

Vaccine Storage and Handling Toolkit

National Center for Immunization and Respiratory Diseases

Vaccine Inventory Management

Disclaimer: State or local health department immunization programs may recommend or require different inventory accounting practices and different forms from those described here. The information presented here is meant to provide general guidelines only. Contact the state or local health department immunization program staff for details about inventory accounting practices and follow their recommendations.

Vaccine Access

Limit access to the vaccine supply to authorized personnel only. This will help protect the vaccine supply by avoiding inappropriate removal of vaccine or inappropriate handling of vaccine and vaccine storage units by untrained personnel.

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Expiration Dates

Interpreting Expiration Dates

All vaccines and diluents have expiration dates. The expiration date is the date by which the vaccine or diluent should be used. This date is printed on all vaccine and diluent vials and boxes. Expiration dates vary by the type of vaccine or diluent, and by the lot number. The vaccine or diluent may be used up to and including this date **unless** otherwise stated in the product package insert. Vaccine and diluent should not be used after this date has passed. When the expiration date is marked with only a month and year, the vaccine or diluent may be used up to and including the last day of the month indicated on the vial. Any unused vaccine or diluent should not be used after this month has passed.



Vaccine Expiration Date:
1/15/08
Note: Use through January 15, 2008. Do NOT use on or after January 16, 2008.



Vaccine Expiration Date:
1/08
Note: Use through January 31, 2008. Do NOT use on or after February 1, 2008.

Vaccine may be used up to and including the expiration date.

What to Do with Expired and Mishandled Vaccine or Diluent

Expired vaccine and diluent, even if they are only 1 day past the expiration date, should **never** be administered. Likewise, vaccines that have been mishandled and lost their potency because of inappropriate storage conditions should not be administered. If a dose of expired or mishandled vaccine is given by mistake, the dose should not be counted as valid and should be repeated, unless serologic testing indicates that an adequate response to the vaccine has been achieved. Promptly remove expired or mishandled vaccine and diluent from the refrigerator or freezer and dispose of it appropriately. Contact the vaccine supplier, which may be the vaccine manufacturer or the state health department immunization program, for specific policies regarding the disposition of mishandled or expired vaccine. If the expired vaccine is publicly purchased, contact your state health department immunization program for instructions on returning expired vaccine for excise tax credit.

Exceptions to the Expiration Date

The expiration date printed on each vial or box assumes the vaccine has been properly transported and stored at all times and that it has not become contaminated. If vaccine has been inappropriately exposed to excessive heat, cold, or light, its potency may be reduced **before** the expiration date is reached. The only way to determine if proper transport and storage conditions have been maintained is to monitor vaccine and diluent temperatures during every link in the cold chain and to safeguard HPV, MMR, MMRV, rotavirus, varicella, and zoster vaccines from exposure to light. The expiration date printed on each vial or box may also be invalidated after the vial is opened or reconstituted (see [Expiration of Different Vaccine Products](#) in this section for details).

Transferring Vaccine or Diluent That Cannot Be Used Before Expiration

If vaccine or diluent is within 120 days of the expiration date, determine whether or not the product can be used within this time period given the volume of patients vaccinated in your practice. If the product cannot be used within this time frame, contact the vaccine supplier, which may be the vaccine manufacturer or the state health department immunization program, for guidance. You may be able to return the vaccine and diluent for credit or you may be able to transfer the product to another facility where it can be used before it expires. If the vaccine is publicly purchased, you may be instructed to return it to the immunization program, or transfer it to another provider. Your state immunization program may recommend a window period different than 120 days for these considerations.

Expiration of Different Vaccine Products

Multidose premixed vaccine vials contain bacteriostatic agents that prevent the growth of bacteria. These vaccines can be used until the date of expiration printed on the vial unless they become contaminated.

Single-dose vials are meant for one-time use only. Once the protective caps on single-dose vials have been unsealed, it may not be possible to determine if the rubber seals have been

punctured. Therefore, do not open single-dose vials until you are ready to use them. To avoid needless waste of vaccine, **always** check the vial before removing the cap to make sure you have the correct vaccine type, and remove the cap only when you are ready to draw up and administer the vaccine. Single-dose vials without their protective caps should be discarded at the end of the clinic day.



Single dose vials are meant for one-time use only.
Once unsealed, discard vial at end of clinic day.

Once lyophilized (freeze-dried) vaccines have been reconstituted, they must be used within a specified time frame or discarded. Consult the product insert for the most up-to-date information about expiration times and dates following reconstitution. MMRV, varicella, and zoster vaccines must be used within 30 minutes of reconstitution and protected from light at all times. TriHIBit[®] vaccine (DTaP/Hib) and single-dose vials of Menomune[®] must be used within 30 minutes of reconstitution. MMR must be used within 8 hours of reconstitution and protected from light at all times. ActHIB[®] vaccine (Hib) must be used within 24 hours of reconstitution. Multidose vials of Menomune[®] must be used within 35 days of reconstitution. Unused reconstituted vaccines kept beyond these limits should **not** be administered. The best way to avoid such waste is to reconstitute and draw up vaccines immediately before administration (see [Expiration of Reconstituted Vaccine](#) in the Vaccine Preparation and Disposal section for details).

Stock Rotation

The vaccine coordinator should ensure that someone rearranges the placement of vaccine and diluent supplies according to the expiration dates on a weekly basis and each time a vaccine shipment arrives. The vials and boxes with the earliest expiration dates should be placed in front of other vials and boxes of the same type with later expiration dates. This practice avoids waste by ensuring that vaccines and diluents with the shortest expiration dates are easily accessible and will be used first, thereby limiting the amount of unused vaccine that has passed its expiration date.

Expired vaccine and diluent should never be administered. Promptly remove expired vaccine from the refrigerator or freezer to avoid accidental use. Vaccine suppliers have different return policies for outdated vaccine. Contact the vaccine manufacturer for advice on returning privately purchased vaccine. Contact the state health

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department immunization program for advice on returning publicly purchased vaccine for excise tax credit.

Inventory Accounting

General Recommendations

Inventory accounting is important for vaccine quality management. Proper inventory management means knowing the following:

- what quantities of vaccines and diluents have been received;
- what quantities of vaccines and diluents have been administered, wasted, or spoiled;
- which vaccines and diluents are currently in stock;
- which vaccine and diluent vials should be used first;
- which vaccine and diluent vials are expired and must not be administered;
- how many vaccine and diluent vials are in excess supply and may be returned for possible credit; and
- which vaccines and diluents need to be ordered.

Stock Records

Some state or local health department immunization programs have developed stock records or other vaccine inventory protocols and procedures for vaccine providers. Contact program staff for information and follow their recommendations. If stock records **are not** available from the state or local health department immunization program, a Sample Stock Record can be found in the Resources section of this toolkit. This Sample Stock Record shows the components that you may include in your own stock record. A blank version of the Sample Stock Record is also available in the Resources section (see Stock Record).

Maintaining complete and accurate stock records is a critical component of inventory management. The balance of doses remaining in stock as indicated on the stock records should be updated weekly using a tally of doses administered, wasted, spoiled, expired, or transferred that week. A stock

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record that is not accurate is of no value to the vaccine coordinator and can lead to over- or understocking of supplies and disruption to the immunization program.

Record new shipments, vaccines and weekly amounts of doses used.

Vaccine Type: PPV Month and Year: January 2008

Date Received or Usage Talled	Person Receiving Shipment *	Arrival Condition **	Vaccine or Diluent Name	Manufacturer	Vial Type (S, M, Y) ***	Lot Number	Expiration Date	Expiration Date After Reconstitution	Doses Received/ Balance Forward	Doses Used †	Balance (Doses)
01/02/08	BEGINNING BALANCE FOR THE MONTH								2	N/A	2
01/09/08										1	1
01/15/08	LST	✓	Prevnar 23	Merck	M	03958	02/15/09	N/A	5	3	3
01/22/08										1	2
01/29/08										0	2

Sample Stock Record.

Stock records may be kept in either computerized or written formats, depending on the setting. Keep separate records for each type of vaccine. For lyophilized (freeze-dried) vaccine that requires reconstitution, record information for diluents on a separate stock record. Quantities of these vaccines and diluents must be equal at all times.

Each stock record should contain the following information:

- the date each vaccine and diluent arrived at the facility;
- the initials of the person who unpacked and checked the vaccine and diluent upon arrival (this person should also record the shipment on the stock record);
- the condition of each vaccine and diluent upon arrival (i.e., did the vaccine arrive in good condition at the proper temperature or was there a reason to question its integrity);
- the name of each vaccine and diluent;
- the manufacturer of each vaccine and diluent;
- the type of container received (i.e., single-dose vial, multidose vial, or manufacturer-filled syringe);
- the lot number(s) (note there may be more than one lot in a shipment— **each lot should be recorded on a separate line on the stock record**);
- the expiration date(s) for each lot (including the new expiration dates/times for vaccines that have been reconstituted);
- the number of doses received (or the balance of doses carried forward);
- the number of doses used (i.e., administered, wasted, spoiled, expired, or transferred - if vaccine is transferred, note the destination beside the number of doses); and
- the balance remaining (in DOSES) after subtracting the amount used (i.e., administered, wasted, spoiled, expired, or transferred).

If you receive multiple vials of the same vaccine in the same type of container (i.e., single-dose vial, multidose vial, or manufacturer-filled syringe) from the same lot with the same expiration date, these doses may be recorded as one entry on the stock record. Simply indicate the total number of doses of that particular vaccine that were received (regardless of the number of vials or syringes those doses came in). For example, if you receive 10 single-dose vials of the same vaccine meeting the above criteria, these 10 vials can be recorded as a single entry, noting that 10 doses were received.

Tally Sheets

Some state or local health department immunization programs have developed tally sheets or other vaccine inventory protocols and procedures for vaccine providers. Contact program staff for information and follow their recommendations. If tally sheets **are not** available from the state or local health department immunization program, a [Sample Tally Sheet](#) can be found in the Resources section of this toolkit. This Sample Tally Sheet shows the components that you may include in your own tally sheet. A blank version of the Sample Tally Sheet is also available in the Resources section (see [Tally Sheet](#)).

Tally sheets are used to record vaccine doses that were removed from the vaccine storage unit. These include doses that were administered, wasted, spoiled, expired, or transferred.

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Each time a dose of vaccine is removed, it should be marked on a tally sheet that is placed on the outside of the storage unit door or in some other convenient location. Tick marks can be used to record doses that have been removed

from the storage unit. Alternatively, the initials of the person removing the dose may be used.

Week: January 13-19, 2006, (Week 3)

Storage Location (R or F) *	Vaccine Name	Doses Administered (Total)	Doses Wasted	Doses Expired **	Doses Spoiled **	Doses Transferred (Vials) ***	Total
F	Varicella	(8)					9
R	DTP	- (12)					12
R	Hepatitis B / Hib Combination	- - (12)					12
R	IPV	- - (12)					14
R	Hepatitis A (pediatric)	(2)					2
R	Pneumococcal Polysaccharide (PPV)	(1)					1

Sample Tally Sheet.

These tally sheets can be used to keep stock records updated. For example, place a tally sheet on the storage unit door and record the doses removed from the unit during the week. At the end of the week, the vaccine coordinator or a designated person should add up the number of doses of each vaccine used and update the stock records accordingly to determine the new stock balance at the end of the week. The old tally sheet can then be removed and replaced with a new tally sheet to be used for the following week. Store used tally sheets in a file for future reference.

Recording New Shipments

For details, see [Storing and Documenting Vaccine Shipments Upon Arrival](#) in the Vaccine Shipments section.

Recording Administered, Wasted, Spoiled, Expired, and Transferred Doses

Every dose of vaccine and diluent must be accounted for. Contact state or local health department immunization program staff for details about inventory accounting practices and follow their recommendations. The following discussion provides general guidelines only.

Record every dose removed from the vaccine storage unit on the appropriate [tally sheet](#) and [stock record](#). Record how many doses were administered, wasted, spoiled, expired, or transferred. At the end of the week, use the tally sheet to update the stock record and calculate the balance of the vaccine and diluent remaining (i.e., the running balance of doses in stock).

While vaccines and diluents remain in storage, expiration dates should be checked weekly and stock should be rotated accordingly (see [Expiration Dates](#) and [Stock Rotation](#) in this section). Record each time vaccine or diluent doses expire. These records will help you decide how much vaccine to order to minimize waste in the future. Likewise, note each time doses cannot be used because they have been exposed to inappropriate storage conditions or because their vials have been damaged. Subtract these unusable doses from the running balance on the stock record to calculate the new balance of doses. Recording the number of doses that were expired, wasted, or spoiled helps monitor vaccine waste. Contact the state health department

immunization program and the vaccine manufacturer for instructions on how to dispose of these doses. They may have to be discarded but sometimes unused vaccine may be returned for credit.

Some state health department immunization programs accept transfers vaccines with short expiration dates that will expire before they can be used. Occasionally, viable vaccines may also be transferred to other facilities. Contact the state or local health department immunization program for details if such a transfer is required. For each transfer, record the details in the appropriate tally sheet and stock record. Also, record the details of the vaccines and diluents being transferred, a contact name, and a contact telephone number on the delivery note or packing slip which accompanies the shipment. This helps the receiver know exactly what items are being transferred. If vaccine transfer is necessary, contact the state health department immunization program and vaccine manufacturer for information on the process and procedures.

Counting Stock

An actual count of the number of doses of vaccine and diluent in stock is an important component of inventory management and is the responsibility of the vaccine coordinator or designee. Vaccine and diluent doses should be counted at least once a month and before ordering vaccine. This will ensure there are enough supplies to meet the needs of the practice and is useful for checking the accuracy of the running balance of doses in the stock records.

When counting vaccine doses:

- Review the expiration dates of all stock, looking for vaccine with a short expiration date that must be used quickly and for expired vaccine that should not be administered.
- If you have vaccine that will expire within 120 days that cannot be administered during this time period, contact the vaccine supplier, which may be the vaccine manufacturer or the state health department immunization program for further instructions. If the vaccine with a short expiration date is publicly purchased vaccine, in some cases it can be moved to another clinic where it may be used before it expires. Your state immunization program may recommend a window period different than 120 days for these considerations.
- Promptly remove expired vaccine and diluent from the refrigerator or freezer. Contact the vaccine supplier, which may be the vaccine manufacturer or the state health department immunization program, for specific policies regarding the disposition of expired vaccine. If the expired vaccine is publicly purchased, contact your state health department immunization program for instructions on returning expired vaccine for excise tax credit. If expired vaccine cannot be returned, dispose of the vaccine appropriately (see Disposal of Vaccine and Diluent in the Vaccine Preparation and Disposal section for details).
- If the count of vaccine doses is different from the running balance in the stock records, count the stock again and recalculate the running balance to find the error.
- If a discrepancy remains, the stock record is in error and should be corrected. To do this, enter the correct balance from your count on a separate line in the stock record below the old balance. Write a note with your signature beside it to indicate that your count has confirmed the new balance. Use the new corrected balance for all future stock calculations.
- At the end of every month, make a summary of the amount of each vaccine and diluent used during that month and the amount of stock still available at the end of that month. This information is useful for deciding how much vaccine to order and can be used to monitor the seasonality of vaccine use.

- At the end of every year, total the amount of each vaccine and diluent received and the amount used. This information is useful for determining the annual vaccine needs of the practice.

Vaccine Stock Calculations and Vaccine Ordering

In general, there are three main principles to keep in mind when calculating the amount of vaccine supplies needed and when placing vaccine orders:

1. **Order and stock enough vaccine to ensure that there is an adequate supply to meet the needs of the patients.** An adequate supply for most practices would normally be enough vaccine to last 60 days, with a re-ordering threshold of 30 days. Your state health department immunization program may recommend different supply levels, depending on local use.
2. **Do not over order vaccines.** This practice leads to vaccine waste if unused vaccine expires. It also results in unnecessarily large volumes of vaccine being stored, which increases the risk of losing a large quantity of vaccine should there be a storage and handling accident (e.g., mechanical failure of the vaccine storage unit).
3. **Place one large order for all the vaccines required for a specific period of time rather than multiple small orders for individual vaccines.** This reduces the number of vaccine shipments your practice must handle, and also reduces the risk that you will run out of a particular vaccine. If you receive vaccine from the Vaccines for Children (VFC) Program, ordering all vaccines at one time helps the program process orders efficiently.

Contact your state or local health department immunization program for further information about vaccine supply management and ordering. Follow the specific recommendations for your state regarding methods for calculating vaccine supply needs, amounts of vaccine inventory to keep in stock, frequency of ordering, and methods of ordering vaccine. While vaccine orders usually arrive within 1-2 weeks, delays can occur. Avoid placing last minute or rush orders so as to minimize the risk that you will run out of vaccine.

After ordering vaccine, alert office staff that an order has been placed. The primary vaccine coordinator or designated backup person should be notified immediately upon arrival of a vaccine shipment so that the vaccine is stored under appropriate conditions and the cold chain is maintained (see the section on [Vaccine Shipments](#)). Vaccine shipments must also be documented in the appropriate stock record.