TotalWellness Administration Information and Guidelines for COVID-19 SPIKEVAX mRNA (2024-2025 Formula)



Type of Vaccine

- Moderna SPIKEVAX COVID-19 vaccine
- Manufacturer-filled syringe
- Preservative free

Vaccine Lot Numbers

When vaccine is made it is given a lot number and there are several different lot numbers each year. It is important to correctly document the lot number on each participant's Consent Form in case the lot proves to be ineffective or recalled.

Beyond Use Date

COVID-19 SPIKEVAX can be stored refrigerated for up to 60 days. When you receive vaccine a refrigeration start date will be provided. The Beyond Use Date (BUD) is 60 days after the documented refrigeration start date. Be sure to use vaccine prior to the BUD and prior to the expiration date.

Physician Standing Order

A Physician Standing Order for COVID-19 vaccinations is included in each paperwork packet.

Storing & Transporting Covid-19 Vaccine

Storing vaccine, transporting vaccine, receiving deliveries, and monitoring vaccine will follow the same TotalWellness protocol as flu vaccine (pages $\underline{39-44}$ in the TotalWellness Contractor Manual).

COVID-19 SPIKEVAX may be stored at TotalWellness in a frozen capacity. Once thawed the vaccine CANNOT be refrozen. The COVID-19 vaccine will be shipped do you refrigerated and should immediately be stored in your refrigerator between 36°F and 46°F (2°C and 8°C). DO NOT freeze COVID-19 SPIKEVAX.

Participant Registration and Participant Care

Follow the same TotalWellness protocols as for the flu vaccination events (pages <u>44-45</u> in the TotalWellness Contractor Manual).

Participant Screening

All participants must be screened for contraindications and precautions prior to receiving a COVID-19 shot, even if he or she has received a COVID-19 vaccination before.

First allow the participant to review the CDC's current Vaccine Information Statement (VIS). A VIS is provided in the event information packet to display for participants. If participants would like to review the VIS in more detail, either provide a copy of the VIS or refer the participant to the CDC link listed on their consent form.

It is TotalWellness policy that we will only administer vaccinations to individualS 18 years of age and older or 19 and older in Nebraska and Alabama. The COVID-19 SPIKEVAX 2024-2025 Formula utilized by TotalWellness is only approved for people 12 years of age and older. The vaccine is approved for pregnant and breastfeeding women.

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Consent Form Review

After verifying the age and ensuring that there are no questions about the VIS, review the consent form to ensure the form has been filled out completely, signed and dated with questions answered and blanks filled in. Review the answers to the questions on the Consent Form.

Have you ever received a dose of COVID-19 Vaccine?

- If no, the participant should pay attention to how they feel after receiving the shot.
 - Allergic reactions are rare, but when you try something new you should be mindful.
 - Ask the participant to remain at the event or at least around other people for at least 15 minutes after the vaccine.
- If yes, assess their knowledge and experience.
 - If the participant has previously been vaccinated with any COVID-19 vaccine, they must wait at least 2 months after the last dose of COVID-19 vaccine before they can receive the SPIKEVAX 2024-2025 Formula vaccination.

Have you been sick or had a fever above 101 degrees in the last 3 days?

• If yes, **do not** administer the vaccine.

Do you have any allergies to medications, food, a vaccine component, or latex?

- If yes, refer to the vaccine package insert to review ingredients. Also review the materials used to administer the vaccination (syringe, needle, gloves, Band-Aids, etc).
 - If the participant is severely allergic to any of the ingredients in the vaccine or any of the materials utilized for administration, **do not** administer the vaccine.

Have you ever had a serious reaction after receiving a vaccine?

• If yes, **do not** administer the vaccine.

Have you ever been diagnosed with a heart condition (myocarditis or pericarditis) or have you had Multisystem Inflammatory Syndrome (MIS-A or MIS-C) after an infection with the virus that causes COVID-19?

• If yes, **do not** administer the vaccine.

If female, are you pregnant?

• If yes, check that the participant has discussed and received approval from their primary care provider to receive the vaccine. SPIKEVAX 2024-2025 Formula can be administered to pregnant women.

Are you immunocompromised?

• If yes, administer the vaccine, but advise the participant to follow up with their primary care provider as additional doses of COVID-19 vaccine may be recommended for optimal protection.







Verbally inform participants of potential side effects including:

- Pain, tenderness and swelling of the lymph nodes in the same arm of the injection, swelling (hardness), and redness.
- Fatigue, headache, muscle pain, chills, nausea, vomiting, fever, and rash.

Remind participants that they cannot get COVID-19 from the COVID-19 shot.

Ask participants if they have any questions (and be prepared to answer them, of course.)

Use your best professional judgement to determine if you should proceed. If in doubt, don't give the shot! Refer the participant to his or her healthcare provider. If you refuse to administer – or an individual refuses to receive- the shot, you will need to complete an Incident Report and attach the report to the participant's consent form.

Preparing the shot

Once you've determined that the individual is a good candidate to receive the COVID-19 shot, continue with shot preparation. For the sake of transparency and as a method of involving the participants in their own healthcare, we ask that you do not attach the needles in advance.

The COVID-19 SPIKEVAX 2024-2025 Formula vaccines are in manufacturer-filled single-dose syringes. Each syringe is one 0.5ML dose of vaccine.

Go through the necessary shot preparation steps verbally with the individual who will be receiving the shot. That way you are less likely to miss steps, the participant is more likely to feel comfortable, and there is a clear opportunity to ask and answer questions as they arise.



Vaccine Administration

Follow the Rights of Administration, site preparation, syringe and needle selection, vaccine inspection, preparing the injection site, administration technique and emergency procedures as outlined in pages 49-63 of the TotalWellness Contractor Manual.

IM Vaccine Co-Administration

In addition to the TotalWellness Information and Guidelines for administering flu vaccine and for administering COVID-19 vaccine, there are additional safeguards which should be followed when BOTH vaccines are being administered at a TotalWellness event. Whenever possible, separate stations should be set up for administration of a single vaccine type at each station. In some circumstances, it will be necessary to administer both the COVID-19 vaccine and the flu vaccine at the same vaccination station. Please follow the guidelines below to prevent mix-ups in vaccine and to ensure that all participants receive the correct vaccine.

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Vaccine Familiarity

- Read the names of the vaccine on the labels of the manufacturer pre-filled syringes and become familiar with how they look.
 - o Take note of the differences in the appearance of the two types of vaccine.
 - The COVID-19 SPIKEVAX syringe is longer and slimmer.
 - The trivalent flu syringe is shorter and wider.

Station Setup

- Keep COVID-19 vaccine and flu vaccine on different sides of your workstation.
 - o Keep COVID-19 vaccine on the left side of your station.
 - o Keep flu vaccine on the right side of your station.
- It is important all stations follow the same setup in case one contractor steps in for another. The same set up is therefore understood by all and will help prevent any mix-up in vaccine.

Consent Forms and Verbal Confirmation #1

- Each consent form includes a watermark that clearly indicates if the consent form is for a flu shot or a COVID-19 shot.
- After you have screened the participant and determined they are a good candidate to receive the vaccine(s), verbally verify with the participant which vaccine(s) they will receive.

Vaccine Selection

- Place the participant's consent form(s) on your workstation.
 - Always keep the flu consent on the right side and the COVID-19 consent on the left side.
- Select the correct vaccine(s) and place the vaccine(s) on top of the matching consent form.
 - o The flu manufacturer-filled syringe should be placed on the flu consent form.
 - o The COVID-19 manufacturer-filled syringe should be placed on the COVID-19 consent form.









Vaccine Administration & Verbal Confirmation #2

Flu Shot Administration

- Always start with flu vaccine administration first. If the participant is not receiving a flu shot skip to the COVID-19 Shot Administration section.
 - o Ask if the right or left arm is preferred for the flu shot injection site.
 - If the participant is receiving both vaccines, they can choose to receive both vaccines in the same arm, or they can choose to use separate arms for each vaccine.
 - Mark the injection site on the flu consent form.
 - If the participant has more than one consent form, double check that you marked the correct consent form.

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- o Prepare to give the flu shot.
 - Double check the label on the syringe to verify that you have selected the correct vaccine.
 - Verbalize the steps and allow the participant to watch as you open packaging and attach the needle to the syringe.
 - When you are ready to give the flu IM injection, before you administer it, verify what you are doing with the participant.
 - i.e. "Ok I'm giving you the flu vaccine in your left arm, is that correct?".
- o Administer the flu shot using proper IM techniques as outlined in the TotalWellness Contractor Manual.
- o Document flu vaccine administration in the Nurse's box on the flu consent form.

COVID-19 Shot Administration

- Give the COVID-19 shot second, if the participant is receiving both a flu and COVID-19 shot.
 - o Ask if the right or left arm is preferred for the COVID-19 shot injection site.
 - If the participant is receiving **both** IM vaccines in the same arm, **the injection sites must be at least 1" apart from each other** in the "upside down triangle" of the deltoid muscle, 2-3 fingerbreadths (~2") below the acromion process.
 - o Mark the injection site on the COVID-19 consent form.
 - If the participant has more than one consent form, double check that you marked the correct consent form.
 - Prepare to give the COVID-19 shot.
 - Double check the label on the syringe to verify that you have selected the correct vaccine.
 - Verbalize the steps and allow the participant to watch as you open packaging and attach the needle to the syringe.
 - When you are ready to give the COVID-19 IM injection, before you administer it, verify what you are doing with the participant.
 - i.e. "Ok I'm giving you the COVID-19 vaccine in your right arm, is that correct?".
 - o Administer the COVID-19 shot using proper IM techniques as outlined in the TotalWellness Contractor Manual.
 - Document COVID-19 vaccine administration in the Nurse's box on the COVID consent form.

Always keep in mind the **"5 Rights of Medication Administration"** as outlined in the Total Wellness Contractor Manual, pages 49-50. See pages 44-63 of the Total Wellness Contractor Manual for the TotalWellness vaccine administration guidelines and emergency procedures.

Remember to take your time when co-administering vaccines. It is extremely important to ensure the participant is receiving the vaccine(s) they intended to receive. TotalWellness has reduced the expected throughput for events offering flu and COVID-19 shots at one station, allowing the nurse 4 minutes per shot or 8 minutes total with a participant receiving both a flu and COVID-19 shot to ensure each nurse has ample time to slow down and double check before each vaccine is administered.

Questions

Contact the TotalWellness Director of Nursing at 888.434.4358 x1210.

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