Key Messages:

Expiration dates vary by type of vaccine or diluent and lot number. They indicate the date by which a product should be used (package inserts).

Once lyophilized (freeze-dried) vaccine is mixed with diluent (liquid) and reconstituted, there is a limited time frame in which vaccine can be used (package inserts).

If inadvertently administered, an expired or mishandled dose generally should not be counted as valid and should be repeated. Contact your immunization program and/or vaccine manufacturer(s) for guidance on revaccination.

At least 1 time each week and each time vaccines are delivered, vaccine coordinator should ensure that someone checks and rearranges placement of vaccines and diluents in storage unit according to expiration dates.

If you receive multiple doses of same vaccine with same presentation (i.e., single-dose vial, multidose vial, or manufacturer-filled syringe) from same lot with same expiration date, these doses may be documented as one entry on stock record.

Number of vaccine doses in unit and number of doses reflected on stock records should match.

Order smaller quantities to help prevent over-ordering and subsequent risk of expired, wasted vaccines.

If you provide VFC vaccines or other vaccines purchased with public funds, contact your immunization program regarding requirements pertaining to vaccine inventory management.

Vaccine Access

Only authorized staff should have access to vaccine supplies.

Expiration Dates

Interpreting Expiration Dates

All vaccines and diluents have expiration dates. These dates vary by type of vaccine or diluent and lot number and are printed on vials, manufacturer-filled syringes, and packages. They indicate the date by which a product should be used (package insert).

When the expiration date is marked with only month and year, vaccine or diluent may be used up to and including the last day of the month indicated. If a day is included with month and year, the vaccine may only be used through that day.
Vaccine Inventory Management

Exceptions to Expiration Dates on Labels (Beyond Use Date)

There are 3 instances when vaccines must be used prior to the expiration date printed on the label.

1. **Reconstitution**
   Once a lyophilized (freeze-dried) vaccine is mixed with a diluent (liquid) and reconstituted into a liquid form, there is a limited time frame in which the vaccine can be used. This time frame is indicated in the manufacturer’s package insert. Also see Reconstitution and IAC’s Vaccines with Diluents: How to Use Them.

2. **Multidose vials**
   Most multidose vials may be used until the expiration date printed on the vial unless contaminated or compromised in some way. However, some multidose vials have a specified time frame for use once the vial is entered with a needle (package insert). Also see Multidose Vials.

3. **Manufacturer shortened expiration date**
   If vaccine has been exposed to inappropriate storage conditions, its potency may be reduced before the expiration date printed on the label. A manufacturer may determine that the vaccine can be used, but with a shortened expiration date. Contact your immunization program and/or the vaccine manufacturer(s) per your protocol for further guidance in determining if the vaccine can be used with a shortened expiration date or if it should be discarded.

When vaccines must be used prior to the expiration date on the label, this is referred to as the “beyond use date” or “BUD” noted in the package insert. For reconstituted vaccines, this may be a date and/or time after which the vaccine cannot be used. The “BUD” (date and/or time) should be noted on the label along with the initials of the person changing the date/time.
Vaccines and Diluents that Cannot Be Used Before Expiration

If vaccine transfer is necessary so vaccine can be used before expiration, contact your immunization program and/or vaccine manufacturer(s) per your protocol for guidance (Emergency or Off-site/Satellite Facility Transport). Appropriate inventory management can be helpful in reducing need for transfer and transport of vaccines.

What to Do with Expired and Mishandled Vaccines and Diluents

Contact your immunization program and/or vaccine manufacturer(s), as appropriate for your situation, for specific policies regarding disposition of expired or mishandled vaccines. If inadvertently administered, the dose generally should not be counted as valid and should be repeated. If this occurs, contact your immunization program and/or vaccine manufacturer(s) for guidance on revaccination.

Stock Rotation

Immediately unpack vaccine deliveries.

At least 1 time each week and each time vaccines are delivered, vaccine coordinator should ensure that someone checks and rearranges placement of vaccines and diluents in storage unit according to expiration dates. Vaccines with soonest expiration dates should be placed in front of other vaccines of same type that have later expiration dates.

Immediately remove expired vaccines and diluents from storage units to avoid risk of inadvertent administration.

Vaccine Inventory Accounting

General Recommendations

Proper vaccine and diluent inventory management includes recording quantities:

- Received
- Administered, wasted, spoiled, expired, transferred
- Currently in stock
- To be used first
- Which need to be ordered

Vaccine Stock Records

All vaccine doses removed from unit should be totaled by vaccine type and recorded on a stock record. Stock records should be completed weekly. The balance of doses remaining in stock is indicated on stock record using tally of doses administered, wasted, spoiled, expired, or transferred during that week. For lyophilized (freeze-dried) vaccines that require reconstitution, document information for diluents on a separate vaccine stock record. Quantities of these vaccines and diluents should be equal at all times. Stock records may be kept in either computerized or written formats. One benefit of participation in an immunization information system (IIS) is ability to manage vaccine inventory electronically.

Stock records should contain the following:

- Date each vaccine and diluent delivered
- Initials of person who unpacked delivery (this person should document delivery on stock record)
- Condition of each vaccine and diluent upon arrival (i.e., did vaccine arrive in good condition at proper temperature)
- Cold chain monitor (CCM) readings if
included in shipping container and actions taken if monitor was triggered (Unpacking Deliveries)

• Name of each vaccine and diluent
• Name of manufacturer(s)
• Vaccine presentation (i.e., single-dose vial, multidose vial, or manufacturer-filled syringe)
• Lot number(s) (each lot should be documented separately)
• Expiration date(s) for each lot (including new expiration dates/times based on beyond use date [BUD] guidance in manufacturers’ product information/package insert)
• Number of doses received (or balance of doses carried forward)
• Number of doses used (i.e., administered, wasted, compromised, expired, or transferred – if vaccine is transferred, note destination beside number of doses)
• Balance remaining (in DOSES) after subtracting amount used (i.e., administered, wasted, compromised, expired, or transferred)

If you receive multiple doses of same vaccine with same presentations from same lot with same expiration date, these doses may be documented as 1 entry on stock record. Simply indicate total number of doses received of that particular presentation (regardless of number of vials or syringes those doses came in). For example, if you receive 10 single-dose vials of same vaccine meeting above criteria, these 10 vials can be documented as single entry, noting that 10 doses were received.

If you do not have a stock record, see Sample Stock Record for information that should be included. A blank Stock Record is also available. If you are a VFC provider or have other vaccines purchased with public funds, contact your immunization program for information about stock records and inventory protocols and procedures.

Sample Stock Record
Tally Sheets

These should be placed in easily accessible locations (e.g., outside unit door) and used to document each time doses are removed from unit, including administered, wasted, compromised, expired, or transferred. This can be documented with tick marks.

Tally sheets can be used to keep stock records updated. For example, at the end of the week, the vaccine coordinator or designated person should add up number of doses on tally sheet of each vaccine used and update stock record accordingly. The old tally sheet should then be removed and replaced with a new one for the following week. Store and maintain used tally sheets in a file for future reference.

If you do not have a tally sheet, see Sample Tally Sheet for information that should be included. A blank Tally Sheet is also available. If you are a VFC provider or have other vaccines purchased with public funds, contact your immunization program for information about tally sheets and inventory protocols and procedures.

Documenting Administered, Wasted, Compromised, Expired, and Transferred Doses

Contact your immunization program for details about inventory accounting practices.

General Guidelines

Document every dose removed from storage unit whether administered, wasted, compromised, expired, or transferred. Expiration dates should be checked a minimum of 1 time each week and stock should be rotated to ensure that soonest to expire is in front (Expiration Dates and Stock Rotation). Document each time vaccine or diluent doses expire and immediately remove from unit. These records will help you decide how much vaccine to order to minimize future waste. Note each time vaccine doses cannot be used because they have been exposed to inappropriate storage conditions or because vials have been damaged. Once confirmed unusable by your immunization program or manufacturer(s), immediately remove these vaccines from unit. Subtract these unusable doses from running balance on stock record to calculate new balance of doses. Contact your

<table>
<thead>
<tr>
<th>Storage Location (R or F)</th>
<th>Vaccine or Diluent Name</th>
<th>Doses Administered</th>
<th>Doses Wasted</th>
<th>Doses Expired **</th>
<th>Doses Unusable</th>
<th>Doses Transferred (Viable) ***</th>
<th>Total</th>
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<tbody>
<tr>
<td>F</td>
<td>VAR</td>
<td>### ###</td>
<td>(8)</td>
<td></td>
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<td>9</td>
</tr>
<tr>
<td>R</td>
<td>DTaP</td>
<td>### ###</td>
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</tr>
<tr>
<td>R</td>
<td>Hib-HepB</td>
<td>### ###</td>
<td>(12)</td>
<td></td>
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</tr>
<tr>
<td>R</td>
<td>IPV</td>
<td>### ###</td>
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<td></td>
<td>14</td>
</tr>
<tr>
<td>R</td>
<td>HepA (pediatric)</td>
<td>#</td>
<td>(2)</td>
<td></td>
<td></td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>R</td>
<td>PPSV23</td>
<td>#</td>
<td>(1)</td>
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<td></td>
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</tr>
</tbody>
</table>

Sample Tally Sheet
immunization program for instructions on how to dispose of these doses. They may have to be discarded, but sometimes unused vaccines may be returned for credit.

Contact immunization program and/or vaccine manufacturer(s) for guidance if vaccine transfer is required. Document transfer details on appropriate tally sheet and stock record, including:

- Vaccine(s)/diluent(s) transferred
- Contact name
- Telephone number on delivery note or packing slip that accompanies transfer

This helps recipient know exactly what items are being transferred. Copies of temperature logs that document appropriate storage also can be included.

Counting Stock

At least 1 time each month and before ordering, vaccine and diluent doses should be counted. This will ensure there are enough vaccine doses to meet needs of the facility, and is useful for checking accuracy of running balance of doses in the stock record. Number of vaccine doses in unit and number of doses reflected on stock records should match.

When counting vaccine doses:

- Always review expiration dates.
- Immediately remove expired vaccines and diluents. Contact your immunization program and/or vaccine manufacturer(s) for specific policies regarding disposition of expired vaccines. If expired vaccines are VFC vaccines or other vaccines purchased with public funds, contact your immunization program for instructions on returning them. If expired vaccines cannot be returned, dispose of them appropriately (Vaccine Disposal).
- If there is a difference between count of doses in unit and stock record balance, enter correct balance from your count on a separate line in stock record below old balance. Write a note with your signature beside it to indicate that your count has confirmed new balance. Use new corrected balance for all future stock calculations. If there are inventory discrepancies of VFC vaccines or other vaccines purchased with public funds, contact your immunization program for guidance.
- At end of every month, make a summary of amount of each vaccine and diluent used during that month and amount of stock still available at end of that month.
- At end of every year, total amount of each vaccine and diluent received and amount used. This information is useful for determining annual vaccine needs of facility.

Vaccine Stock Calculations and Ordering

There are three main principles for calculating amount of vaccine needed when placing orders:

1. Order and stock only enough vaccines to ensure there is an adequate supply to meet patient needs. Vaccines and presentations ordered should be appropriate for ages and types of patients facility serves. An adequate supply for most facilities would normally be enough vaccines to last 60 days, with re-ordering threshold of 30 days. While vaccine orders usually arrive within 1-2 weeks, delays can occur. Avoid placing last-minute or rush orders to minimize the risk that you will run out of vaccines.
2. Order smaller quantities to help prevent over-ordering and subsequent risk of expired, wasted vaccines. Over-ordering can lead to unnecessarily large volumes of vaccine being stored, increasing risk of losing a large quantity should vaccines be compromised (e.g., mechanical failure of the storage unit).