is present in the community) and at other times when the risk of influenza exists.</td>
<td>Adults who have experienced a severe reaction to egg containing influenza vaccine, including RIV3 which does not contain egg protein. The vaccine should be administered in a medical setting (e.g., a health department or physician office) and should be supervised by a healthcare provider who is able to recognize and manage severe allergic conditions.</td>
</tr>
<tr>
<td></td>
<td>Adults age 18 through 64 yrs may be given any intramuscular IV product (Fluzone, Fluvirin, Afluria, Flucelvax Fluvirin, Fluzone, Fluvirin, Fluzone High-Dose), or the intradermal IV product (Fluzone Intradermal), or RIV3 (Flublok).</td>
<td>• Live attenuated influenza vaccine (LAIV) should not be used during the 2016-17 influenza season.</td>
<td>Precautions: Moderate or severe acute illness with or without fever.</td>
</tr>
<tr>
<td></td>
<td>Adults age 65yrs and older may be given any standard dose IV vaccine licensed in the second calendar year.</td>
<td>• For people who are unvaccinated or behind, complete the primary Td series (3 doses with an interval of 1-2 months between doses 1 and 2, and an interval of 6-12 months between dose 2 and 3), substitute a one-time dose of Tdap for one of the doses in the series, preferably the first.</td>
<td>History of Guillain-Barré syndrome (GBS) within 6 weeks following previous influenza vaccination.</td>
</tr>
<tr>
<td></td>
<td>Live attenuated influenza vaccine (LAIV)</td>
<td>• Give Td booster every 10 yrs after the primary series has been completed.</td>
<td>For adults who experience only hives with exposure to eggs, give any age-appropriate influenza vaccine.</td>
</tr>
<tr>
<td></td>
<td>(LAIV) should not be used during the 2016-17 influenza season.</td>
<td>• Td should be given regardless of interval since previous Td.</td>
<td>For adults who experience only hives with exposure to eggs, give any age-appropriate influenza vaccine.</td>
</tr>
</tbody>
</table>


This document was adapted from the recommendations of the Advisory Committee on Immunization Practices (ACIP). To obtain copies of these recommendations, visit CDC’s website at www.cdc.gov/vaccines/hcp/ACIP/index.html or visit the Immunization Action Coalition (IAC) website at www.immunize.org/aci.

This table is revised periodically. Visit IAC’s website at www.immunize.org/adults to make sure you have the most current version.

For the purposes of calculating intervals between doses, 4 weeks = 28 days. Intervals of 4 months or greater are determined by calendar months. A vaccine series does not need to be restarted, regardless of the time that has elapsed between doses.
Meningococcal Vaccines—Routine Risk

[Table with routine risk information]

For Health Professionals

HPV Vaccine – 2 or 3 Doses?

[Table with vaccination schedules]

Pneumococcal Vaccine Timing—For Adults

[Table with timing information]

Immunization Schedule with Combination Vaccines

[Table with vaccination schedules]

http://eziz.org/administration/schedules-recons
And/or check with your state immunization registry about when the next dose should be given (before you give it!)
Resources to help immunization providers AVOID errors

- Vaccine Storage and Handling
- Administration
- Scheduling
- Documentation
Vaccine documentation resources

• CDC’s “Document the Vaccination(s)” web section (includes info about IIS and VAERS reporting)
  www.cdc.gov/vaccines/hcp/admin/document-vaccines.html

• CDC’s “Standards for Practice: Vaccine Documentation”
  www.cdc.gov/vaccines/hcp/adults/for-practice/standards/documentation.html
Vaccine documentation resources

- IAC's “Documenting Vaccination" print resources
  www.immunize.org/handouts/document-vaccines.asp
- IAC’s “Clinic Tools: Documenting Vaccination” web page
  www.immunize.org/clinic/documenting-vaccination.asp
- IAC's “Vaccine Information Statements" web page
  www.immunize.org/vis
- IAC’s “Screening Checklists” web page
  www.immunize.org/handouts/screening-vaccines.asp
Vaccine documentation resources

- **Current Dates of Vaccine Information Statements**

- **Decision to Not Vaccinate My Child**

- **Vaccine Administration Record for Adults**

- **Vaccine Administration Record for Children & Teens**

- Screening checklists and more...
## Current Dates of Vaccine Information Statements (VISs) as of March 21, 2018

Check your supply of VISs against this list. If you have outdated VISs, get current versions at [www.immunize.org/vis](http://www.immunize.org/vis).

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adenovirus</td>
<td>6/11/14</td>
</tr>
<tr>
<td>Anthrax</td>
<td>3/21/18</td>
</tr>
<tr>
<td>Cholera</td>
<td>7/6/17</td>
</tr>
<tr>
<td>DTaP</td>
<td>5/17/07</td>
</tr>
<tr>
<td>Hib</td>
<td>4/2/15</td>
</tr>
<tr>
<td>Hepatitis A</td>
<td>7/20/16</td>
</tr>
<tr>
<td>Hepatitis B</td>
<td>7/20/16</td>
</tr>
<tr>
<td>HPV</td>
<td>12/2/16</td>
</tr>
<tr>
<td>Influenza</td>
<td>8/7/15</td>
</tr>
<tr>
<td>Japanese enceph</td>
<td>1/24/14</td>
</tr>
<tr>
<td>MenACWY</td>
<td>3/31/16</td>
</tr>
<tr>
<td>MenB</td>
<td>8/9/16</td>
</tr>
<tr>
<td>MMR</td>
<td>2/12/18</td>
</tr>
<tr>
<td>MMRV</td>
<td>2/12/18</td>
</tr>
<tr>
<td>Multi-vaccine</td>
<td>11/5/15</td>
</tr>
<tr>
<td>PCV13</td>
<td>11/5/15</td>
</tr>
<tr>
<td>PPSV</td>
<td>4/24/15</td>
</tr>
<tr>
<td>Polio</td>
<td>7/20/16</td>
</tr>
<tr>
<td>Rabies</td>
<td>10/6/09</td>
</tr>
<tr>
<td>Rotavirus</td>
<td>2/23/18</td>
</tr>
<tr>
<td>Td</td>
<td>4/11/17</td>
</tr>
<tr>
<td>Tdap</td>
<td>2/24/15</td>
</tr>
<tr>
<td>Typhoid</td>
<td>5/29/12</td>
</tr>
<tr>
<td>Varicella</td>
<td>2/12/18</td>
</tr>
<tr>
<td>Yellow fever</td>
<td>3/30/11</td>
</tr>
<tr>
<td>Zoster</td>
<td>2/12/18</td>
</tr>
</tbody>
</table>
Screening for contraindication and precautions to vaccination, and documenting such, is crucial to avoiding serious errors.

www.immunize.org/handouts/screening-vaccines.asp
Vaccine documentation resources


- Michigan’s *Refusal to Consent to Child & Adolescent Vaccination: Birth through 18 years* (also available in Spanish and Arabic) and *Refusal to Consent to Adult Vaccination: 19 Years and Older*  [www.aimtoolkit.org/health-care/vaccine-administration.php](http://www.aimtoolkit.org/health-care/vaccine-administration.php)
Immunization Site Maps

www.immunize.org/clinic/documenting-vaccination.asp
Additional general resources

- ACIP’s *General Best Practice Guidelines for Immunization*
  www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html

- CDC’s “Pink Book”
  www.cdc.gov/vaccines/pubs/pinkbook/index.html#chapters

- CDC’s “Immunization Schedules” web section
  www.cdc.gov/vaccines/schedules/hcp/child-adolescent.html

- IAC’s “Ask the Experts” web section
  www.immunize.org/askexperts

- IAC’s *To Err Is Human; Not To Err Is Better!* slide set
  www.immunize.org/catg.d/s8020.pdf
In March 2015, ISMP published an excellent guide titled *Recommendations For Practitioners To Prevent Vaccine Errors Part 2: Analysis Of ISMP Vaccine Errors Reporting Program (VERP)*

www.ismp.org/newsletters/acutecare/showarticle.aspx?id=104
Questions?

• Email CDC’s experts: nipinfo@cdc.gov.

• Contact your vaccine representative or call the manufacturer.

• Call your state immunization coordinator (contact information for all state immunization programs can be found at www.vaccineinformation.org/state-immunization-programs).

• Email IAC: admin@immunize.org
Reports of shoulder dysfunction following immunization with inactivated influenza vaccine, Vaccine Adverse Event Reporting System (VAERS), 2010-2016

Beth Hibbs, RN, MPH, Immunization Safety Office Centers for Disease Control and Prevention (CDC)

National Immunization Conference
May 15, 2018, Session (B4) 11:30-12:30
Disclaimer

The findings and conclusions in this presentation are those of the presenters and do not necessarily represent the official position of the Centers for Disease Control and Prevention.
Background: shoulder injury following vaccination

- Atanasoff et al. (2010)¹
  - Review of 13 claims in the National Childhood Vaccine Injury Program (VICP) between 2006-2010 in which limited and painful range of motion of the shoulder following vaccination was claimed

- Institute of Medicine (2012)²
  - Based on Atanasoff et al. paper and other case series and case reports:
    - Evidence convincingly supports a causal relationship between the injection of a vaccine and deltotoid bursitis

- Shoulder injury related to vaccine administration (SIRVA) added to the VICP Vaccine Injury Table in 2017³

---

Background: Vaccine Injury Table

- Shoulder injury related to vaccine administration (SIRVA) manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm.

- These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g. tendons, ligaments, bursae, etc.).

- SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis (even if the condition causing the neurological abnormality is not known).

Reference: Vaccine Injury Table (https://www.hrsa.gov/sites/default/files/vaccinecompensation/vaccineinjurytable.pdf)

1Reference: Vaccine Injury Table (https://www.hrsa.gov/sites/default/files/vaccinecompensation/vaccineinjurytable.pdf)
Surface landmarks and structures in the upper arm

Anterior View of Right Shoulder

Lateral View of Right Shoulder

Image by Alissa Eckert, CDC Division of Communication Services
Vaccine Adverse Event Reporting System (VAERS)\(^1\)

**National spontaneous reporting system for adverse events after US-licensed vaccines**

### Strengths
- National data
- Accepts reports from anyone
- Rapidly detects safety signals
- Can detect rare adverse events
- Data available to public

### Limitations
- Reporting bias
- Inconsistent data quality and completeness
- Lack of unvaccinated comparison group
- Generally cannot assess causality
- Coding practices can affect types and numbers of adverse events identified in reports

---

\(^1\)Vaccine Adverse Event Reporting System: [http://vaers.hhs.gov](http://vaers.hhs.gov); jointly managed by CDC and FDA
## Vaccination errors categorized into 11 error groups, VAERS, 2000-2016

<table>
<thead>
<tr>
<th>Vaccination Error Groups¹</th>
<th>N (% total errors)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Storage and Dispensing</td>
<td>37,782 (57)</td>
</tr>
<tr>
<td>Inappropriate Schedule</td>
<td>10,662 (16)</td>
</tr>
<tr>
<td>Wrong Vaccine</td>
<td>4,996 (8)</td>
</tr>
<tr>
<td>Incorrect Dose</td>
<td>4,772 (7)</td>
</tr>
<tr>
<td>Administration Errors</td>
<td>3,382 (5)</td>
</tr>
<tr>
<td>General Error</td>
<td>2,634 (4)</td>
</tr>
<tr>
<td>Accidental</td>
<td>504 (1)</td>
</tr>
<tr>
<td>Product Quality</td>
<td>442 (1)</td>
</tr>
<tr>
<td>Equipment</td>
<td>434 (1)</td>
</tr>
<tr>
<td>Contraindication</td>
<td>281 (&lt;1)</td>
</tr>
<tr>
<td>Product Labeling/Packaging</td>
<td>124 (&lt;1)</td>
</tr>
<tr>
<td><strong>Total Errors</strong>²</td>
<td><strong>66,013</strong></td>
</tr>
</tbody>
</table>

¹Vaccination error groups contain multiple MedDRA Codes

²Vaccination error groups are not mutually exclusive; Total Vaccination Error Reports =63,759
Objective

- Describe reports submitted to the Vaccine Adverse Event Reporting System (VAERS) of shoulder dysfunction following immunization with inactivated influenza vaccine (IIV)
Methods: study definition of shoulder dysfunction following immunization with inactivated influenza vaccine (IIV)¹

- Shoulder pain and restricted range of motion following injection of IIV into the upper arm
- Affected shoulder must be of same arm in which (IIV) was administered alone, with no other vaccinations
- Exclude reports where more than one vaccination – in addition to IIV – was given in the arm with the affected shoulder (e.g., IIV and PPSV23, Tdap/Td, etc.)
- Onset within 48 hours after IIV vaccination
- Symptoms last longer than one week (to differentiate from injection site reactions)
- Exclude reports of neurological injuries (e.g., brachial neuritis)

¹Adapted from the Vaccine Injury Compensation Program definition for shoulder injury following vaccine administration (SIRVA) with modification
Methods: VAERS search strategy and case reviews

- Searched VAERS database for reports of shoulder dysfunction following immunization with IIV from July 1, 2010 through June 30, 2016
  - Used MedDRA\(^1\) terms that potentially described shoulder dysfunction and selected vaccine administration error terms
  - And text string search of reports for “arm” or “shoulder”
- All reports identified in initial search were reviewed and classified into three categories: “Not a case,” “Indeterminate case,” or “Possible shoulder dysfunction case”
- Key information from reports entered into an electronic database using a standardized extraction form in MS Access

\(^1\)Medical Dictionary for Regulatory Activities (https://www.meddra.org/)
Results

VAERS reports met the initial search criteria for shoulder dysfunction following immunization with IIV\(^1\)

2,315 Total

- Not a shoulder dysfunction case
  - 768 (33%)

- Indeterminate shoulder dysfunction case
  - 503 (22%)

- Possible shoulder dysfunction case
  - 1,044 (45%)

- We included possible shoulder dysfunction cases following IIV in the analysis

\(^1\)VAERS reports vaccinated and received July 1, 2010 through June 30, 2016
Possible shoulder dysfunction cases by influenza season, 2010-2016 N (% among all IIV VAERS reports by season)
Characteristics of VAERS shoulder dysfunction (SD) vs. non-shoulder dysfunction reports following IIIV, July 2010-June 2016

<table>
<thead>
<tr>
<th></th>
<th>SD following IIIV, N (%)</th>
<th>Non-SD following IIIV, N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total reports</strong></td>
<td>1,044</td>
<td>49,215</td>
</tr>
<tr>
<td><strong>Non-serious</strong></td>
<td>971 (93)</td>
<td>45,721 (93)</td>
</tr>
<tr>
<td><strong>Female</strong></td>
<td>859 (82)</td>
<td>33,505 (68)</td>
</tr>
<tr>
<td><strong>Median age in years</strong></td>
<td>51 (range 16-94 years)</td>
<td>50 (range 0-102 years)</td>
</tr>
<tr>
<td><strong>Age groups</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0-17</td>
<td>2 (&lt;1)</td>
<td>8,370 (17)</td>
</tr>
<tr>
<td>18-49</td>
<td>468 (45)</td>
<td>15,322 (31)</td>
</tr>
<tr>
<td>50-64</td>
<td>354 (34)</td>
<td>11,269 (23)</td>
</tr>
<tr>
<td>65+</td>
<td>207 (20)</td>
<td>13,248 (27)</td>
</tr>
<tr>
<td>Unknown</td>
<td>13 (1)</td>
<td>1,006 (2)</td>
</tr>
<tr>
<td><strong>Type of reporter</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient</td>
<td>541 (52)</td>
<td>10,627 (22)</td>
</tr>
<tr>
<td>Vaccine provider</td>
<td>286 (27)</td>
<td>23,317 (47)</td>
</tr>
<tr>
<td>Manufacturer</td>
<td>39 (4)</td>
<td>4,363 (9)</td>
</tr>
<tr>
<td>Other/Unknown</td>
<td>178 (17)</td>
<td>10,627 (22)</td>
</tr>
<tr>
<td>CHARACTERISTIC</td>
<td>N (%)</td>
<td></td>
</tr>
<tr>
<td>-------------------------------------------------------------------------------</td>
<td>---------</td>
<td></td>
</tr>
<tr>
<td><strong>Total reports</strong></td>
<td>1,044</td>
<td></td>
</tr>
<tr>
<td><strong>Median onset interval</strong>&lt;sup&gt;1&lt;/sup&gt; (days)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Symptoms occurring on day of vaccination</td>
<td>740 (71)</td>
<td></td>
</tr>
<tr>
<td><strong>Pain had not resolved at time report was made to VAERS</strong></td>
<td>1024 (98)</td>
<td></td>
</tr>
<tr>
<td><strong>Seen by healthcare provider for shoulder dysfunction</strong></td>
<td>509 (49)</td>
<td></td>
</tr>
<tr>
<td><strong>Referred to specialist</strong>&lt;sup&gt;2&lt;/sup&gt;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Orthopedist</td>
<td>136</td>
<td></td>
</tr>
<tr>
<td>Surgeon (not specified)</td>
<td>18</td>
<td></td>
</tr>
<tr>
<td>Other specialist&lt;sup&gt;3&lt;/sup&gt;</td>
<td>55</td>
<td></td>
</tr>
</tbody>
</table>

<sup>1</sup>By definition, onset interval for Shoulder dysfunction is within 48 hours following vaccination, day 0 = day of vaccination

<sup>2</sup>Not mutually exclusive more than specialist could be listed

<sup>3</sup>Includes specialist such as rehabilitation medicine (13), chiropractor (13), neurologist (10), acupuncturist (4), occupational health provider (2), osteopathic doctor (2) and other (10)
Characteristics of VAERS shoulder dysfunction reports following IIV, July 2010-June 2016

<table>
<thead>
<tr>
<th>Most commonly reported adverse events¹</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total reports</td>
<td>1,044</td>
</tr>
<tr>
<td>Shoulder pain</td>
<td>458 (44)</td>
</tr>
<tr>
<td>Injected limb mobility decreased</td>
<td>422 (40)</td>
</tr>
<tr>
<td>Joint range of motion decreased</td>
<td>201 (19)</td>
</tr>
<tr>
<td>Drug administered at inappropriate site</td>
<td>161 (15)</td>
</tr>
<tr>
<td>Bursitis</td>
<td>98 (9)</td>
</tr>
<tr>
<td>Arthralgia</td>
<td>95 (9)</td>
</tr>
<tr>
<td>Rotator cuff syndrome</td>
<td>93 (9)</td>
</tr>
<tr>
<td>Frozen shoulder</td>
<td>59 (6)</td>
</tr>
<tr>
<td>Pain in joint involving shoulder region</td>
<td>36 (3)</td>
</tr>
<tr>
<td>Shoulder bursitis</td>
<td>31 (3)</td>
</tr>
</tbody>
</table>

¹Not mutually exclusive
VAERS shoulder dysfunction reports following IIV where a contributing factor was described (224 of 1,044 reports), July 2010-June 2016

<table>
<thead>
<tr>
<th>Contributing factors reported in narrative¹</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total reports</strong></td>
<td>224</td>
</tr>
<tr>
<td>Vaccination given too high on arm</td>
<td>182</td>
</tr>
<tr>
<td>Improper/poor administration technique</td>
<td>35</td>
</tr>
<tr>
<td>Uneven position between vaccinator and patient (vaccinator standing, patient sitting)</td>
<td>5</td>
</tr>
<tr>
<td>Wrong needle length</td>
<td>2</td>
</tr>
<tr>
<td>Other ( e.g. past history of shoulder pain, difficulty injecting vaccine)</td>
<td>14</td>
</tr>
</tbody>
</table>

¹Not mutually exclusive
Place of vaccination in VAERS shoulder dysfunction reports following IIV, July 2010-June 2016

Number of shoulder dysfunction reports

- Doctor's office/Hospital: 328 (31%)
- Pharmacy/Store: 421 (40%)
- Workplace: 123 (12%)
- Health department: 50 (5%)
- School/University: 29 (3%)
- Nursing home/Senior facility: 5 (<1%)
- Mobile clinics: 6 (<1%)
- Other: 18 (2%)
- Unknown: 64 (6%)
Summary

- Number of VAERS shoulder dysfunction of IIV reports ranged from 137-234 reports per influenza season from 2010 to 2016.
  - During that time period more than 130 million doses of IIV were distributed per season in the US

- Higher percentage of females experienced shoulder dysfunction of IIV. Most common age group was 18-49 years.
  - Few reports were in children 0-17 years (<1%)

- Vaccination given too high on the arm was the most common reported contributing factor to the shoulder dysfunction of IIV.
Summary (Continued)

- Most common places of vaccination was in pharmacies and medical offices
- Most were non-serious reports (93%)
- Pain had not resolved at time of reporting in the majority of reports
- ~50% of reports stated patient had seen a healthcare provider for shoulder pain
Conclusion

- Shoulder dysfunction following immunization of inactivated influenza vaccination was approximately 2% of all IIV VAERS reports, July 1, 2010 through June 30, 2016

- Shoulder dysfunction following immunization while rare may be preventable
  - Proper vaccine administration is an important consideration

Image by Alissa Eckert, CDC Division of Communication Services
CDC Resources

Infographic: https://www.cdc.gov/vaccines/hcp/infographics/call-the-shots.html

Vaccine Administration e-learn: https://www.cdc.gov/vaccines/hcp/admin/admin-protocols.html
Acknowledgements

CDC
Carmen Ng
Oidda Museru
Pedro Moro
Paige Lewis
Alissa Eckert
Maria Cano
Tom Shimabukuro

FDA
Jane Woo
Thank you

For more information, contact CDC
1-800-CDC-INFO (232-4636)

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.
Back-up slides
Serious reports clinically reviewed VAERS shoulder dysfunction following IIV, July 2010 - June 2016

- **Serious criteria** (N=73)
  - 55 (85%) resulted in permanent disability (per reporter)
  - 8 hospitalized (for shoulder related injury)
  - 2 considered as life threatening

- **Sex**: 45 Females, 18 Males, 2 Unknown

- **Median age (range) years**: 54 (24 – 92)

- **Seven patients required surgical treatment for management of shoulder dysfunction**

- **Main diagnosis of hospitalized cases (n=9)**:
  - Adhesive capsulitis (2)
  - Rotator cuff tear (2)
  - Shoulder pain (2)
  - Bursitis (1)
  - Impingement syndrome of right shoulder (1)
  - Rotator cuff tendinitis (1)

1 Eight did not meet serious criteria
2 Age unknown in 4 reports
Duration\(^1\) of resolved and unresolved VAERS shoulder dysfunction following IIV reports, June 2010 – July 2016

- Pain had not resolved at time report was made to VAERS (n=1024, 98%)
  - Duration range at time of report 8-1969 days
  - Median 50 days

- Pain had resolved at time of report (n=20, 2%)
  - Duration range 18-365 days
  - Median 80.5 days

\(^1\)Duration is calculated by date of report – date of adverse event onset, if date of report was missing, receive date was used
Report: Type of reporter among VAERS shoulder dysfunction following IIV compared to non-shoulder dysfunction following IIV reports, July 2010 - June 2016.
Place of Flu vaccination for adults(%): National flu survey 2015-16\(^1\) vs. VAERS 2015-16 reports of shoulder dysfunction and IIV in adults 2015-16

1 Data for national flu survey 2015-16 through July - November
Reported impact on activities of daily living\(^1\) among VAERS Shoulder dysfunction reports following IIIV, July 2010-June 2016

<table>
<thead>
<tr>
<th>Total reports</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total reports</td>
<td>1,044</td>
</tr>
<tr>
<td>Noticeable but does not interfere with activities of daily living (ADLs) or result in absenteeism from work</td>
<td>4 (&lt;1)</td>
</tr>
<tr>
<td>Interferes with ADLs, but unknown if it resulted in absenteeism from work</td>
<td>354 (34)</td>
</tr>
<tr>
<td>Prevents performing ADLs and/or results in absenteeism from work</td>
<td>236 (23)</td>
</tr>
<tr>
<td>Unknown/not stated in report how pain affected ADLs and/or absenteeism from work</td>
<td>450 (43)</td>
</tr>
</tbody>
</table>

\(^1\)Activities of daily living scale developed by researchers, limited by what was stated in reports
<table>
<thead>
<tr>
<th>MedDRA Terms used in search for shoulder dysfunction following IIV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute osteomyelitis involving shoulder region</td>
</tr>
<tr>
<td>Acute synovitis</td>
</tr>
<tr>
<td>Adhesive capsulitis of shoulder</td>
</tr>
<tr>
<td>Administration site joint discomfort</td>
</tr>
<tr>
<td>Administration site joint effusion</td>
</tr>
<tr>
<td>Administration site joint erythema</td>
</tr>
<tr>
<td>Administration site joint infection</td>
</tr>
<tr>
<td>Administration site joint inflammation</td>
</tr>
<tr>
<td>Administration site joint movement impairment</td>
</tr>
<tr>
<td>Administration site joint pain</td>
</tr>
<tr>
<td>Allergic arthritis involving shoulder region</td>
</tr>
<tr>
<td>arthralgia</td>
</tr>
<tr>
<td>Arthropathy involving shoulder region</td>
</tr>
<tr>
<td>Arthropathy unspecified, involving upper arm</td>
</tr>
<tr>
<td>Arthropathy, unspecified, involving shoulder region</td>
</tr>
<tr>
<td>Brachialgia</td>
</tr>
<tr>
<td>Bursa calcification</td>
</tr>
<tr>
<td>Bursa disorder</td>
</tr>
<tr>
<td>Bursa injury</td>
</tr>
<tr>
<td>Bursal fluid accumulation</td>
</tr>
<tr>
<td>Bursal synovitis</td>
</tr>
<tr>
<td>Bursitis</td>
</tr>
<tr>
<td>Capsulitis of shoulder</td>
</tr>
<tr>
<td>Cervicobrachalgia</td>
</tr>
<tr>
<td>Cervicobrachial syndrome</td>
</tr>
<tr>
<td>drug administration error</td>
</tr>
<tr>
<td>Effusion of joint of shoulder region</td>
</tr>
<tr>
<td>Effusion of upper arm joint</td>
</tr>
<tr>
<td>Injected limb mobility decreased</td>
</tr>
<tr>
<td>Injection site joint discomfort</td>
</tr>
<tr>
<td>Injection site joint erythema</td>
</tr>
<tr>
<td>Injection site joint infection</td>
</tr>
<tr>
<td>Injection site joint inflammation</td>
</tr>
<tr>
<td>Injection site joint movement impairment</td>
</tr>
<tr>
<td>Injection site joint pain</td>
</tr>
<tr>
<td>Injury to other specified nerve(s) of shoulder girdle and upper limb</td>
</tr>
<tr>
<td>Injury to peripheral nerve(s) of shoulder girdle and upper limb</td>
</tr>
<tr>
<td>Joint injury</td>
</tr>
<tr>
<td>Joint range of motion decreased</td>
</tr>
<tr>
<td>Joint swelling inflammatory</td>
</tr>
<tr>
<td>Late effect of injury to peripheral nerve of shoulder girdle and upper limb</td>
</tr>
<tr>
<td>Loose body in joint of shoulder region</td>
</tr>
<tr>
<td>Neck, shoulder and arm syndrome</td>
</tr>
<tr>
<td>Osteoarthrosis, localised, primary, involving shoulder region</td>
</tr>
<tr>
<td>Osteoarthrosis, localised, secondary, involving shoulder region</td>
</tr>
<tr>
<td>Osteoarthrosis, localized, not specified whether primary or secondary, involving shoulder region</td>
</tr>
<tr>
<td>Osteoarthrosis, unspecified whether generalized or localized, involving shoulder region</td>
</tr>
<tr>
<td>Other affections of shoulder region, not elsewhere classified</td>
</tr>
<tr>
<td>Other and unspecified injury to shoulder and upper arm</td>
</tr>
<tr>
<td>Other and unspecified superficial injury of shoulder and upper arm, infected</td>
</tr>
<tr>
<td>Other and unspecified superficial injury of shoulder and upper arm, without mention of infection</td>
</tr>
<tr>
<td>Other specified arthropathy involving shoulder region</td>
</tr>
<tr>
<td>Other specified arthropathy involving upper arm</td>
</tr>
<tr>
<td>Other specified crystal arthropathies involving shoulder region</td>
</tr>
<tr>
<td>Other specified disorders of bursae and tendons in shoulder region</td>
</tr>
<tr>
<td>Other specified disorders of joint of shoulder region</td>
</tr>
<tr>
<td>Other symptoms referable to joint of shoulder region</td>
</tr>
<tr>
<td>Other symptoms referable to upper arm joint</td>
</tr>
</tbody>
</table>
MedDRA Terms used in search for shoulder dysfunction following IIIV (cont.)

- Pain in (l) shoulder
- Pain in (r) shoulder
- Pain in joint involving shoulder region
- Pain in joint involving upper arm
- Pain in upper extremities
- Palindromic rheumatism involving shoulder region
- Periarthritis scapulohumeralis
- Purulent synovitis
- Pyogenic arthritis involving shoulder region
- Rotator cuff syndrome
- Rotator cuff syndrome of shoulder and allied disorders
- Scapula pain
- Shoulder bursitis
- Shoulder discomfort
- Shoulder dystocia
- Shoulder hand syndrome
- Shoulder joint pain associated with
- Shoulder ligament rupture
- Shoulder muscle stiffness

- Shoulder osteoarthritis
- Shoulder pain
- Shoulder pain (due joint disorder)
- Shoulder region stiffness of joint, not elsewhere classified, involving upper arm skeletal injury
- Stiffness shoulder
- Subacromial bursitis
- Synovial cyst
- Synovial disorder
- Synovial rupture
- Synovitis
- Synovitis of shoulder
- Tendon injury
- Tendon rupture
- Transient arthropathy involving shoulder region
- Transient arthropathy involving upper arm
- Traumatic arthritis
- Traumatic arthropathy involving shoulder region
- Traumatic arthropathy involving upper arm
- Unspecified disorder of joint of shoulder region
- Unspecified disorder of upper arm joint
- Unspecified infective arthritis involving shoulder region
- Unspecified monoarthritis involving shoulder region
- Unspecified monoarthritis involving upper arm
- Unspecified osteomyelitis involving shoulder region
- Unspecified polyarthropathy or polyarthritis involving shoulder region
- Vaccination site joint discomfort
- Vaccination site joint effusion
- Vaccination site joint erythema
- Vaccination site joint infection
- Vaccination site joint inflammation
- Vaccination site joint movement impairment
- Vaccination site joint pain
- Vaccination site joint swelling
- Villonodular synovitis involving shoulder region
- Villonodular synovitis involving upper arm