1. Hello and welcome to this webinar. My name is Elisha Hall and I am part of the Immunization Services Division at the Centers for Disease Control and Prevention.

In this webinar, we are going to discuss a vaccine’s expiration date, beyond-use date, and beyond-use time.

1. Proper vaccine storage and handling are important factors in preventing and eradicating many common vaccine-preventable diseases. Failure to store and prepare vaccines properly can reduce vaccine potency, resulting in inadequate immune responses in patients and poor protection against disease.
2. As a health care provider you should be knowledgeable about the vaccines including how to store, prepare and administer vaccines. This includes determining if a vaccine can be administered based on the expiration date, or a beyond use date or time, if applicable.

The expiration date and beyond-use date or BUD may sound interchangeable, but they have key differences that are important to know when preparing and administering vaccines.

1. The objectives for this webinar include:
   * **Describe how to determine the expiration date, beyond-use date or beyond-use time;**
   * **Identify when to use the expiration date and when to use the BUD; and**
   * **Identify comprehensive vaccine storage and preparation resources for clinical staff**
2. Let’s get started.

Today I’m going to discuss:

* Vaccine expiration dates
* Vaccine beyond-use dates
* Best practices
* Clinical resources

1. Let’s get started by discussing expiration date.

* All vaccine products, like other medications, have an expiration date, sometimes referred to as the expiry date.
* The expiration date is **the final day that the vaccine can be administered**. Vaccines past the expiration date should NEVER be used.
* The expiration date is determined by the **manufacturer**.
  + - Food and Drug Administration or FDA regulations require manufacturers to provide stability data with a proposed expiration date and storage conditions when they submit an application for FDA approval.
    - This testing provides confidence that the vaccine will meet the applicable standards of strength, quality, and purity throughout its shelf-life. It is the final day that the manufacturer guarantees the full potency and safety of the vaccine.

1. Manufacturers display the expiration date on the vial different ways. This may include:
2. The month, date and year. In this case, the vaccine may be used through the end of that day specified. For example, if November 30, 2021 is printed on the vial, it may be used through 11:59pm on November 30.
3. Only the month and year may be printed on the vial. In this case, the vaccine may be used up to and including the last day of the month. If the date is printed as December 2021, it may be used up through 11:59pm on December 31st, 2021
4. Rather than a date, the manufacturer may provide a QR code, website, or phone number to communicate the expiration. In this case to determine the expiration, the QR code should be scanned using a smartphone or other device. Or, you may navigate to the website or call the phone number provided.
5. Rarely, the manufacture date may be printed on the vial rather than the expiration date. If this is the case, the package insert or Emergency Use Authorization (EUA) Fact Sheet for Health Care Providers should specify how to calculate the expiration date based on the manufacture date.
6. Sometimes manufacturer-shortened expiration dates may apply when vaccine is exposed to inappropriate storage conditions, also referred to as a temperature excursion. If vaccine experiences a temperature excursion, contact the manufacturer for guidance. The manufacturer might determine the vaccine can still be used but will expire on an earlier date than the date on the label. When this happens, the new expiration date should be noted on the vial.
7. In some cases, the FDA may approve an expiration date extension when data supporting the extension are available. Similarly, the extended expiration date should be noted on the vial.
8. Now that we have discussed determining the expiration date, let’s talk about beyond-use dates and times.

* **The Beyond-Use Date** is different from expiration date. The beyond-use date, or BUD, is the last date or time that a vaccine can be safely used after it has been transitioned between storage states or altered for patient use. It is a new deadline after which the product should not be used. The BUD varies by product and type of transition. This is sometimes also called a beyond-use time if it falls on the same day at a different time of day.
* Unlike the expiration that is determined by the manufacturer, this is determined by the health care provider when they transition or alter the vaccine.
* The BUD replaces the manufacturer’s expiration date but never extends it. Always use the earlier date between the two.
* Not all vaccine products have a BUD. The package insert or Emergency Use Authorization (EUA) Fact Sheet for Healthcare Providers will specify if there is a BUD and how to calculate it. Always review this informational material to determine if a BUD applies.

1. For those vaccine products that have a BUD, the designated timeframe is not the same and varies from product to product.

Specific information regarding the BUD and how it is calculated can be found in the vaccine’s package insert or Fact Sheet.

1. For example, the package insert for some inactivated influenza vaccine products in a multidose vial indicates when the vial is punctured for the first time, the vaccine must be used within 28 days. The vial and any residual vaccine not used within the BUD should be discarded – even if the expiration date has not passed.

The day the vial of vaccine is punctured is considered day 0. So in this example, if a vial of vaccine with a BUD of 28 days was punctured on December 15th, we would start with day 0 and count forward 28 days. Day 28 would be January 12th, 2022. This is the last day that the vaccine can be used.

1. Let us look at some situations in which BUDs would apply.

As mentioned, some vaccines have a BUD when transitioned from one storage state to another.

For example, when moving Moderna COVID-19 Vaccine from a freezer to a refrigerator, the vaccine must be used within 30 days.

* Some vaccines are mixed with a diluent. Once mixed with its diluent, vaccines have a limited period for use.
* The BUD can vary from minutes to hours.
* For example, once mixed, varicella vaccine must be used within 30 minutes whereas ActHib vaccine should be used within 24 hours.
* The clinical job aid shown on the slide is from the Immunization Action Coalition. It includes the BUD timeframes for reconstituted vaccines.
* Some vaccine products come in a multidose vial. A multidose vial is a vial of vaccine that contains more than one dose. Multidose vials are labeled as such by the manufacturer and typically contain an antimicrobial preservative to help prevent the growth of bacteria. The preservative has no effect on viruses and does not protect against contamination when health care personnel fail to follow safe injection practices.
* Some multidose vials have a specified time frame they should be used by after the vial is first punctured with a needle. Again, this time frame varies from product to product and can be hours or days. For example, the package insert may state that the vaccine must be discarded 28 days after it is entered. If the vial is entered on November 1, 2022, the BUD is November 29, 2022.
* In addition to a BUD, some multidose vials have a specific number of doses that can be withdrawn or a maximum number of punctures to the vial stopper. Once you have reached the maximum number of doses or punctures, discard the vial and any residual vaccine in the vial.

1. Now let’s review. What do you think? Fill in the blanks below to identify who determines the expiration date and the BUD.

The blank determines the expiration date and the blank determines the BUD.

Pause your video to think about your answer and resume when you are ready to review.

1. Time to review. The correct answer is that the manufacturer determines the expiration date and the health care provider determines the BUD.
2. Now we will transition to best practices with BUDs.
3. There are a variety of best practices you should engage in to assure that vaccine is given safely and effectively.
4. The package insert or Fact Sheet for the vaccine identifies any beyond-use information that should be considered. Review this information and assure it is available for any staff storing, preparing, and administering vaccines.
5. Once calculated, label the vial with the BUD and staff initials of the person making the calculation. This can be done a variety of ways. If writing this information on only one vial, you may write it on the label on the vial or use a sticker on the vial. If multiple vials need to be labeled, for example if multiple vials are moved from one storage state to another at the same time, keep the vials together in a tray or resealable plastic bag, and label that instead of the vial.

CDC has developed printable examples of stickers that can be used for each COVID-19 product. Similar labels can be used for other recommended vaccines. Resources at the end of this webinar will identify where to find example labels.

1. The BUD replaces but never exceeds the expiration date. You should always use the earlier date between the expiration and BUD. Many times this is the BUD, but not always.

* For example, let’s say you have a vaccine that expires March 31st, 2022. The package insert states its BUD when moved to the refrigerator is 10 weeks.
* If you move this vaccine to the refrigerator on December 1st, 2021, the beyond-use date will be February 9, 2022, 10 weeks from when it was moved.
* In this case, the BUD is earlier than the expiration. The correct date to use this vaccine by is February 9th, 2022. Vaccine should not be used after the BUD.
* However, if you moved this same vaccine to the refrigerator March 1st, 2022, 10 weeks from this date would be May 10, 2022.
* May 10th is past the expiration of March 31st.
* In this case, you may NOT keep the vaccine through this date because the BUD cannot exceed the original manufacturer’s expiration date.
* You must use the vaccine by March 31st, which is the earlier of the two dates.

1. Always check the expiration date or BUD, if applicable, before administering any vaccine. Expired vaccine or vaccine past the BUD time frame should NEVER be administered. If inadvertently administered, this would be considered a vaccine administration error.
2. If a vaccine administration error occurs

* Inform the recipient of error.
* Consult with the state immunization program or immunization information systems to determine how the dose should be entered into the IIS
* Report the error to the Vaccine Adverse Event Reporting System (or VAERS). COVID-19 providers are required by law to report ALL COVID-19 vaccine administration errors to the Vaccine Adverse Event Reporting System. Reporting administration errors that may occur with other vaccines to VAERS is HIGHLY encouraged.

And finally

* Determine how the error occurred and implement strategies to prevent it from happening again.
* On this slide is a job aid on actions to prevent vaccine administration errors. You can access this on the link on the slide.

1. Discard any vial not used within the expiration or BUD, even if there is residual vaccine in the vial.

Sometimes unused vaccine and diluent doses, unopened vials, expired vials, and potentially compromised vaccine may be returned for credit, even if they must be discarded. Contact your immunization program and/or the vaccine manufacturer for vaccine-specific information.

1. Let’s review a scenario.

Janet punctures a multidose vial of vaccine on December 15th, 2021. According to the package insert, it must be discarded within 28 days after puncture, resulting in a beyond-use date of January 12th, 2022. The original expiration of this vial is December 31st, 2021. What is the last day Janet can administer vaccine?

Pause your video to think about your answer and resume when you are ready to review.

1. The latest date Janet can use vaccine is December 31st, 2021.

Although this is the expiration and not the BUD, you should always use the earlier of the two dates between the BUD and the expiration date. The BUD cannot exceed the manufacturer’s expiration. In this case, since the BUD is later and the expiration is earlier, Janet can administer vaccine through the expiration date of 12/31/2021, then should discard the vial and any remaining vaccine.

1. Now that we have covered several concepts on expiration dates and BUDs, I want to drive home three key points:
2. The manufacturer determines the expiration. This means the expiration comes with the vaccine. It may be formatted differently depending on the vaccine.
3. YOU determine the BUD by your actions with the vaccine. You will have started the BUD clock when you move the vaccine from one storage state to another, puncture a multidose vial, or mix vaccine with a diluent.
4. Use whichever date comes FIRST. In many cases, this will be the BUD; however, if you are nearing the expiration date when you determine the BUD, the expiration might come first.
5. Finally, I’ll share some clinical resources that will help you with expiration and beyond-use dates.

43. This concludes our webinar on Expiration Date, Beyond-Use Date, and Beyond-Use Time. Thank you so much for viewing.