

JOHNSON AND JOHNSON (JANSSEN) COVID-19 VACCINE



Indiana
Department
of
Health

Division of
Immunization

VACCINE SAFETY AND ADMINISTRATION **TOOLKIT**

MARCH 2021



Disclaimer

Please refer to the manufacturer, Johnson and Johnson (Janssen), www.janssencovid19vaccine.com for most up-to-date information. This toolkit will be updated as the website and Fact Sheets are updated.



Updated: March 2021

JOHNSON AND JOHNSON (JANSSEN) COVID-19 VACCINE VACCINE SAFETY AND ADMINISTRATION TOOLKIT

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Introduction



FDA has authorized the emergency use of the Johnson and Johnson (Janssen) COVID-19 Vaccine, which is not an FDA-approved vaccine. **The recipient or their caregiver has the option to accept or refuse the Johnson and Johnson (Janssen) COVID-19 Vaccine.**

Use of unapproved Johnson and Johnson (Janssen) COVID-19 Vaccine for active immunization to prevent COVID-19 under this EUA is limited to the following (all requirements must be met):

1. Johnson and Johnson (Janssen) COVID-19 Vaccine is authorized for use in individuals 18 years of age and older.
2. The vaccination provider must communicate to the individual receiving the Johnson and Johnson (Janssen) COVID-19 Vaccine or their caregiver, information consistent with the “Fact Sheet for Recipients and Caregivers” prior to the individual receiving Johnson and Johnson (Janssen) COVID-19 Vaccine.
3. The vaccination provider must include vaccination information in the state/local jurisdiction’s Immunization Information System (IIS) or other designated system.
4. The vaccination provider is responsible for mandatory reporting of the following to the Vaccine Adverse Event Reporting System (VAERS):
 - vaccine administration errors whether or not associated with an adverse event,
 - serious adverse events* (irrespective of attribution to vaccination),
 - cases of Multisystem Inflammatory Syndrome (MIS) in adults and children, and
 - cases of COVID-19 that result in hospitalization or death.
 - Complete and submit reports to VAERS online at <https://vaers.hhs.gov/reportevent.html> or by calling 1-800-822-7967. The reports should include the words “Johnson and Johnson (Janssen) COVID-19 Vaccine EUA” in the description section of the report.
5. The vaccination provider is responsible for responding to FDA requests for information about vaccine administration errors, adverse events, cases of MIS in adults and children, and cases of COVID-19 that result in hospitalization or death following administration of Johnson and Johnson (Janssen) COVID-19 Vaccine to recipients.

*Please refer to Fact Sheet for more information on known adverse events

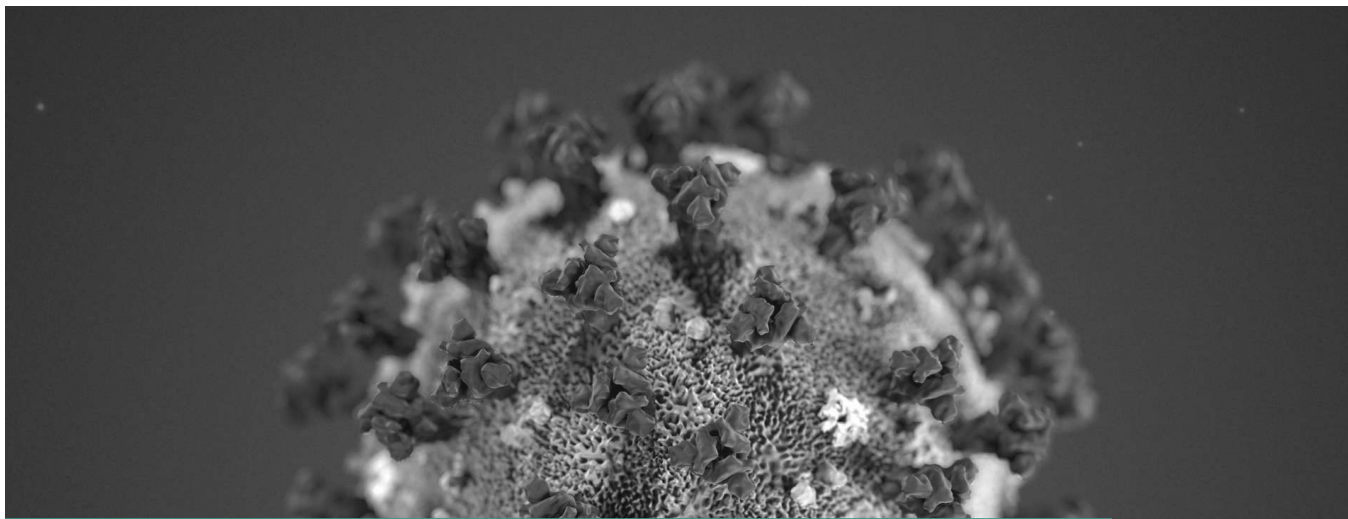
Source: Janssen: . (2021). Fact Sheet For Healthcare Providers Administering Vaccine. Retrieved from <https://www.janssenlabels.com/emergency-use-authorization/Janssen+COVID-19+Vaccine-HCP-fact-sheet.pdf>.

The first section, Vaccine Safety and Administration Checklist, is an overview of the vaccination visit. You may use this as a starting point and refer to the respective section for each checklist item.

To access educational materials and Healthcare and Recipient Fact Sheets, please visit the [Janssen COVID-19 Vaccine website](#). We encourage you to visit their website frequently as these fact sheets may be updated frequently and will have the most up-to date information.

You can also refer to our division's Learning Management System, also known as [LMS:INvest](#), located on the CHIRP Dashboard, or check out our website at www.in.gov/isdh/17094.htm for the latest provider training materials. We will continue to update materials as changes or updates are made on the manufacturer's website.

Source: Janssen: . (2021). Fact Sheet For Healthcare Providers Administering Vaccine. Retrieved from <https://www.janssenlabels.com/emergency-use-authorization/Janssen+COVID-19+Vaccine-HCP-fact-sheet.pdf>.



Vaccine Safety and Administration Checklist



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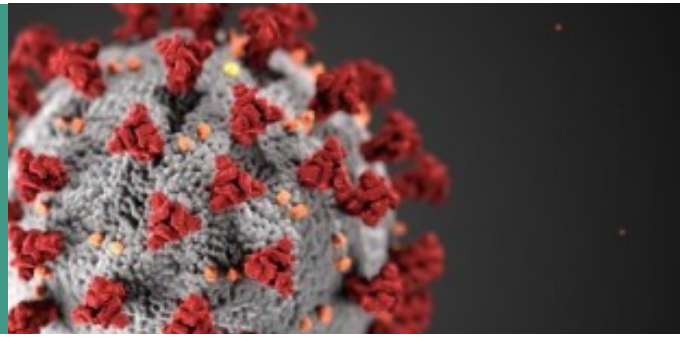
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Steps to Take Before Johnson and Johnson (Janssen) COVID-19 Vaccine Administration



1. REGISTER/CHECK IN PATIENT ON ZOTEC

- Zotec is used to register patient's appointment and vaccination record documentation.
- Patient search must be completed in Zotec prior to COVID-19 vaccine administration. The data will automatically be entered into CHIRP, our state immunization registry.
- Please refer to the **Registering and Checking In the Patient** section or www.in.gov/isdh/28690.htm for more information.



2. PROVIDE RECIPIENT EUA FACT SHEET

- Required under the National Childhood Vaccine Injury Act .
- Must be given prior to administration of each dose of the vaccine. Must provide the most current version. Please check the manufacturer website for the most recent version. The Johnson and Johnson (Janssen) Provider and Recipient Fact Sheets can be found on <https://vaxcheck.inj/>.



3. SCREENING THE PATIENT

- The key to preventing the majority of serious adverse reactions is through patient screening.
- Every person who administers the COVID-19 Vaccine should screen every patient for contraindications, previous allergies, and precautions prior to administering the vaccine dose.
- The contraindications can be found on the Provider Fact Sheet. The Johnson and Johnson (Janssen) COVID-19 Vaccine website is located at <https://vaxcheck.inj/>.
- Refer to the **Screening the Patient** section for more guidance.



Steps to Take During Johnson and Johnson (Janssen) COVID-19 Vaccine Administration



1. CHECKING VIAL EXPIRATION DATE

- You can confirm the vial expiration date by looking up the lot number at <https://vaxcheck.jnj/>.
- Refer to the **Preparing the Vaccine** section for more information or visit <https://www.janssencovid19vaccine.com/hcp.html>.



2. VACCINE PREPARATION (NO DILUTION REQUIRED)

- The Johnson and Johnson (Janssen) COVID-19 Vaccine does not require dilution.
- The vaccine should be fully thawed before administration.
- Record the date and time for first use on the Johnson and Johnson (Janssen) COVID-19 Vaccine vial label. Punctured vials can be kept for 6 hours at 2°C to 8°C , or for 2 hours at room temperature (9°C to 25°C).
- Refer to the **Preparing the Vaccine** section for more information on thawing and room temperature exposure time restrictions or <https://www.janssencovid19vaccine.com/hcp.html>.



3. ADMINISTER INTRAMUSCULAR ROUTE

- Make sure staff are wearing appropriate PPE.
- Practice hand hygiene before administration, between patients, and when changing gloves (if worn), and any time your hands/gloves are soiled.
- Administer a single 0.5mL dose.
- Use appropriate gauge needle for body type (23-25 gauge).
- Administer intramuscularly in the deltoid muscle.
- Refer to the **Administering the Vaccine** section or <https://www.janssencovid19vaccine.com/hcp.html> for more information.

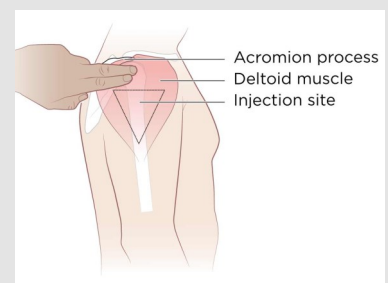


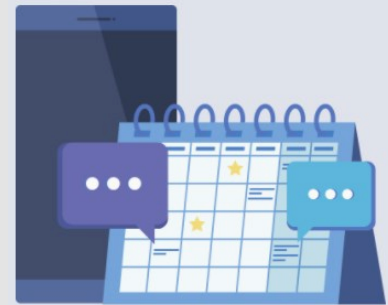
Image source: Intramuscular Injection Sites. Healthline. Medically reviewed by Deborah Weatherspoon, Ph.D., R.N., CRNA. Written by Jacquelyn Cafasso. Updated on March 7, 2019. Retrieved from <https://www.healthline.com/health/intramuscular-injection>

Steps to Take After Johnson and Johnson (Janssen) COVID-19 Vaccine Administration



1. WAIT 15 MIN. & PROVIDE COVID-19 VACCINATION RECORD CARD

- Discard all used materials in appropriate waste receptacles.
- Monitor your patient after the vaccination for 15 minutes in a designated area to monitor for potential vaccine reaction. Monitor patient for 30 minutes if known reactions or allergies to vaccines.
- Using the COVID-19 vaccination record card provided in the ancillary kit, please record the date of vaccination.
- No second dose is required and it is not interchangeable with other COVID-19 vaccines.
- Refer to the **Closing the Loop** section for more information.



2. CLOSING THE LOOP

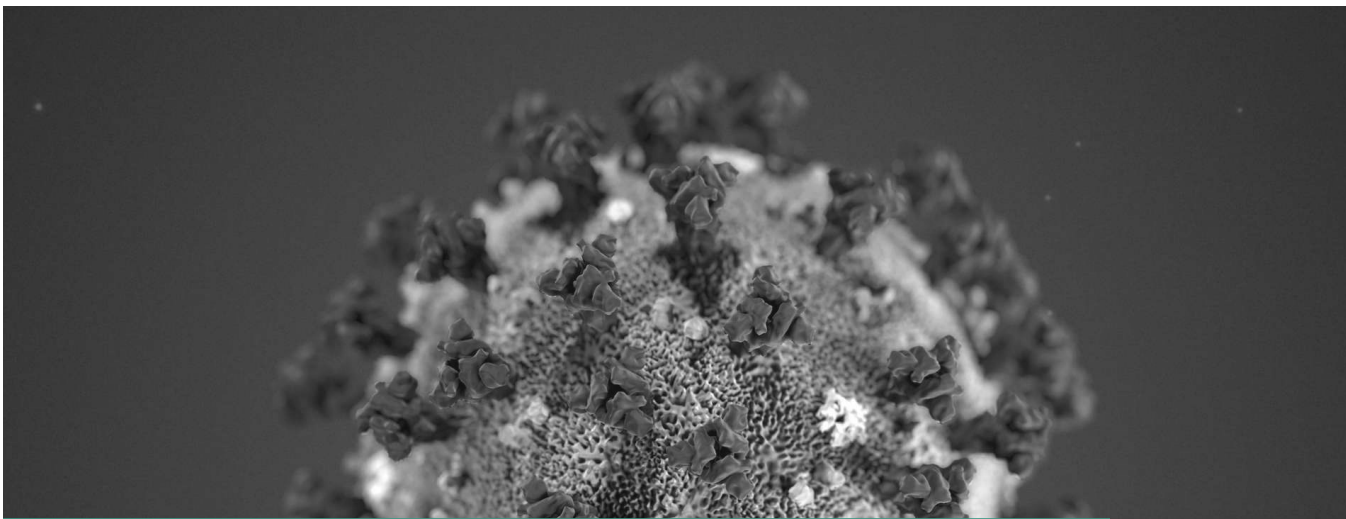
- [V-safe](#) is a new smartphone-based, after-vaccination health checker for people who receive COVID-19 Vaccines. Facilities are required to provide information on the V-safe program to vaccinated individuals and counsel them on the importance of enrolling.
- [Vaccine Adverse Event Reporting System \(VAERS\)](#) (www.vaers.hhs.gov) is an early warning system, co-managed by CDC and FDA, which monitors for potential vaccine safety problems; anyone can report possible vaccine side effects to VAERS. Click [here](#) for an informational video on VAERS.
- Refer to the **Closing the Loop** section for more information.



3. DOCUMENT VACCINATION IN ZOTEC

- Each COVID-19 dose administered must be entered into Zotec at the time of vaccination.
- Vaccinations must be reported within 24 hours of administration.
- Refer to the **Documenting the Vaccination Visit section** or www.in.gov/isdh/28690.htm for more guidance.





General Vaccine Safety Measures



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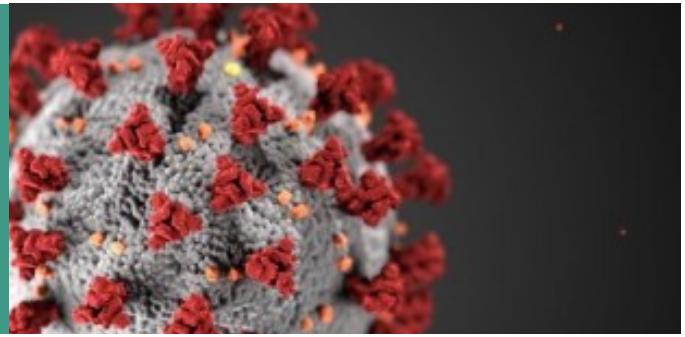
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Infection Control During the COVID-19 Pandemic



General Infection Control Measures for Healthcare Facilities

The general principles outlined for healthcare facilities should also be applied to alternative vaccination sites, with additional precautions for physical distancing that are particularly relevant for mass vaccination clinics, such as:



- **Providing specific appointment times** or other strategies to manage patient flow and avoid crowding



- **Ensuring sufficient staff and resources** to help move patients through the clinic flow as quickly as possible



- **Limiting the overall number of attendees** at any given time, particularly for populations at increased risk for [severe illness from COVID-19](#)



- **Setting up a unidirectional site flow** with signs, ropes, or other measures to direct site traffic and ensure physical distancing between patients



- When feasible, **arranging a separate vaccination area** or separate hours for persons at increased risk for severe illness from COVID-19, such as older adults and persons with underlying medical conditions



- Making available a point of contact for any reasonable **accommodation needs for people with disabilities** and ensuring vaccination locations are accessible to individuals with disabilities consistent with the statutes the American with Disabilities Act and Section 504 of the Rehabilitation Act of 1973

Continued Infection Control Measures Before Vaccination

To help ensure the safe delivery of care during vaccination visits, providers should:



- **Take temperatures** Screen for [symptoms](#) of COVID-19 and contact with persons with possible COVID-19 [prior to](#) and upon arrival at the facility and isolate symptomatic patients as soon as possible



- **Provide the correct personal protection equipment** for all staff (refer to pg.15)



- **Limit and monitor points of entry** to the facility and install barriers, such as clear plastic sneeze guards, to limit physical contact with patients at triage



- **Implement policies** for the use of a [cloth face covering](#) in persons over the age of 2 years (if tolerated)



- **Ensure adherence** to respiratory hygiene, cough etiquette, and [hand hygiene](#)

Continued Infection Control Measures During Vaccination

To help ensure the safe delivery of care during vaccination visits, providers should:



- **Ensure all staff adhere** to the following infection prevention and control procedures
- **Follow [Standard Precautions](#)**, which includes guidance for hand hygiene and cleaning the environment between patients



- **Wear a medical facemask** at all times

- **Use eye protection** based on level of [community transmission](#):



- * Moderate to substantial: Healthcare providers should wear eye protection given the increased likelihood of encountering asymptomatic COVID-19 patients such as goggles or face shields
- * Minimal to none: Universal eye protection is considered optional, unless otherwise indicated as a part of [Standard Precautions](#)



- **If gloves are worn during [intramuscular or subcutaneous vaccine administration](#)**, they should be changed between patients in addition to performing hand hygiene.

- **Ensure physical distancing** by implementing strategies, such as:



- * Separating sick from well patients by scheduling these visits during different times of the day placing patients with sick visits in different areas of the facility, or scheduling patients with sick visits in a different location from well visits (when available)
- * Reduce crowding in waiting areas by asking patients to remain outside or stay in their vehicles until they are called into the facility for their appointment
- * Utilize electronic communications as much as possible to minimize time in the office as well as reuse of materials (e.g., clipboards, pens)
- * Separation of at least 6 feet between patients and visitors, are maintained during all aspects of the visit by using physical barriers, signs, and floor markings

Source: CDC (2021). General Practices for the Safe Delivery of Vaccination Services. Retrieved from <https://www.cdc.gov/vaccines/pandemic-guidance/index.html>

Vaccinating during COVID-19

The Indiana State Department of Health (ISDH) Immunization Division wants to ensure all providers are staying safe and keeping patients healthy, while continuing to vaccinate patients.

Below are **five (5) key standard precautionary measures** providers can take to safely vaccinate patients. These range from wearing personal protective equipment (PPE) to hand hygiene.

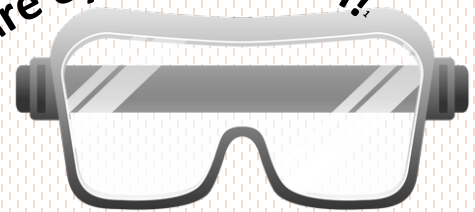
Take the necessary actions to protect you and your community!

Wear a medical facemask!



*N-95 is not required for intranasal or oral vaccines. But should be used if you suspect a patient has/been exposed to COVID-19.¹

Use secure eye protection!



*Goggles or a disposable face shield may be used.¹

Change gloves between patients!



*Wearing gloves is not a substitute for hand hygiene!
*Gloves should be utilized¹ when giving the following vaccinations:

- Intranasal
- Oral

Practice hand hygiene!



*Wash your hands before and after patient contact.¹

Throw PPE waste in a trash can!



*Do not leave used or soiled PPE on surfaces. Directly dispose used and soiled PPE in the trash.²

1. Centers for Disease Control and Prevention [CDC]. (2020, June 9). *Vaccination guidance during a pandemic: Interim guidance for immunization services during COVID-19*. Retrieved from <https://www.cdc.gov/vaccines/pandemic-guidance/index.html>
2. Centers for Disease Control and Prevention [CDC]. (2020, May 3). *General business frequently asked questions*. Retrieved from <https://www.cdc.gov/coronavirus/2019-ncov/community/general-business-faq.html#:~:text=Discard%20PPE%20into%20a%20trash,needs%20any%20additional%20disinfection.>

Additional Resources:

- Centers for Disease Control and Prevention [CDC]. (2020, April 2). *When and how to wash your hands*. Retrieved from <https://www.cdc.gov/handwashing/when-how-handwashing.html>
- Centers for Disease Control and Prevention [CDC]. (2020, June 5). *Healthcare infection prevention and control FAQs for COVID-19*. Retrieved from <https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-faq.html#asymptomatic>



Preventing Vaccination Injuries: Needle Safety



Needle safety is crucial. Needles and syringes should be sterile and disposable. A separate needle and syringe should be used for each injection. To prevent inadvertent needlesticks, safety mechanisms should be deployed after use, and needles discarded immediately in a labeled, puncture proof container. NEVER recap a needle.

Steps to Take Before Vaccination

- 1) Perform proper hand hygiene
- 2) Ensure vaccine has been stored within proper range; check expiration date
- 3) Double check vial, dosage, content prior to drawing up vaccine contents
- 4) Remove any air bubbles in the syringe, for safety needle of appropriate size
- 5) Ensure the proper size needle/gauge is being used for injection
- 6) Maintain aseptic technique throughout, clean rubber stopper on vial if prior to piercing the seal
- 7) Identify landmarks for proper placement (deltoid, anterolateral thigh, etc.)
- 8) Educate patient on vaccine administration

Steps to Take During Vaccination

- 1) Ensure proper positioning of patient
- 2) Prep site with alcohol wipe, using a circular motion from the center to 2-3" circle, allow to dry
- 3) Control limb with non-dominant hand, hold needle 1" from the skin, insert quickly at 90 degree angle
- 4) Inject with steady pressure for several seconds, withdraw needle at angle of insertion
- 5) Apply gentle pressure with gauze, bandaid, etc.

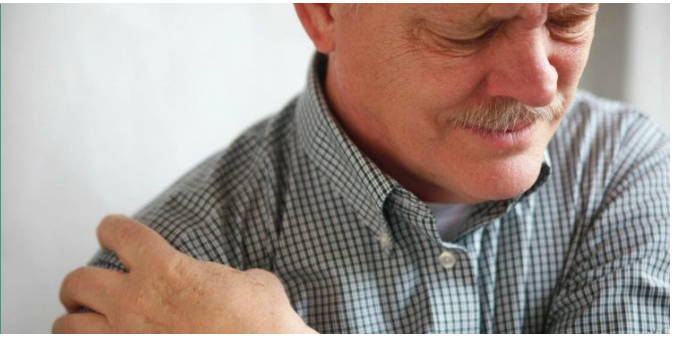
Steps to Take After Vaccination

- 1) Properly dispose of materials
 - Used needles should not be detached, recapped or cut before disposal
 - Immediately after use, all used syringe/needle devices should be placed in biohazard containers that are closable, puncture-resistant, leak proof on sides and bottom and labeled or color-coded
 - Empty or expired vaccine vials are considered medical waste and should be disposed of in appropriate containers

- 2) Fully document as directed noting the LOT number, date, manufacturer, etc.
- 3) Record vaccine administration into Zotec



Preventing Vaccination Injuries: Shoulder Dysfunction



Shoulder dysfunction is caused by injury to the musculoskeletal structures of the shoulder including tendons, ligaments, bursae, etc. after the administration of a vaccine. Known as SIRVA (Shoulder Injury Related to Vaccine Administration), this injury may induce shoulder pain and limit range of motion, weakness, and loss of function. In some cases, these issues may become chronic conditions for the patient. These symptoms are likely to occur because of unintentional injection of vaccine antigen, trauma from the injection, or in relation to the needle being inserted into the underlying bursa of the shoulder, resulting in an inflammatory reaction. Proper vaccination technique is key to prevent shoulder dysfunction.

- **The Right Site:** Find the boney part of the shoulder (acromion process), move your finger down approximately 2" to the center of the deltoid, and administer the injection at a 90-degree-angle to the skin. It is best to be seated when giving a vaccine or be standing at the same level as the patient.
- Inflammatory issues may arise even if vaccine is administered correctly, however, proper technique will ensure this is not cause by the provider administering the vaccine.

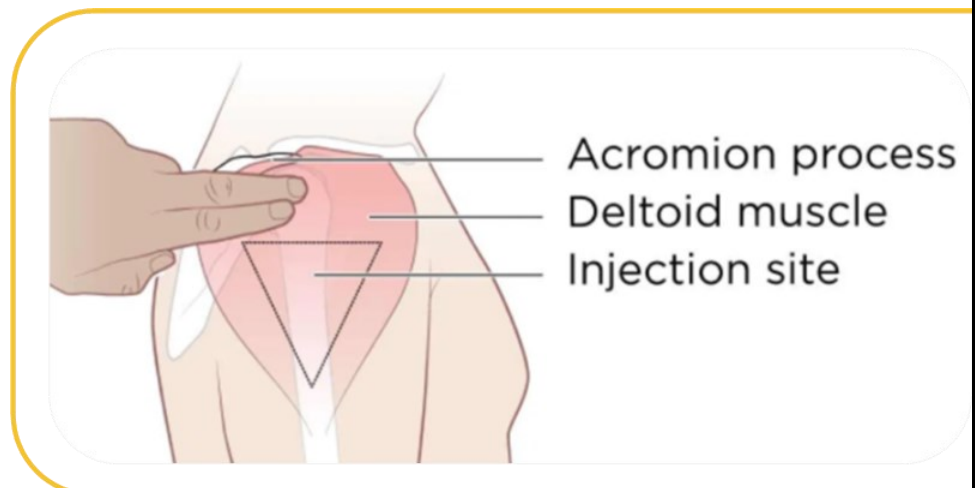
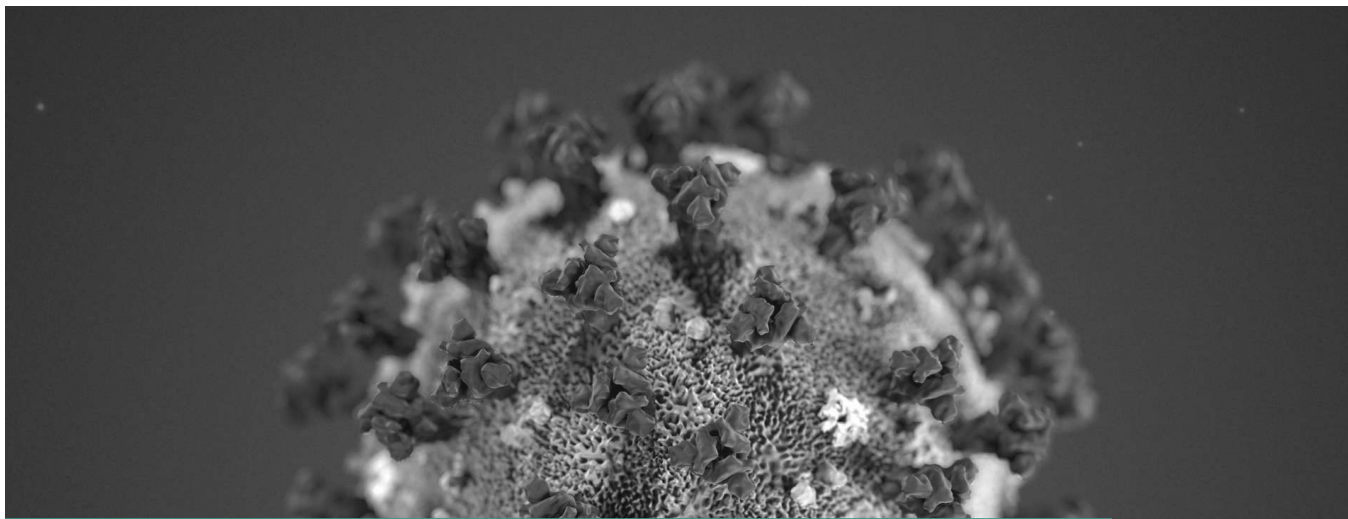


Image source: Intramuscular Injection Sites. Healthline. Medically reviewed by Deborah Weatherspoon, Ph.D., R.N., CRNA. Written by Jacquelyn Cafasso. Updated on March 7, 2019. Retrieved from <https://www.healthline.com/health/intramuscular-injection>

Source: CDC. (2021). Preventing and managing adverse reactions. Retrieved from <https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/adverse-reactions.html>

Wexler, D. (2018). How to avoid shoulder injury with deltoid intramuscular injections. Retrieved from <https://www.immunize.org/technically-speaking/20181023.asp>



COVID-19 Vaccine Recipient Safety



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Vaccine Adverse Event Reporting System (VAERS)



Vaccine Adverse Event Reporting System (VAERS) Overview

VAERS serves as the nation's early warning system to detect possible safety issues with U.S. vaccines. VAERS traditionally has provided initial data on the safety profile of new vaccines when they are introduced for use in the population.

Creation of VAERS

The National Childhood Vaccine Injury Act of 1986 requires health care personnel and vaccine manufacturers to report to VAERS specific adverse events that occur after vaccination. The reporting requirements are different for manufacturers and health care personnel. Manufacturers are required to report all adverse events that occur after vaccination to VAERS, whereas health-care providers are required to report events that appear in the reportable events table on the VAERS website.

In addition to the mandated reporting of events listed on the reportable events table, health care personnel should report to VAERS all events listed in product inserts as contraindications, as well as all clinically significant adverse events, even if they are uncertain that the adverse event is related causally to vaccination.

General information on VAERS is available at this [website](#). Specific information for healthcare providers is available [here](#). You can also watch an informational video about VAERS on CDC's YouTube Channel [here](#). Reporting to VAERS is fully electronic and can be done using an online reporting tool or a writable PDF; instructions are available at this website.

Purpose of VAERS

The purpose of VAERS is to detect new, unusual, or rare adverse events that happen after vaccination. VAERS is used to monitor for increases in known side effects, identify potential patients risk factors for particular types of health problems related to vaccines, assess the safety of newly licensed vaccines, and detect unexpected or unusual patterns in adverse event reports.

Source: CDC. (2021). Reporting to the Vaccine Adverse Reporting System (VAERS). Retrieved from <https://www2.cdc.gov/vaccines/ed/covid19/SHVA/40020.asp>

When to Use VAERS

Per the CDC COVID-19 Vaccination Program Provider Agreement, COVID-19 vaccination providers are required to report adverse events following COVID-19 vaccination and should report clinically important adverse events even if they are not sure if the vaccination caused the event.

For the COVID-19 Vaccine Clinically important adverse events are defined as symptoms that resulted in the vaccine recipient :	Healthcare providers are also required to report any of the following in VAERS:
<ul style="list-style-type: none"> • Missing work • Being unable to perform normal daily activities • Getting care from a doctor or other health professional 	<ul style="list-style-type: none"> • Vaccine administration errors (whether associated with an adverse event or not) • Serious Adverse Events (irrespective of attribution to vaccination like death, vasovagal syncope, asphyxiation, hospitalization) • Multisystem inflammatory syndrome (MIS) in children (if vaccine is authorized for use in children) or adults • Cases of COVID-19 that result in hospitalization or death after the recipient has received COVID-19 vaccine

In addition, you can report side effects to Johnson and Johnson (Janssen) at the contact information

Email	Fax Number	Telephone Number
JNJvaccineAE@its.jnj.com	1-215-293-9955	1-800-565-4008

Source: CDC. (2021). Reporting to the Vaccine Adverse Reporting System (VAERS). Retrieved from <https://www2.cdc.gov/vaccines/ed/covid19/SHVA/40020.asp>

How to Report in VAERS

Option 1: Submit a VAERS Report Online at <https://vaers.hhs.gov/esub/index.jsp>

The online VAERS Report must be completed and submitted in the same session; it cannot be saved and edited at a later time.

Option 2: Download a Writable PDF Form and Upload at <https://vaers.hhs.gov/uploadFile/index.jsp>

The writable PDF form can be downloaded and completed electronically on your own time. When ready, return the VAERS Writable PDF web page and follow instructions to upload the form.

For assistance email info@VAERS.org or call 1-800-822-7967.

Information Needed to File a Report in VAERS

- Patient information (age, date of birth, sex)
- Vaccine information (brand name, dosage)
- Date, time, and location administered
- Date and time when adverse event started
- Symptoms and outcome of the adverse event(s)
- Medical tests and laboratory results (if applicable)
- Physicians Contact information (if applicable)

Note: VAERS will still accept a report even if you cannot provide all requested information.



Source: CDC. (2021). Vaccine Adverse Reporting System (VAERS). Retrieved from <https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vaers/index.html>

V-safe After Vaccination Health Checker

v-safeSM

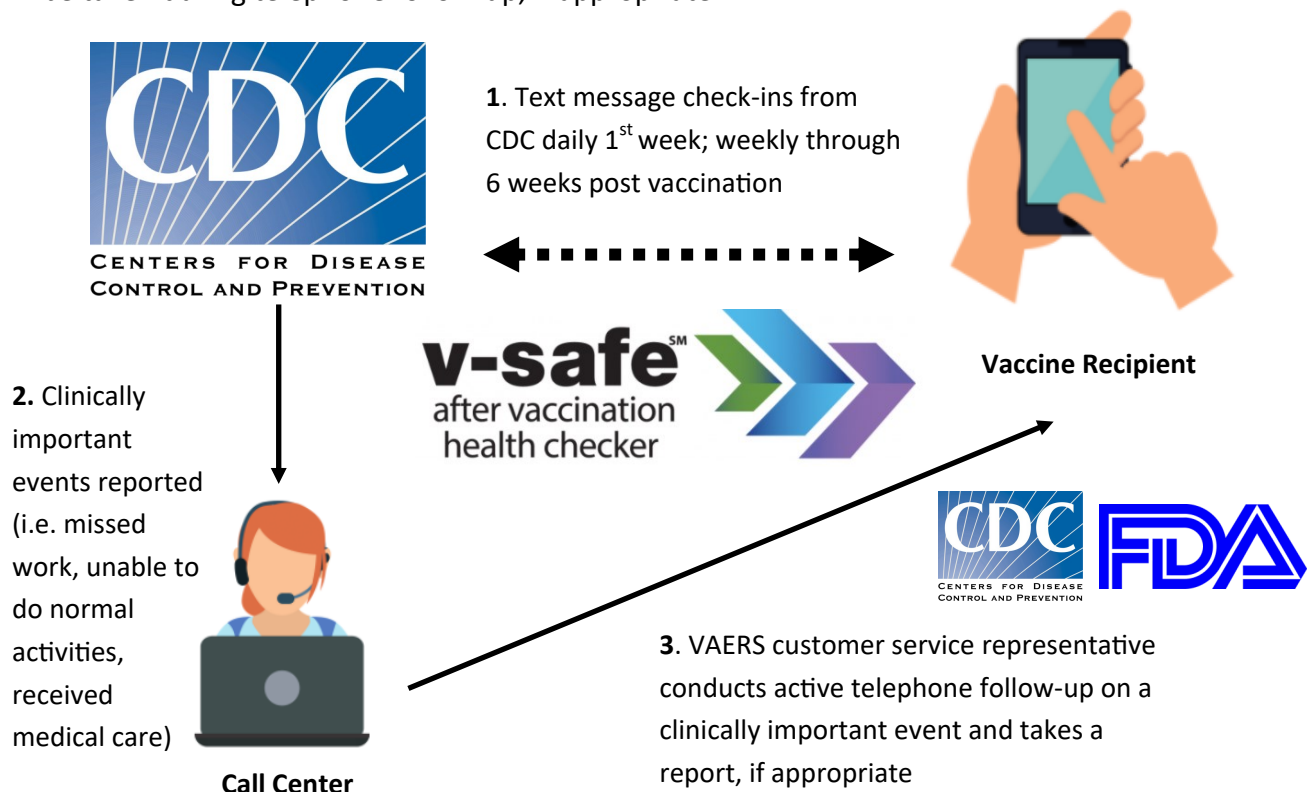
after vaccination health checker



V-safe Overview

The [V-safe Monitoring System](#) is a smart phone-based system that uses text messaging and web surveys to provide personalized health check-ins after a patient receives a COVID-19 vaccination. The V-safe monitoring system will be used to monitor potential adverse reactions in healthcare worker and essential workers.

The system uses contact information supplied in the registration process for COVID-19 vaccination of essential workers to conduct health checks via text and email. In the first week following vaccination, vaccine recipient will receive a check-in daily. After the first week, recipients will receive a check-in on a weekly basis for 6 weeks post vaccination. Active telephone follow-up will be conducted with a person reporting a clinically significant adverse event during any V-safe health check. A VAERS report will be taken during telephone follow-up, if appropriate.



Source: CDC. (2021). V-safe After Vaccination Health Checker. Retrieved from <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html>

Purpose of V-safe

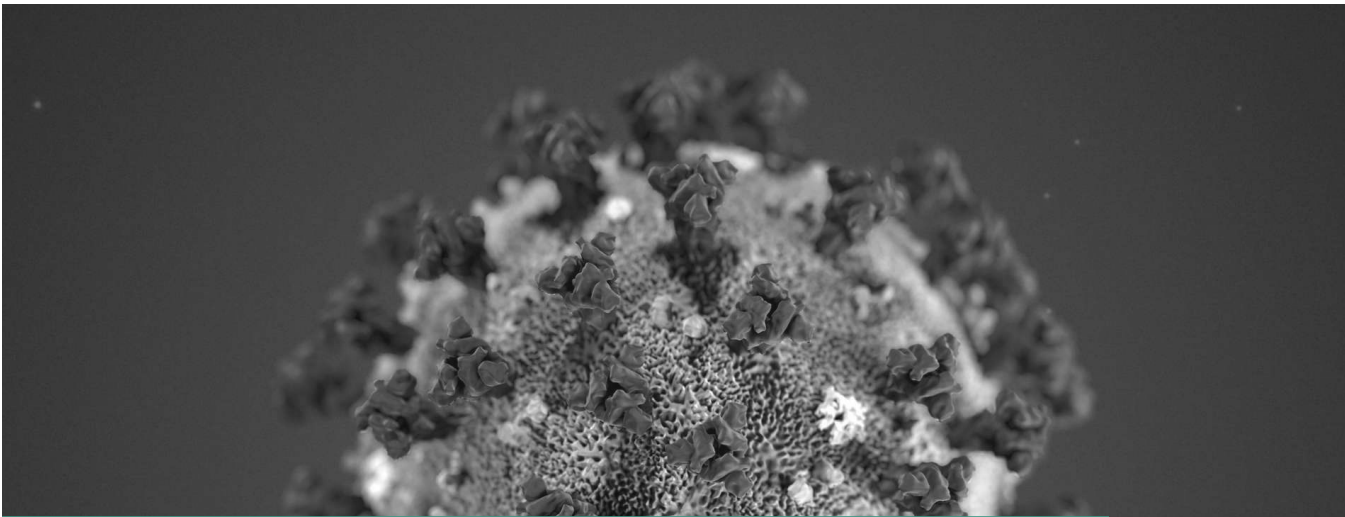
V-safe will enhance the monitoring capabilities of VAERS. Smartphone-based monitoring of early COVID-19 vaccine recipients will allow the estimation of rates of local and systemic adverse events, as well as, rates of clinically important adverse events following immunization. The V-safe system will also allow for the comparison of observed rates of adverse events, with known rates following other types of vaccinations such as the seasonal flu vaccine.

What to Give to Recipients

Provide patients with the V-safe information sheet, this sheet provides instructions on how to register and use V-safe. Patients will need a smartphone to participate in V-safe. They will also the information about the vaccine they received, this can be found on their vaccination record card that is given after receiving the vaccine.

Please refer to the Appendix: Patient Education Packet for the V-safe Information Sheet.

Source: CDC. (2021). V-safe After Vaccination Health Checker. Retrieved from <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html>



Before COVID-19 Vaccine Administration



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VACCINE SAFETY AND ADMINISTRATION TOOLKIT

MARCH 2021



Indiana Department of Health and ZOTEC - Quick Reference Guide

Gaining User Access to Zotec (for Facilities)

What is ZOTEC?

The Indiana Department of Health (IDOH) has partnered with Zotec during Phase 1A of COVID-19 vaccination efforts. Zotec has the available features needed to collect important data on patient demographics. You will document vaccine administration for your facility's patients using Zotec.



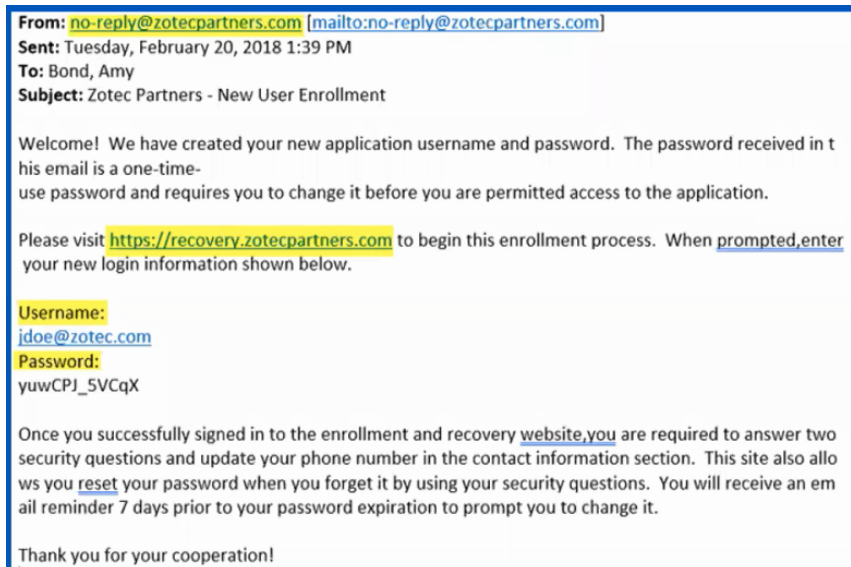
Questions? Please Contact our IDOH Help Desk Portal (<https://eportal.isdh.in.gov/C19VaxHelpDeskCustomer>)



Tip: Do not use Internet Explorer. Please use Chrome or Firefox.

User Access for Facilities

1. You will receive an email from [No-reply@zotecpartners.com](mailto:no-reply@zotecpartners.com) with the subject line New User Enrollment.



2. Use the credentials received via email. You will be able to change the temporary password after logging in.
3. Please begin the enrollment process at <https://recovery.zotecpartners.com>



Welcome to our Self-Service User Account Management System

First Time Users - Please sign in using the credentials received via email. You will then be able to change your temporary password and complete the enrollment.

[Enrollment Documentation](#)

Returning Users - If your current password will expire soon or has already, sign in using your credentials and update as required.

[Password Reset Documentation](#)

* Enrolled User Self-Service *



Reset Password

Reset your forgotten password



Unlock Account

Unlock your locked out account

- For First Time and Existing Users -

Sign in

User Name:

Password:

Login



Indiana Department of Health and ZOTEC - Quick Reference Guide

Registering and Checking In Patients in Zotec

What is ZOTEC?

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Registering Patients

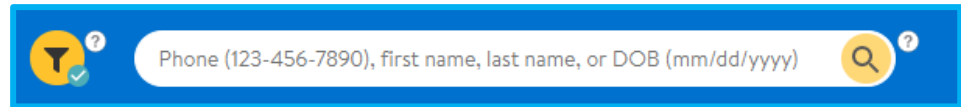
1. Login on <https://checkin.coronavirus.in.gov> using your credentials. If you do not have user access to Zotec, please refer to the **Gaining Access to Zotec (for Facilities)** Quick Reference Guide.
2. Once you have logged in you will need to confirm your location and current date is correct. If the location is incorrect you can change the location by clicking on the icon  shown below.

The screenshot shows the main interface of the Zotec application. At the top, there is a navigation bar with a menu icon, the date and time "Monday, Dec 07, 2020 8:23 AM", and a "Date" field. Below the navigation bar is a search bar with a placeholder "Phone (123-456-7890), first name, last name, or DOB (mm/dd/yyyy)" and a "Schedule Appointment" button. The main content area features a table with columns for Time, First Name, Last Name, DOB, Service, Appointment type, and Status. A "Facility" dropdown menu is visible above the table, currently set to "DEMO LOCATION 1".

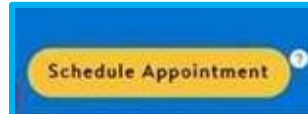
Time	First Name	Last Name	DOB	Service	Appointment type	Status
9:00 AM	Test	Test	12/12/1990	Immunizations	COVID VACCINE	Checked In
9:00 AM	John	Test	01/01/1990	Immunizations	COVID VACCINE	Unregistered

The screenshot shows the "Check-In App" interface. It features a "Location" dropdown menu currently set to "DEMO LOCATION 1". Below the location menu, the user's name "Kruse, Kaitlin" and title "Client Administrator" are displayed. A "Logout" button is located at the bottom of the app interface.

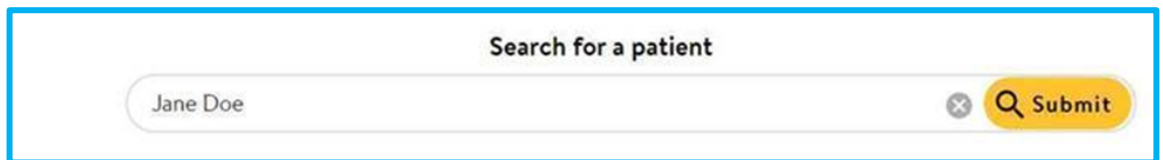
3. Start by searching for the patient on the main screen or typing in their first and last name in the search bar. (If the patient has already started the registration process please go to Step 12)



4. If you cannot find the patient, you can create a new patient by clicking the yellow **Scheduling Appointment** button on the upper right-hand corner.



5. Enter the patient's first and last name and click the **Submit** button.



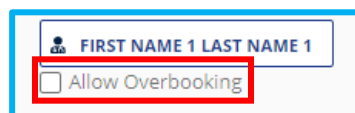
6. Click the **Continue as New** button on the bottom of the page.



7. Select **Immunization** as the type of appointment.



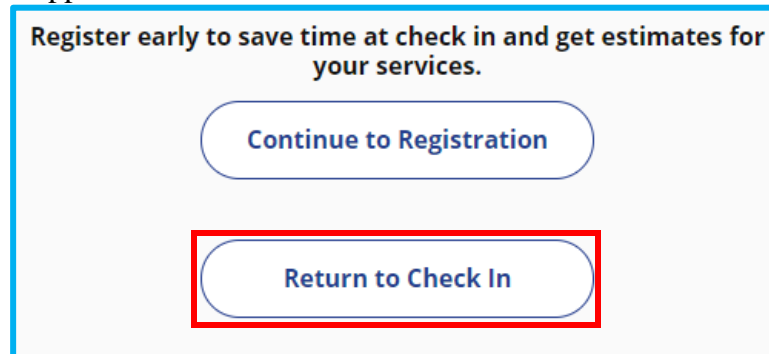
8. Select the date and time the vaccination visit will occur. If there are no time slots available check the **Allow Overbooking** box.



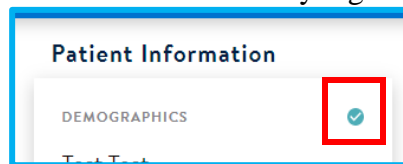
9. The next page will ask for recipient information (First name, last name, date of birth, sex, contact information) **For residents, please enter your facility email and phone number.**
10. After you have verified that all the information is correct, click **Confirm Appointment.**

Checking In Patients

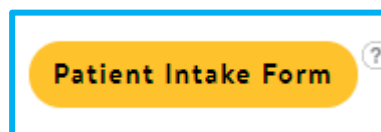
11. Once the appointment is confirmed: Select **Return to Check In**



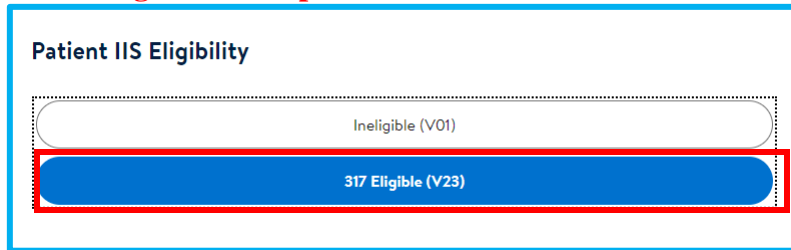
12. You will be redirected to the main screen main screen where you should see the patient listed next to their time lot. Select that patient and **EDIT the demographic areas until you have a green check mark** to successfully register a patient for testing.



13. Make sure you edit each section on the main screen
 - a. Demographics
 - b. Additional Demographics
 - c. Fill out the insurance information so the facility can bill insurance for the administration. (The patient will not be charged for this visit)
 - d. Consents - choose **Collect Manually** and enter patient name & relationship to Patient. (If the Patient is under 18 then you will have to have parental consent and can change the drop down to Parent).
14. You will also need to complete the **Patient Intake Form** before you can check the patient in and select **Return to Appointment** when complete.
 - Intake Demographics
 - Health Habits

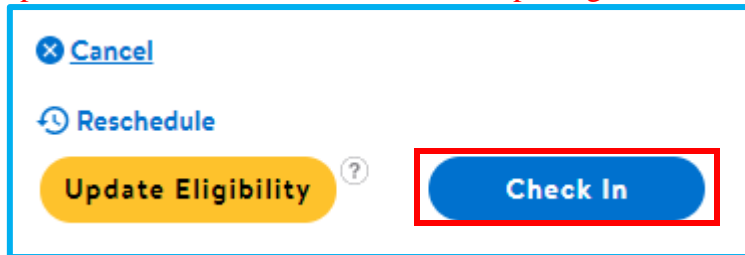


15. The last thing to complete is to **Update Eligibility**. **You will choose 317 for all patients receiving a dose for phase 1A.**



The screenshot shows a form titled "Patient IIS Eligibility". It contains two radio button options. The top option is "Ineligible (V01)" and is currently selected, indicated by a dotted border. The bottom option is "317 Eligible (V23)" and is highlighted with a blue background and a red border, indicating it is the correct selection for phase 1A.

16. Once you have completed all the sections and received all green check marks the **Check In** button will be able to be selected. **Make sure you verify all the demographic information is correct before completing the check-in.**



The screenshot shows a set of action buttons. From top to bottom: a blue "Cancel" button with a close icon, a blue "Reschedule" button with a clock icon, a yellow "Update Eligibility" button with a question mark icon, and a blue "Check In" button which is highlighted with a red border, indicating it is the next step.

Patient Education



To start patient education, please review the following pages with your patient and provide a print copy of the **Appendix: Patient Education Packet** located at the end of this toolkit or on our [website](#).

The Patient Education Packet includes:

- COVID-19 Vaccine FAQ for Patients
- Vaccine Finder Handout
- V-safe Information Sheet

During the **Closing the Loop Section**, you will find additional information and review the contents of the **Patient Education Packet**.

Emergency Use Authorization

An Emergency Use Authorization (EUA) is a mechanism to facilitate the availability and use of medical countermeasures, including vaccines, during public health emergencies, such as the current COVID-19 pandemic. Under an EUA, FDA may allow the use of unapproved medical products, or unapproved uses of approved medical products in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions when certain statutory criteria have been met, including that there are no adequate, approved, and available alternatives. Johnson and Johnson (Janssen) Covid-19 Vaccine has been authorized for emergency use by the FDA under an Emergency Use Authorization to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 18 years of age and older. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner.

The FDA must ensure that recipients of the vaccine under an EUA are informed, to the extent practicable given the circumstances, that the FDA has authorized the emergency use of the vaccine, of the known and potential benefits and risks, the extent to which such benefits and risks are unknown, that they have the option to accept or refuse the vaccine, and of any available alternatives to the product. This information is provided in [Janssen's Fact Sheet For Recipients and Caregivers](#).

Source: FDA. (2021). Emergency Use Authorization for Vaccines Explained. Retrieved from <https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained>

Source: HHS. (2021). Fact Sheet: Explaining Operation Warp Speed. Retrieved from <https://www.hhs.gov/coronavirus/explaining-operation-warp-speed/>

Importance of Patient Education

COVID-19 vaccines will be an important tool to help stop this pandemic. Willingness to accept the COVID-19 falls on a continuum. Many people will fall in the middle of the spectrum with a wait-and-see approach. A strong recommendation from a healthcare provider is one of the most important factors in determining whether or not someone gets vaccinated. Build patient trust by sharing clear, complete, and accurate messages about the COVID-19 vaccine.

Information to Provide to Vaccine Recipients

As the vaccination providers, you must communicate to the vaccine recipient information consistent with the [Fact Sheet for Recipients and Caregivers](#) prior to administering the Johnson and Johnson (Janssen) COVID-19 Vaccine and provide the following:

- FDA has authorized the emergency use of the Johnson and Johnson (Janssen) COVID-19 Vaccine, which is not an FDA-approved vaccine.
- The recipient or their caregiver has the option to accept or refuse the Johnson and Johnson (Janssen) COVID-19 Vaccine.
- The significant known and potential risks and benefits of the Johnson and Johnson (Janssen) COVID-19 Vaccine, and the extent to which such risks and benefits are unknown.
- Information about available alternative vaccines and the risks and benefits of those alternatives.

Source: Janssen: . (2021). Fact Sheet For Healthcare Providers Administering Vaccine. Retrieved from <https://www.janssenlabels.com/emergency-use-authorization/Janssen+COVID-19+Vaccine-HCP-fact-sheet.pdf>.

Adverse Reactions or Side Effects

Side effects that have been reported with the Johnson and Johnson (Janssen) COVID-19 Vaccine include:

- Injection site pain
- Tiredness
- Headache
- Muscle Pain
- Nausea
- Axillary Swelling/ Tenderness
- Fever
- Injection site swelling
- Injection site Erythema

There is a remote chance that the Johnson and Johnson (Janssen) COVID-19 Vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the Johnson and Johnson (Janssen) COVID-19 Vaccine. Signs of a severe allergic reaction can include:

- Difficulty breathing
- Swelling of your face and throat
- A fast heartbeat
- A bad rash all over your body
- Dizziness and weakness
-

These may not be all the possible side effects of the Johnson and Johnson (Janssen) COVID-19 Vaccine. Serious and unexpected side effects may occur. Johnson and Johnson (Janssen) COVID-19 Vaccine is still being studied in clinical trials.

If your patient experiences a severe allergic reaction, please have them call 9-1-1, or go to the nearest hospital. Please let them know they should call the vaccination provider or their healthcare provider if they have any side effects that bother them or do not go away.

Source: Janssen: . (2021). Fact Sheet For Healthcare Providers Administering Vaccine. Retrieved from <https://www.janssenlabels.com/emergency-use-authorization/Janssen+COVID-19+Vaccine-HCP-fact-sheet.pdf>.

Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Johnson and Johnson (Janssen) COVID-19 Vaccine.

You can also refer your patient to the [Recipient Fact Sheet](#), where the side effects and this information is also available.

Most Common Side Effects from the Johnson and Johnson (Janssen) COVID-19 Vaccine

Pain at the Injection Site	48.6%
Headache	38.9%
Fatigue	38.2%
Muscle Pain	33.2%
Nausea	14.2%

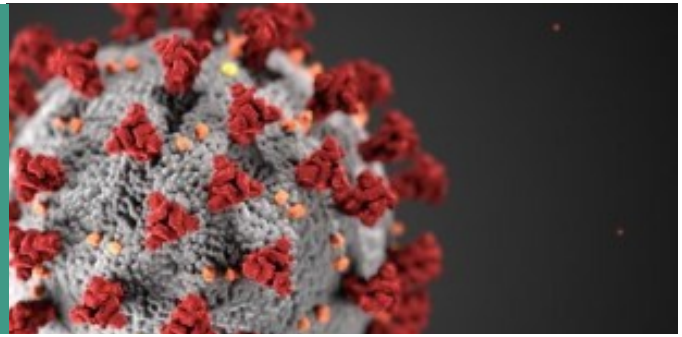
Clinical Trail Data

*Available data on [Janssen's COVID-19 Vaccine website](#) administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy

*Data are not available to assess the effects of Johnson and Johnson (Janssen) COVID-19 Vaccine on the breastfed infant or on milk production/excretion

*There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to Janssen COVID-19 Vaccine during pregnancy. Women who are vaccinated with Janssen COVID-19 Vaccine during pregnancy are encouraged to enroll in the registry by visiting <https://cviper.pregistry.com>.

Screening the Patient



As mentioned in the **Patient Education (Information to Provide to Vaccine Recipients)** section, providers must give patients a print copy of the [Recipient Fact Sheet](#). Please review the information below. This information is also located on the [Janssen COVID-19 Vaccine Provider Fact Sheet](#).

Reviewing Johnson and Johnson (Janssen) COVID-19 Vaccine Contraindications

Do not administer Johnson and Johnson (Janssen) COVID-19 Vaccine to individuals with a known history of severe allergic reaction (e.g. Anaphylaxis) to any component of the Johnson and Johnson (Janssen) COVID-19 Vaccine.

Reviewing the Johnson and Johnson (Janssen) COVID-19 Vaccine Ingredients

A 0.5 mL dose of the Johnson and Johnson (Janssen) COVID-19 Vaccine contains 5×10^{10} virus particles (VP) and the following inactive ingredients: citric acid monohydrate (0.14 mg), trisodium citrate dihydrate (2.02 mg), ethanol (2.04 mg), 2-hydroxypropyl- β -cyclodextrin (HBCD) (25.50 mg), polysorbate-80 (0.16 mg), sodium chloride (2.19 mg). Each dose may also contain residual amounts of host cell proteins (≤ 0.15 mcg) and/or host cell DNA (≤ 3 ng).

Reviewing Warnings

Management of Acute Allergic Reactions	Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of Johnson and Johnson (Janssen) COVID-19 Vaccine.
Altered Immunocompetence	Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Johnson and Johnson (Janssen) COVID-19 Vaccine.
Limitation of Effectiveness	The Johnson and Johnson (Janssen) COVID-19 Vaccine may not protect all vaccine recipients

Source: Janssen: . (2021). Fact Sheet For Healthcare Providers Administering Vaccine. Retrieved from <https://www.janssenlabels.com/emergency-use-authorization/Janssen+COVID-19+Vaccine-HCP-fact-sheet.pdf>.

Algorithm for the Triage of Recipients Presenting for the Johnson and Johnson (Janssen) COVID-19 Vaccine

MAY PROCEED WITH VACCINATION	PRECAUTION TO VACCINATION	CONTRAINDICATION TO VACCINATION
<p>Among people without a contraindication or precaution, a history of:</p> <ul style="list-style-type: none"> Allergy to oral medications (including the oral equivalent of an injectable medication) History of food, pet, insect, venom, environmental, latex, etc., allergies Family history of allergies 	<p>Among people without a contraindication, a history of:</p> <ul style="list-style-type: none"> Any immediate allergic reaction* to other vaccines or injectable therapies‡ Note: people with a contraindication to mRNA COVID-19 vaccines have a precaution to Janssen COVID-19 vaccine, and vice versa. See footnote for additional information on additional measures to take in these people#. 	<p>History of the following:</p> <ul style="list-style-type: none"> Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to component of the vaccine† Immediate allergic reaction* of any severity after a previous dose or known (diagnosed) allergy to a component of the vaccine†
<p>Actions:</p> <ul style="list-style-type: none"> 30-minute observation period: people with history of anaphylaxis (due to any cause) 15-minute observation period: all other people 	<p>Actions:</p> <ul style="list-style-type: none"> Risk assessment Consider referral to allergist-immunologist 30-minute observation period if vaccinated 	<p>Actions:</p> <ul style="list-style-type: none"> Do not vaccinate. Consider referral to allergist-immunologist. Consider other vaccine alternative.

* Immediate allergic reaction to a vaccine or medication is defined as any hypersensitivity-related signs or symptoms consistent with urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within four hours following administration.

‡Includes people with a reaction to a vaccine or injectable therapy that contains multiple components, one of which is a vaccine component, but in whom it is unknown which component elicited the immediate allergic reaction.

#Polyethylene glycol (PEG) is an ingredient in both mRNA COVID-19 vaccines, and polysorbate 80 is an ingredient in Janssen COVID-19 vaccine. PEG and polysorbate are structurally related, and cross-reactive hypersensitivity between these compounds may occur. People with a contraindication to mRNA COVID-19 vaccines (including due to a known allergy to PEG) have a precaution to Janssen COVID-19 vaccine. Among people who received one mRNA COVID-19 dose but for whom the second dose is contraindicated, consideration may be given to vaccination with Janssen COVID-19 vaccine (administered at least 28 days after the mRNA COVID-19 dose). People with a contraindication to Janssen COVID-19 vaccine (including due to a known allergy to polysorbate) have a precaution to mRNA COVID-19 vaccines. For people with these precautions, referral to an allergist-immunologist should be considered. Healthcare providers and health departments may also request a consultation from the [Clinical Immunization Safety Assessment COVIDvax](https://www.cdc.gov/vaccines/imz/by-product/clinical-considerations.html) project. In patients with these precautions, vaccination should only be undertaken in an appropriate setting under the supervision of a health care provider experienced in the management of severe allergic reactions.

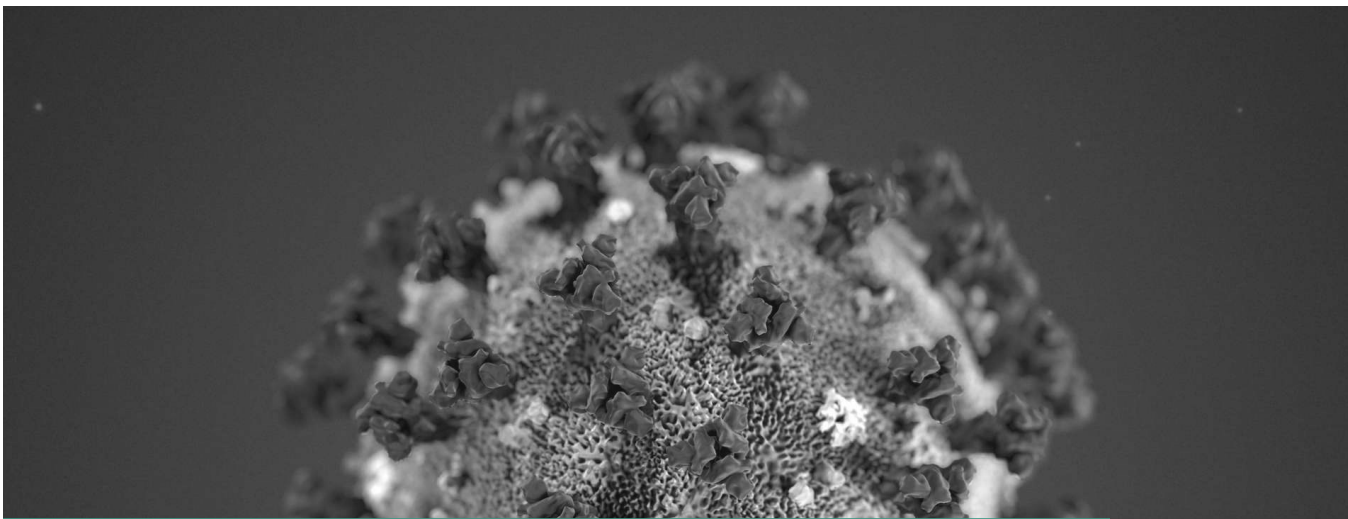
Source: CDC. (March 2021). Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States. Retrieved from <https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html>

Review Important Safety Information

- Do not administer Johnson and Johnson (Janssen) COVID-19 Vaccine to individuals with known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Johnson and Johnson (Janssen) COVID-19 Vaccine
- Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of Johnson and Johnson (Janssen) COVID-19 Vaccine
- Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Johnson and Johnson (Janssen) COVID-19 Vaccine
- The Johnson and Johnson (Janssen) COVID-19 Vaccine may not protect all vaccine recipients
- In clinical studies, the adverse reactions in participants 18 years of age and older were pain at the injection site (48.6%), fatigue (38.2%), headache (38.9%), myalgia (33.2%), nausea/vomiting (14.2%).
- Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Johnson and Johnson (Janssen) COVID-19 Vaccine.
- Available data on Johnson and Johnson (Janssen) COVID-19 Vaccine administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy
- Data are not available to assess the effects of Johnson and Johnson (Janssen) COVID-19 Vaccine on the breastfed infant or on milk production/excretion
- There are no data available on the interchangeability of the Johnson and Johnson (Janssen) COVID-19 Vaccine with other COVID-19 vaccines to complete the vaccination series. |
- Vaccination providers must report Adverse Events in accordance with the Fact Sheet to VAERS at <https://vaers.hhs.gov/reportevent.html> or by calling 1-800-822-7967. The reports should include the words “Johnson and Johnson (Janssen) COVID-19 Vaccine EUA” in the description section of the report
- Vaccination providers should review the Fact Sheet for mandatory requirements and Information to Provide to Vaccine Recipients/Caregivers and the Full EUA Prescribing Information for Requirements and Instructions for Reporting Adverse Events and Vaccine Administration Errors
- Please see Emergency Use Authorization (EUA) Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers), including Full EUA Prescribing Information available at www.cvdvaccine.com

You may find a copy of all of this on the [Johnson and Johnson \(Janssen\) COVID-19 Vaccine Dosing and Administration website](#).

Source: Janssen: . (2021). Fact Sheet For Healthcare Providers Administering Vaccine. Retrieved from <https://www.janssenlabels.com/emergency-use-authorization/Janssen+COVID-19+Vaccine-HCP-fact-sheet.pdf>.



During COVID-19 Vaccine Administration



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VACCINE SAFETY AND ADMINISTRATION TOOLKIT

MARCH 2021



Preparing the Vaccine



Ancillary Kits

Ancillary kits will come with COVID-19 orders and will automatically match the amounts of vaccine orders. Supplies will be packaged in kits and will be automatically ordered in amounts to match vaccine orders in VTckS. For centrally distributed vaccines, each kit will contain supplies to administer 100 doses of vaccine. Please refer to the list on the right. Please refer to the [Product Information Guide for COVID-19 Vaccines and Associated Products](#) for more information on ancillary kit contents.

Ancillary supply kits will not include sharps containers, gloves, and bandages. Additional personal protective equipment (PPE) may be needed depending on vaccination provider site needs. Facilities ordering outside of their jurisdiction's allocation (i.e., commercial and federal entities with federal MOUs in place) will order directly from CDC, and CDC will be responsible for approval of those orders.

COVID-19 Ancillary Kits Include:

- Needles (various sizes for the population served)
- Syringes
- Alcohol prep pads
- Surgical masks and face shields for vaccinators
- COVID-19 vaccination record cards for vaccine recipients
- Vaccine needle and length guide

Source: CDC. (2021). Vaccine Storage and Handling Toolkit with Addendum added November 20, 2020 Retrieved from <https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf>

Supplies Needed

- 5 dosing syringes/needles (1mL syringe/IM injection needle)
- Other materials such as alcohol swabs, gloves, PPE

All of these supplies will be included in the Johnson and Johnson (Janssen) Vaccination kit and will support 100 doses of vaccines with some overage. This combined kit will include administration supplies, and vaccination record cards. Providers will not have the option to opt out of requesting this combined ancillary kit.

Please refer to the [Product Information Guide for COVID-19 Vaccines and Associated Products](#) for possible ancillary kits for the Johnson and Johnson (Janssen) COVID-19 Vaccine. All kits are configured for 100 doses with 5% surplus. Examples include:

Needle and Syringe Sizes for Johnson and Johnson (Janssen) Adult Ancillary Kits	
Product	Quantity
Needle (22–25G x 1")	85
Needle (22–25G x 1.5")	20
Syringe (1mL or 3mL)	105
Alcohol Pad (sterile, individually sealed)	210
Vaccination Record Card	100
Needle Gauge and Length Chart	1
Face Shield	2
Surgical Mask	4

Source: CDC (March 2021). Product Information Guide for COVID-19 Vaccines and Associated Products. https://www.in.gov/isdh/files/Product%20information%20guide_12.04.20_CLEAN.pdf

Thawing the Vaccine Options

The vaccine is initially frozen by the manufacturer and then shipped under refrigerated conditions. The vaccine should arrive thawed, however, if the vaccine arrives partially frozen, allow it to thaw either in the fridge or at room temperature. The vaccine should be completely thawed before administering. Record the date and time of first use on the vial label.

Checking Vial Expiration

You can confirm vaccine expiration date by looking up the lot number at <https://vaxcheck.jnj/>.

Option 1: For Later Use	Option 2: For Immediate Use
<ul style="list-style-type: none">• Thaw vials in the fridge if not need for immediate use.• Unpunctured Vials may be stored in refrigerator at 2°C to 8°C (36°F to 46°F).• Punctured vials may be stored up to 6 hours in refrigerator at 2°C to 8°C (36°F to 46°F).	<ul style="list-style-type: none">• Vials needed for immediate use can be thawed at room temperature.• A carton of 10 vials will take 2 hours to thaw.• An individual vial will take 1 hour to thaw.• Unpunctured vials may be stored at 9°C to 25°C (47°F to 77°F) for up to 12 hours.• Punctured vials can be stored at 9°C to 25°C (47°F to 77°F) for up to 2 hours.

Source: Janssen: . (2021). Fact Sheet For Healthcare Providers Administering Vaccine. Retrieved from <https://www.janssenlabels.com/emergency-use-authorization/Janssen+COVID-19+Vaccine-HCP-fact-sheet.pdf>.

Administering the Vaccine



Choosing the Correct Needle Gauge and Length

At the point of vaccination, you will determine the appropriate needle gauge and length depending on the size of your patient's arm. Please refer to the [Needle Gauge and Length Chart](#) for further reference.

Administering Intramuscular (IM) Route

The Johnson and Johnson (Janssen) COVID-19 Vaccine via the IM route. Please refer to the image below to administer the vaccine. You may also refer to the **Preventing Shoulder Dysfunction section** for more information. **Please follow aseptic technique throughout administration.**

1. Confirm liquid is colorless to slightly yellow, clear to very opalescent suspension in both vial and syringe. Do not administer if there are particulates or discoloration.
2. Verify syringe volume of 0.5 mL

[If you are new to vaccine administration via the IM Route please refer to this source by the \[www.immunize.org\]\(http://www.immunize.org\).](#)

You may also refer to [CDC](#) for more resources on how to administer vaccines or our [website](#) for vaccine administration resources and refreshers.

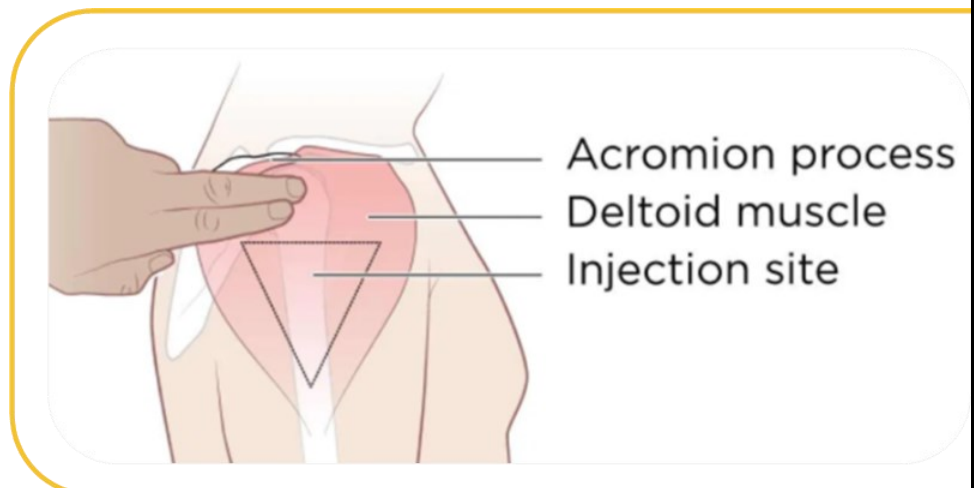
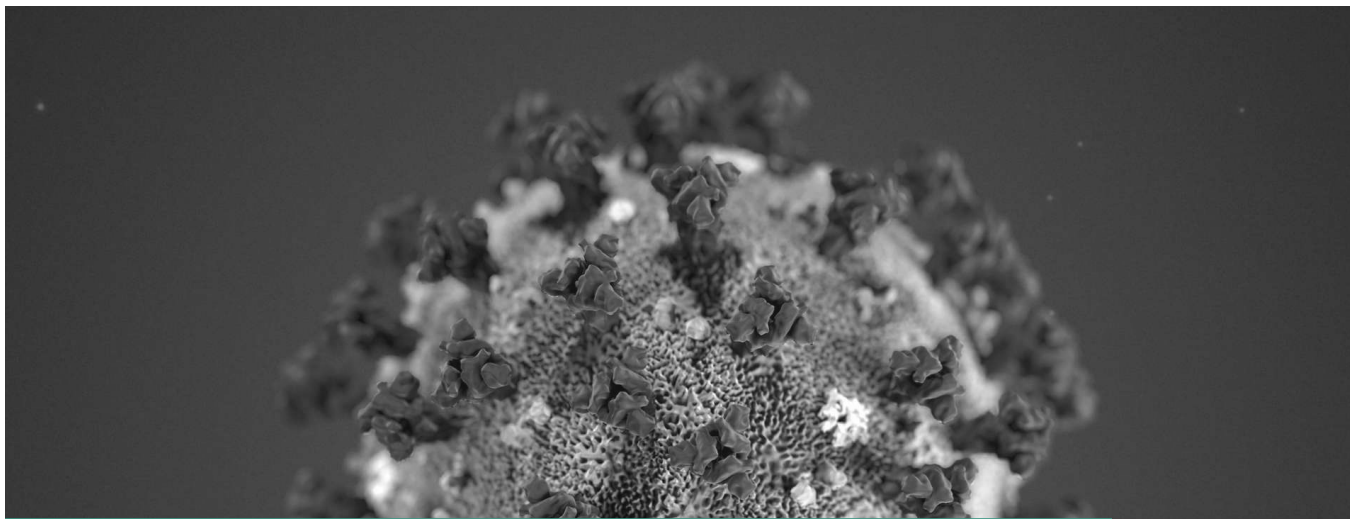


Image source: Intramuscular Injection Sites. Healthline. Medically reviewed by Deborah Weatherspoon, Ph.D., R.N., CRNA. Written by Jacquelyn Cafasso. Updated on March 7, 2019. Retrieved from <https://www.healthline.com/health/intramuscular-injection>

Source: CDC. (March 2021). You Call the Shots. <https://www.cdc.gov/vaccines/hcp/admin/downloads/vaccine-administration-needle-length.pdf>



After COVID-19 Vaccine Administration



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VACCINE SAFETY AND ADMINISTRATION TOOLKIT

MARCH 2021



Closing the Loop



To close the loop, please review the following pages with your patient and provide a print copy of the **Appendix: Patient Education Packet** located at the end of this toolkit or on our [website](#).

COVID-19 Vaccination Record Card

The ancillary supply administration kit will include the vaccination record cards. You can find more information about what is included in the ancillary kit on the [Product Information Guide for COVID-19 Vaccines and Associated Products](#).

The COVID-19 Vaccination Record Card will be given to patients after their first dose is administered. The vaccination record card will contain the following information:

- Last Name, First Name, MI, DOB
- Patient IIS Number
- Manufacturer, Lot Number
- Date 1st Dose Administered
- Healthcare Professional or Facility where doses were administered



The Johnson and Johnson (Janssen) COVID-19 Vaccine is administered as a single dose administered intramuscularly. **The back of the COVID-19 Vaccination Record Card will serve as a written reminder for patients for their second dose.** Please encourage patients to also set a reminder in their smartphone or tablet, in case they lose their COVID-19 Vaccination Record Card. The reminder on the back is also available in Spanish.

The Johnson and Johnson (Janssen) COVID-19 vaccine it is not interchangeable with other COVID-19 vaccines. [Vaccine Finder](#) will be useful for patients to locate where they can get their first dose. Please refer to the next page for more information.

Vaccine Finder

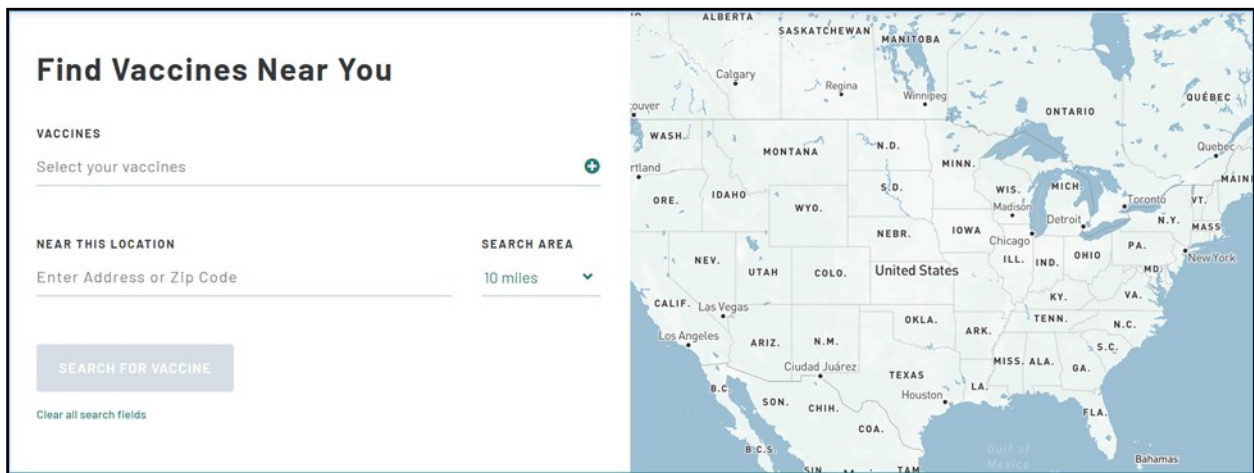
Vaccine Finder is an online database that uses geo-mapping to find healthcare providers in a given area that provide immunizations. The Vaccine Finder's data are sourced from the platform Locating Health. The goal of the Vaccine Finder is to simplify the process of finding and choosing a vaccine provider, therefore increasing vaccine coverage. By entering a zip code, individuals can find all the providers in their area that meet their vaccination needs.

How to Use Vaccine Finder:

1. Go to <https://vaccinefinder.org/>.



2. Click on “Find Vaccines” and you will be redirected to the following screen.



Please refer to the **Appendix: Patient Education Packet** for a print-out version you may give your patient.

Source: Vaccine Finder. (2021). COVID-19 Vaccine Provider Information. Retrieved from <https://vaccinefinder.org>

V-safe and VAERS

V-safe is a new smartphone-based, after-vaccination health checker for people who receive COVID-19 Vaccines. Facilities are required to provide information on the V-safe program to vaccinated individuals and counsel them on the importance of enrolling. The system uses contact information supplied in the registration process for COVID-19 vaccination of essential workers to conduct health checks via text and email. You should counsel and encourage your patients to sign up for the V-safe Monitoring Program. A copy of the patient handout is located in the **Appendix: Patient Education Packet section**.

[Vaccine Adverse Event Reporting System \(VAERS\)](http://www.vaers.hhs.gov) (www.vaers.hhs.gov) is an early warning system, co-managed by CDC and FDA, which monitors for potential vaccine safety problems; anyone can report possible vaccine side effects to VAERS. Vaccination providers must report Adverse Events in accordance with the Fact Sheet to VAERS at <https://vaers.hhs.gov/reportevent.html> or by calling [1-800-822-7967](tel:1-800-822-7967). The reports should include the words “Johnson and Johnson (Janssen) COVID-19 Vaccine EUA” in the description section of the report¹. In addition, you can report side effects to Johnson and Johnson (Janssen), at the contact information provided below.

Website	Fax Number	Telephone Number
JNJvaccineAE@its.jnj.com	1-866-599-1342	1-866-663-3762

Please refer to the **COVID-19 Vaccine Recipient Safety section** for more information on these two monitoring systems.

Known Side Effects and Steps You Can Take

Side effects that have been reported with the Johnson and Johnson (Janssen) COVID-19 Vaccine include:

- Injection site pain
- Tiredness
- Headache
- Muscle Pain
- Joint pain
- Chills
- Nausea
- Axillary Swelling/ Tenderness
- Fever
- Injection site swelling
- Injection site Erythema

¹Source: Janssen. (March 2021). Fact Sheet for Recipients and Caregivers. Retrieved from: <https://www.janssenlabels.com/emergency-use-authorization/Janssen+COVID-19+Vaccine-HCP-fact-sheet.pdf>

There is a remote chance that the Johnson and Johnson (Janssen) COVID-19 Vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the Johnson and Johnson (Janssen) COVID-19 Vaccine. Signs of a severe allergic reaction can include:

- Difficulty breathing
- Swelling of your face and throat
- A fast heartbeat
- A bad rash all over your body
- Dizziness and weakness

These may not be all the possible side effects of the Johnson and Johnson (Janssen) COVID-19 Vaccine. Serious and unexpected side effects may occur. Johnson and Johnson (Janssen) COVID-19 Vaccine is still being studied in clinical trials.

If your patient experiences a severe allergic reaction, please have them call 9-1-1, or go to the nearest hospital. Please let them know they should call the vaccination provider or your healthcare provider if you have any side effects that bother you or do not go away.

Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Johnson and Johnson (Janssen) COVID-19 Vaccine.

You can also refer your patient to the [Recipient Fact Sheet](#), where the side effects and this information is also available.

After Care Instructions

As a healthcare or vaccinator provider, you may provide guidance on after care following the appointment. Generally speaking, if a patient has mild side effects, he/she/they can take the following steps to feel better:

- Drinks lots of fluids
- Put a cool, wet washcloth on places where you're sore
- With provider approval, recipient may take a non-aspirin pain reliever.
- If the patient's arm is sore after getting the vaccine, try moving their arm around; it can help with pain and swelling.

You can find more information on after-care instructions [here](#).


Source: Janssen: . (2021). Fact Sheet For Healthcare Providers Administering Vaccine. Retrieved from <https://www.janssenlabels.com/emergency-use-authorization/Janssen+COVID-19+Vaccine-HCP-fact-sheet.pdf>.

Indiana Department of Health and ZOTEC - Quick Reference Guide

Documenting Vaccination

What is ZOTEC?


The Indiana Department of Health (IDOH) has partnered with Zotec during Phase 1A of COVID-19 vaccination efforts. Zotec has the available features needed to collect important data on patient demographics. You will document vaccine administration for your facility's patients using Zotec.

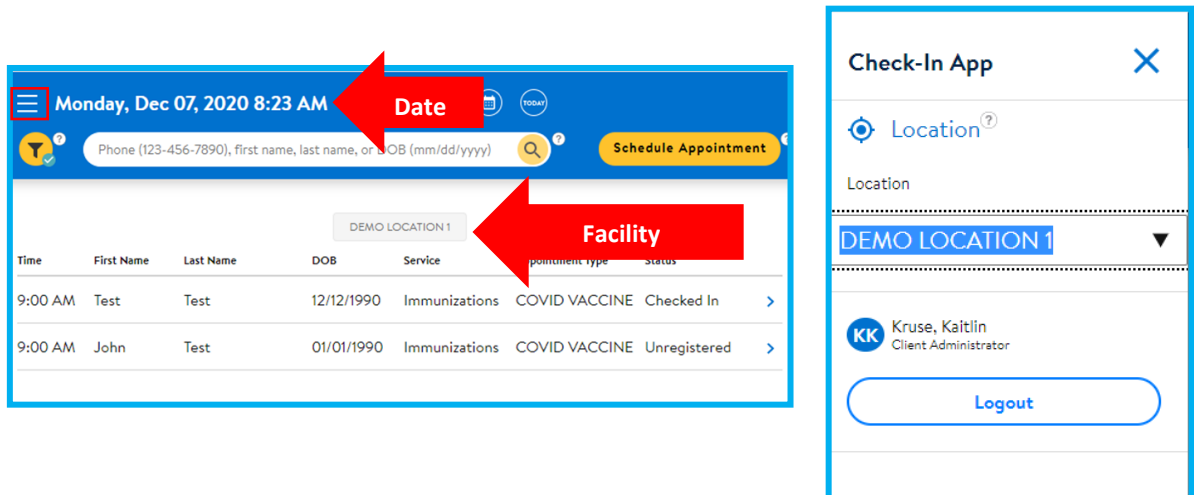
 **Questions?** Please Contact our IDOH Help Desk Portal (<https://eportal.isdh.in.gov/C19VaxHelpDeskCustomer>)



Tip: Do not use Internet Explorer. Please use Chrome or Firefox.

Documenting Vaccination

1. Login to <https://checkin.coronavirus.in.gov> using your credentials. If you do not have user access to Zotec, please refer to the **Gaining Access to Zotec (for Facilities)** Quick Reference Guide.
2. Once you have logged in you will need to confirm the facility location and current date. If the location is incorrect you can change the location by clicking on the icon  shown below.



Time	First Name	Last Name	DOB	Service	Appointment Type	Status
9:00 AM	Test	Test	12/12/1990	Immunizations	COVID VACCINE	Checked In
9:00 AM	John	Test	01/01/1990	Immunizations	COVID VACCINE	Unregistered

3. Once you have selected the correct patient you will be taken to the demographics page. There will be 2 different brands of COVID-19 Vaccine to choose from.

Pfizer will be listed as 30 Mcg/0.3MI and Moderna will be listed as 100Mcg/0.5ML.

SCHEDULED VACCINATION Checked In ?
COVID-19, Mrna, LNP-S, PF 100 Mcg/ 0.5 ML
Dose
[Add Vaccine Info](#) [Remove Vaccine](#)

SCHEDULED VACCINATION Checked In ?
COVID-19, Mrna, LNP-S, PF 30 Mcg/0.3 MI
Dose
[Add Vaccine Info](#) [Remove Vaccine](#)

[Add Additional Vaccine](#)
[Return to Appointments](#)

4. When you select **Add Vaccine Info** you will have the option to scan the vaccine information or to enter the information manually.

Scan Vaccine Packaging

[Enter Vaccine Info Manually](#)
[Decline Vaccine](#)
[Cancel](#)



Tip: Only vaccine administrators will have login access to add vaccine information.

- The name and manufacturer will be prepopulated when you open the vaccine info. **Make sure you are checking a second time to see if the manufacturer is correct.** You will input the vaccine info and provide the **temporary expiration date as 12/31/9999.**

Edit Vaccine Immunization Information

Vaccine Name
COVID-19, Mrna, LNP-S, PF, 30 Mcg/0.3 MI Dose

Manufacturer
Pfizer, Inc - Pfizer-BioNTech COVID-19 Vaccine

Lot Number
1234

Expiration Date
12/31/9999

- One you have entered the vaccine information and saved that section you will need to **Document Administration.** The patient can decline the vaccine at this point as well.

Decline Vaccine

Document Administration

- You will need to verify that all the vaccine information listed at the top is correct. When entering the administration site and route the selections available will appear after you start typing.

Add Vaccine Administration Information

Please Enter the Vaccine Administration Information

Vaccine Name	COVID-19, Mrna, LNP-S, PF, 100 Mcg/ 0.5 MI Dose
CVX Code	207
Lot Number	1234
Manufacturer	Moderna US, Inc.
VIS Publication Date	
Expiration Date	12/31/2999
Administering Facility	ISDH24
Administering Date	12/08/2020 11:14:05

Administration Site

Administration Route

Dosage Amount mL

8. Once you have filled out all the information for the vaccine administered you will have to remove the vaccine that was not administered. In this example the Pfizer vaccine was given and Moderna vaccine needs to be removed.

SCHEDULED VACCINATION Checked In ⓘ
COVID-19, Mrna, LNP-S, PF, 100 Mcg/ 0.5 MI
Dose
[Add Vaccine Info](#) [Remove Vaccine](#)

SCHEDULED VACCINATION ✓ Checked In
COVID-19, Mrna, LNP-S, PF, 30 Mcg/0.3 MI
Dose
Vaccine Name COVID-19, Mrna, LNP-S, PF, 30 Mcg/0.3...
CVX Code 208
Lot Number 1234
Manufacturer Pfizer, Inc
VIS Publication Date
Expiration Date 12/31/9999
[Edit Vaccine Information](#)

9. The patient can then be checked out by front desk registration or the vaccinator that has dual access to both registration and vaccination.

Accession IDs ⓘ
SARS-COV-2 (COVID-19) vaccine, 30 mcg/0.3mL dose : ---
[Cancel](#)
[Reschedule](#) [Complete Appointment](#)
[Print Labels](#)



Tip: The patient can choose to decline the vaccination at any point in the registration and administration process. The print labels button does not need to be used for vaccination and is for testing purposes only.

Indiana Department of Health and ZOTEC - Quick Reference Guide

Checking Out Patients in Zotec

What is ZOTEC?

The Indiana Department of Health (IDOH) has partnered with Zotec during Phase 1A of COVID-19 vaccination efforts. Zotec has the available features needed to collect important data on patient demographics. You will document vaccine administration for your facility's patients using Zotec.




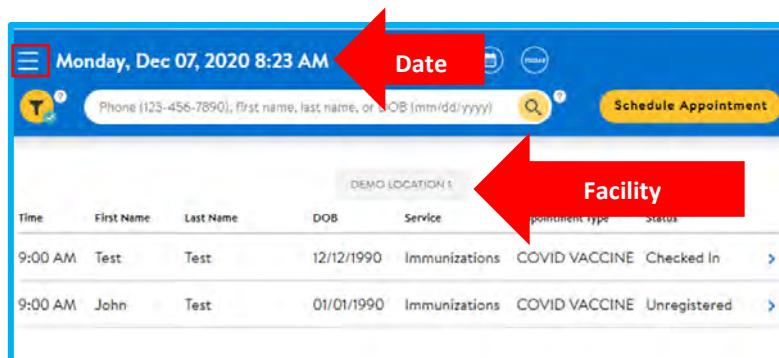
Questions? Please Contact our IDOH Help Desk Portal (<https://eportal.isdh.in.gov/C19VaxHelpDeskCustomer>)



Tip: Do not use Internet Explorer. Please use Chrome or Firefox.

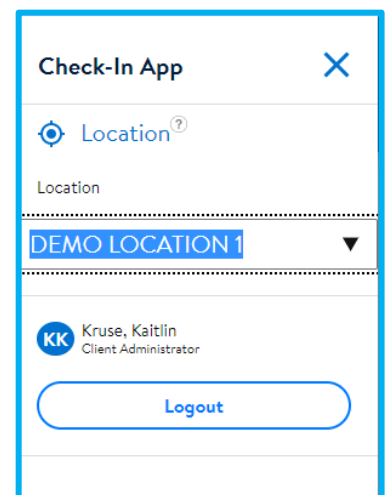
Checking Out

1. Login on <https://checkin.coronavirus.in.gov> using your credentials. If you do not have user access to Zotec, please refer to the **Gaining Access to Zotec (for Facilities)** Quick Reference Guide.
2. Once you have logged in you will need to confirm your location and current date is correct. If the location is incorrect you can change the location by clicking on the icon  shown below.



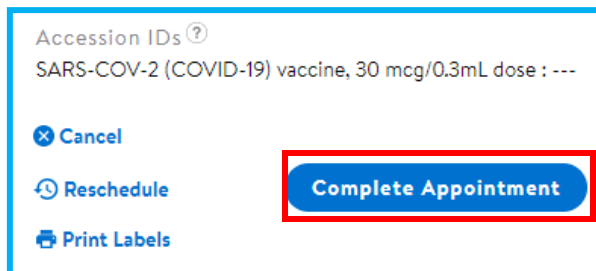
The screenshot shows the top navigation bar of the Zotec application. The date is displayed as "Monday, Dec 07, 2020 8:23 AM". A red arrow points to the date with the label "Date". Below the date is a search bar with a "Schedule Appointment" button. A dropdown menu is open, showing "DEMO LOCATION 1" selected. A red arrow points to this dropdown with the label "Facility". Below the dropdown is a table with columns: Time, First Name, Last Name, DOB, Service, Appointment type, and Status.

Time	First Name	Last Name	DOB	Service	Appointment type	Status
9:00 AM	Test	Test	12/12/1990	Immunizations	COVID VACCINE	Checked In
9:00 AM	John	Test	01/01/1990	Immunizations	COVID VACCINE	Unregistered

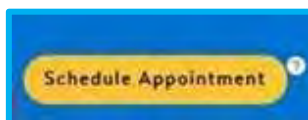


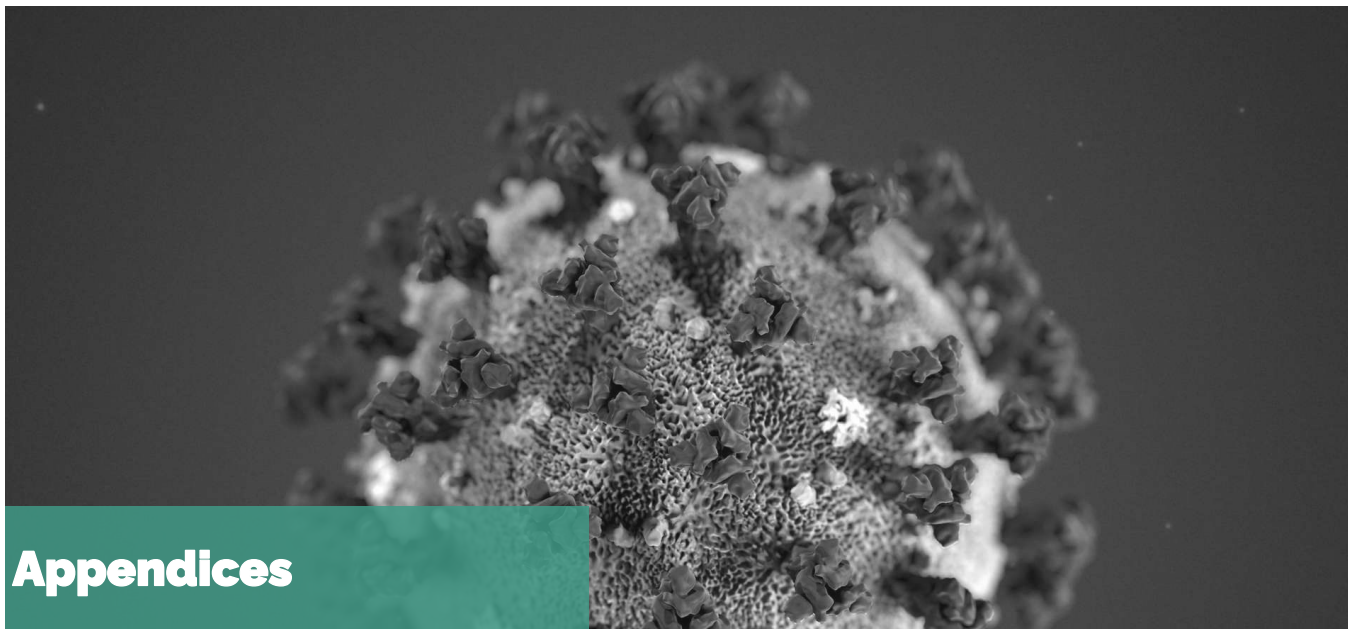
The screenshot shows the "Check-In App" interface. It features a "Location" dropdown menu with "DEMO LOCATION 1" selected. Below the dropdown is the user's name and title: "Kruse, Kaitlin Client Administrator". A "Logout" button is visible at the bottom.

3. The patient can then be checked out by registration or a vaccinator that has dual access to both registration and vaccination. The **Complete Appointment** button will appear after first checking the patient in, receiving the vaccination, and documenting all the vaccination information is complete.



4. You will need to schedule the patients next appointment in Zotec for their 2nd Dose of the vaccine. You can do this by staying on the patient demographic screen and then selecting the Schedule Appointment button on the top right of the screen. The patient's demographic information will transfer over to the next appointment scheduled.





Appendices



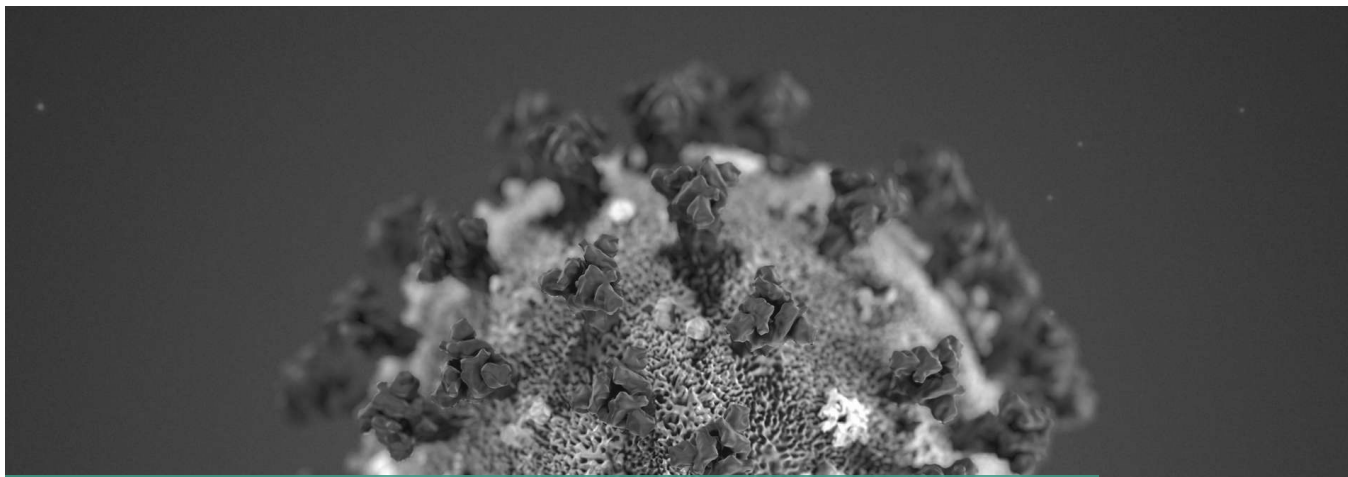
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VACCINE SAFETY AND ADMINISTRATION TOOLKIT

MARCH 2021





Steps to Take Before, During, and After Administration Checklist



Indiana
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Health

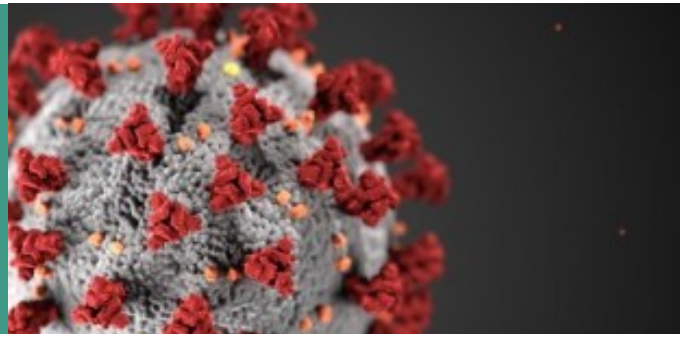
Division of
Immunization

VACCINE SAFETY AND
ADMINISTRATION
TOOLKIT

MARCH 2021



Steps to Take Before Johnson and Johnson (Janssen) COVID-19 Vaccine Administration



1. REGISTER/CHECK IN PATIENT ON ZOTEC

- Zotec is used to register patient's appointment and vaccination record documentation.
- Patient search must be completed in Zotec prior to COVID-19 vaccine administration. The data will automatically be entered into CHIRP, our state immunization registry.
- Please refer to the **Registering and Checking In the Patient** section or www.in.gov/isdh/28690.htm for more information.



2. PROVIDE RECIPIENT EUA FACT SHEET

- Required under the National Childhood Vaccine Injury Act .
- Must be given prior to administration of each dose of the vaccine. Must provide the most current version. Please check the manufacturer website for the most recent version. The Johnson and Johnson (Janssen) Provider and Recipient Fact Sheets can be found on <https://vaxcheck.inj/>.



3. SCREENING THE PATIENT

- The key to preventing the majority of serious adverse reactions is through patient screening.
- Every person who administers the COVID-19 Vaccine should screen every patient for contraindications, previous allergies, and precautions prior to administering the vaccine dose.
- The contraindications can be found on the Provider Fact Sheet. The Johnson and Johnson (Janssen) COVID-19 Vaccine website is located at <https://vaxcheck.inj/>.
- Refer to the **Screening the Patient** section for more guidance.



Steps to Take During Johnson and Johnson (Janssen) COVID-19 Vaccine Administration



1. CHECKING VIAL EXPIRATION DATE

- You can confirm the vial expiration date by looking up the lot number at <https://vaxcheck.jnj/>.
- Refer to the **Preparing the Vaccine** section for more information or visit <https://www.janssencovid19vaccine.com/hcp.html>.



2. VACCINE PREPARATION (NO DILUTION REQUIRED)

- The Johnson and Johnson (Janssen) COVID-19 Vaccine does not require dilution.
- The vaccine should be fully thawed before administration.
- Record the date and time for first use on the Johnson and Johnson (Janssen) COVID-19 Vaccine vial label. Punctured vials can be kept for 6 hours at 2°C to 8°C , or for 2 hours at room temperature (9°C to 25°C).
- Refer to the **Preparing the Vaccine** section for more information on thawing and room temperature exposure time restrictions or <https://www.janssencovid19vaccine.com/hcp.html>.



3. ADMINISTER INTRAMUSCULAR ROUTE

- Make sure staff are wearing appropriate PPE.
- Practice hand hygiene before administration, between patients, and when changing gloves (if worn), and any time your hands/gloves are soiled.
- Administer a single 0.5mL dose.
- Use appropriate gauge needle for body type (23-25 gauge).
- Administer intramuscularly in the deltoid muscle.
- Refer to the **Administering the Vaccine** section or <https://www.janssencovid19vaccine.com/hcp.html> for more information.

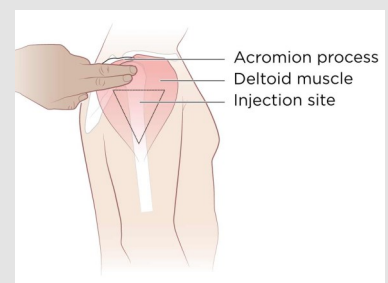


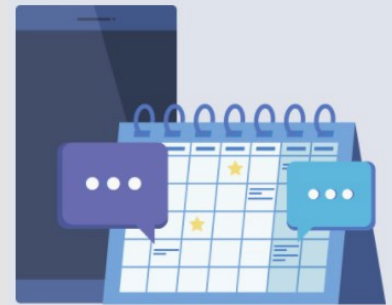
Image source: Intramuscular Injection Sites. Healthline. Medically reviewed by Deborah Weatherspoon, Ph.D., R.N., CRNA. Written by Jacquelyn Cafasso. Updated on March 7, 2019. Retrieved from <https://www.healthline.com/health/intramuscular-injection>

Steps to Take After Johnson and Johnson (Janssen) COVID-19 Vaccine Administration



1. WAIT 15 MIN. & PROVIDE COVID-19 VACCINATION RECORD CARD

- Discard all used materials in appropriate waste receptacles.
- Monitor your patient after the vaccination for 15 minutes in a designated area to monitor for potential vaccine reaction. Monitor patient for 30 minutes if known reactions or allergies to vaccines.
- Using the COVID-19 vaccination record card provided in the ancillary kit, please record the date of vaccination.
- No second dose is required and it is not interchangeable with other COVID-19 vaccines.
- Refer to the **Closing the Loop** section for more information.



2. CLOSING THE LOOP

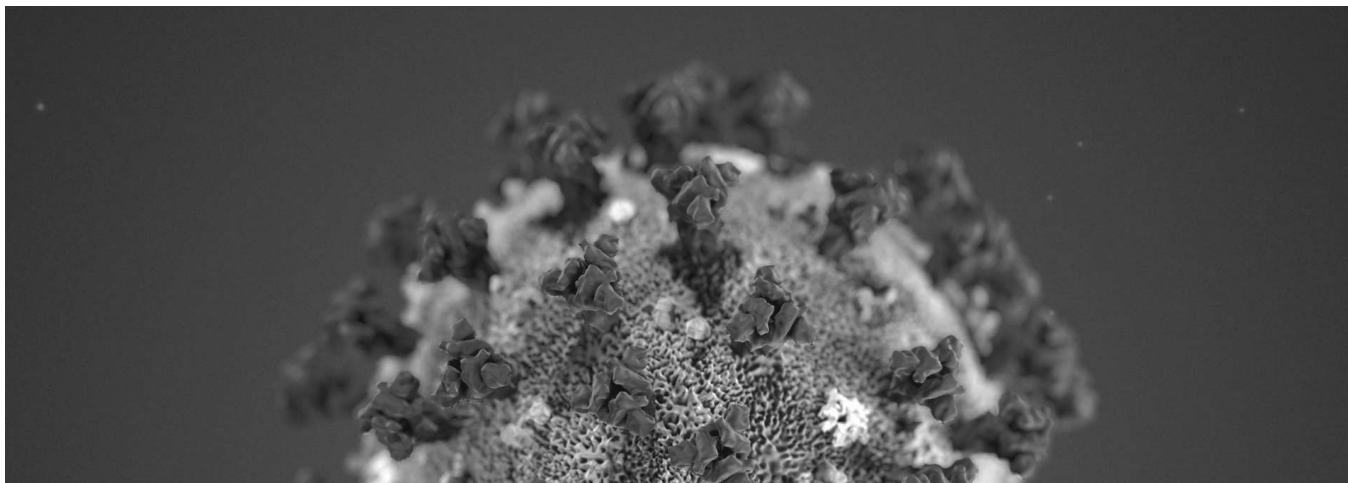
- [V-safe](#) is a new smartphone-based, after-vaccination health checker for people who receive COVID-19 Vaccines. Facilities are required to provide information on the V-safe program to vaccinated individuals and counsel them on the importance of enrolling.
- [Vaccine Adverse Event Reporting System \(VAERS\)](#) (www.vaers.hhs.gov) is an early warning system, co-managed by CDC and FDA, which monitors for potential vaccine safety problems; anyone can report possible vaccine side effects to VAERS. Click [here](#) for an informational video on VAERS.
- Refer to the **Closing the Loop** section for more information.



3. DOCUMENT VACCINATION IN ZOTEC

- Each COVID-19 dose administered must be entered into Zotec at the time of vaccination.
- Vaccinations must be reported within 24 hours of administration.
- Refer to the **Documenting the Vaccination Visit section** or www.in.gov/isdh/28690.htm for more guidance.





Vaccinating During COVID-19 Infographic



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VACCINE SAFETY AND
ADMINISTRATION
TOOLKIT

MARCH 2021



Vaccinating during COVID-19

The Indiana State Department of Health (ISDH) Immunization Division wants to ensure all providers are staying safe and keeping patients healthy, while continuing to vaccinate patients.

Below are **five (5) key standard precautionary measures** providers can take to safely vaccinate patients. These range from wearing personal protective equipment (PPE) to hand hygiene.

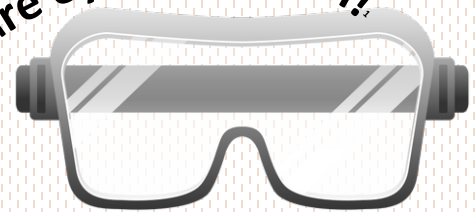
Take the necessary actions to protect you and your community!

Wear a medical facemask!



*N-95 is not required for intranasal or oral vaccines. But should be used if you suspect a patient has/been exposed to COVID-19.¹

Use secure eye protection!



*Goggles or a disposable face shield may be used.¹

Change gloves between patients!



*Wearing gloves is not a substitute for hand hygiene!
*Gloves should be utilized¹ when giving the following vaccinations:

- Intranasal
- Oral

Practice hand hygiene!



*Wash your hands before and after patient contact.¹

Throw PPE waste in a trash can!



*Do not leave used or soiled PPE on surfaces. Directly dispose used and soiled PPE in the trash.²

1. Centers for Disease Control and Prevention [CDC]. (2020, June 9). *Vaccination guidance during a pandemic: Interim guidance for immunization services during COVID-19*. Retrieved from <https://www.cdc.gov/vaccines/pandemic-guidance/index.html>
2. Centers for Disease Control and Prevention [CDC]. (2020, May 3). *General business frequently asked questions*. Retrieved from <https://www.cdc.gov/coronavirus/2019-ncov/community/general-business-faq.html#:~:text=Discard%20PPE%20into%20a%20trash,needs%20any%20additional%20disinfection.>

Additional Resources:

- Centers for Disease Control and Prevention [CDC]. (2020, April 2). *When and how to wash your hands*. Retrieved from <https://www.cdc.gov/handwashing/when-how-handwashing.html>
- Centers for Disease Control and Prevention [CDC]. (2020, June 5). *Healthcare infection prevention and control FAQs for COVID-19*. Retrieved from <https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-faq.html#asymptomatic>





Patient Education Packet



Indiana
Department
of
Health

Division of
Immunization

VACCINE SAFETY AND ADMINISTRATION TOOLKIT

MARCH 2021





**Get vaccinated.
Get your smartphone.
Get started with v-safe.**

What is v-safe?

V-safe is a smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins after you receive a COVID-19 vaccination. Through **v-safe**, you can quickly tell CDC if you have any side effects after getting the COVID-19 vaccine. Depending on your answers, someone from CDC may call to check on you. And **v-safe** will remind you to get your second COVID-19 vaccine dose if you need one.

Your participation in CDC's **v-safe** makes a difference—it helps keep COVID-19 vaccines safe.

How can I participate?

Once you get a COVID-19 vaccine, you can enroll in **v-safe** using your smartphone. Participation is voluntary and you can opt out at any time. You will receive text messages from **v-safe** around 2pm local time. To opt out, simply text "STOP" when **v-safe** sends you a text message. You can also start **v-safe** again by texting "START."

How long do v-safe check-ins last?

During the first week after you get your vaccine, **v-safe** will send you a text message each day to ask how you are doing. Then you will get check-in messages once a week for up to 5 weeks. The questions **v-safe** asks should take less than 5 minutes to answer. If you need a second dose of vaccine, **v-safe** will provide a new 6-week check-in process so you can share your second-dose vaccine experience as well. You'll also receive check-ins 3, 6, and 12 months after your final dose of vaccine.

Is my health information safe?

Yes. Your personal information in **v-safe** is protected so that it stays confidential and private.*

*To the extent **v-safe** uses existing information systems managed by CDC, FDA, and other federal agencies, the systems employ strict security measures appropriate for the data's level of sensitivity. These measures comply, where applicable, with the following federal laws, including the Privacy Act of 1974; standards enacted that are consistent with the Health Insurance Portability and Accountability Act of 1996 (HIPAA); the Federal Information Security Management Act, and the Freedom of Information Act.



Use your smartphone to tell CDC about any side effects after getting the COVID-19 vaccine. You'll also get reminders if you need a second vaccine dose.



Sign up with your smartphone's browser at vsafe.cdc.gov

OR

Aim your smartphone's camera at this code

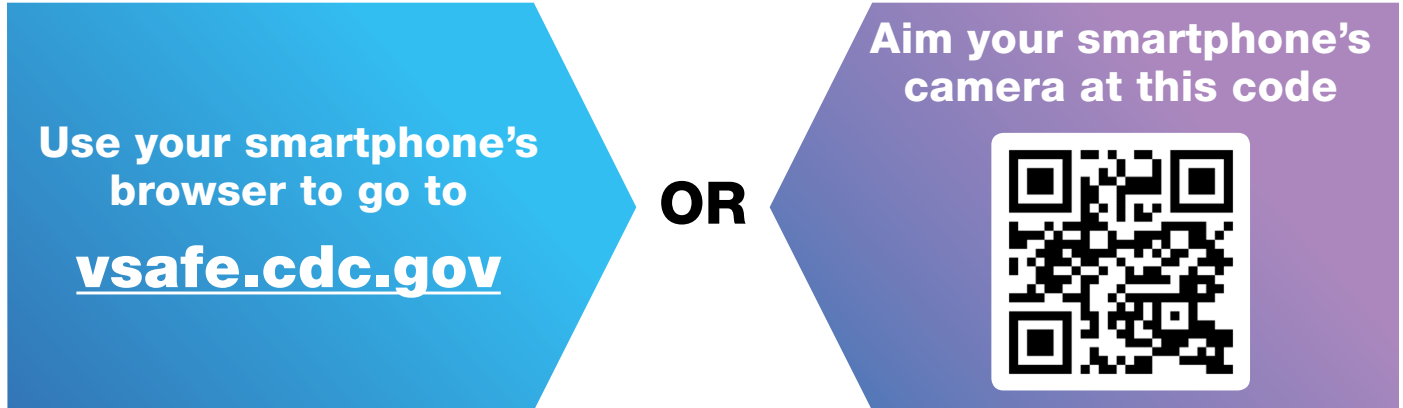


How to register and use v-safe

You will need your smartphone and information about the COVID-19 vaccine you received. This information can be found on your vaccination record card; if you cannot find your card, please contact your healthcare provider.

Register

1. Go to the **v-safe** website using one of the two options below:



2. Read the instructions. Click **Get Started**.
3. Enter your name, mobile number, and other requested information. Click **Register**.
4. You will receive a text message with a verification code on your smartphone. Enter the code in **v-safe** and click **Verify**.
5. At the top of the screen, click **Enter your COVID-19 vaccine information**.
6. Select which COVID-19 vaccine you received (found on your vaccination record card; if you cannot find your card, please contact your healthcare provider). Then enter the date you were vaccinated. Click **Next**.
7. Review your vaccine information. If correct, click **Submit**. If not, click **Go Back**.
8. **Congrats! You're all set!** If you complete your registration before 2pm local time, **v-safe** will start your initial health check-in around 2pm that day. If you register after 2pm, **v-safe** will start your initial health check-in immediately after you register — just follow the instructions.

You will receive a reminder text message from **v-safe** when it's time for the next check-in — around 2pm local time. Just click the link in the text message to start the check-in.

Complete a v-safe health check-in

1. When you receive a **v-safe** check-in text message on your smartphone, click the link when ready.
2. Follow the instructions to complete the check-in.

Troubleshooting

How can I come back and finish a check-in later if I'm interrupted?

- Click the link in the text message reminder to restart and complete your check-in.

How do I update my vaccine information after my second COVID-19 vaccine dose?

- **V-safe** will automatically ask you to update your second dose information. Just follow the instructions.

Need help with v-safe?

Call 800-CDC-INFO (800-232-4636)

TTY 888-232-6348

Open 24 hours, 7 days a week

Visit www.cdc.gov/vsafe



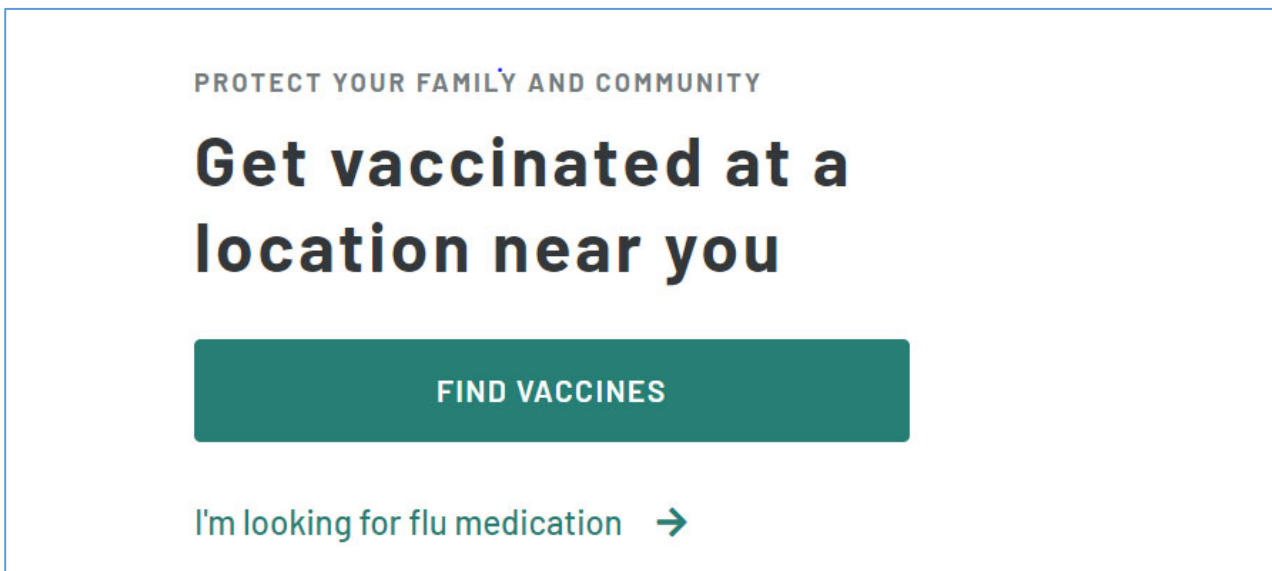
Vaccine Finder

What is Vaccine Finder?

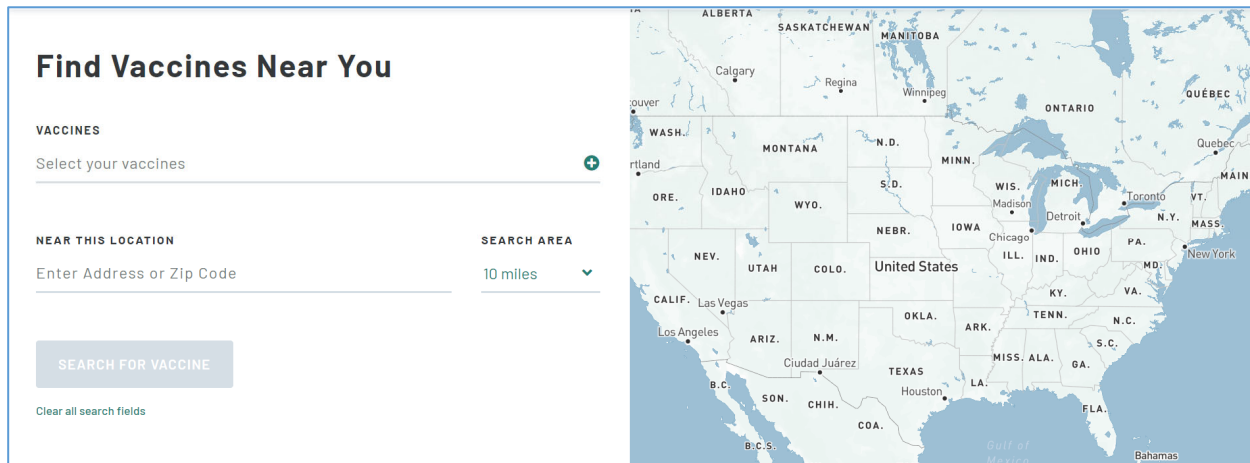
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How Do I Search for a Vaccine in Vaccine Finder?

1. Go to <https://vaccinfinder.org/>.



2. Click on "Find Vaccines" and you will be redirected to the following screen.



COVID-19 Vaccine FAQ for Patients



What is an EUA?

An Emergency Use Authorization is allowed in instances where a public health threat is identified, and there are no approved or adequate existing products. The U.S. Food and Drug Administration (FDA) carefully reviews all safety data from clinical trials and authorizes emergency vaccine use only when the expected benefits outweigh potential risks.

Source: FDA. (2021). Emergency Use Authorization for Vaccine Explained. Retrieved from www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained

Am I better off getting COVID-19 instead of getting the vaccine?

Studies show COVID-19 vaccines are safe and very effective. COVID-19 can have serious, life-threatening complications, and there is no way to predict how COVID-19 will affect a person. It is unknown whether getting COVID-19 protects you from getting the virus again or how long natural immunity lasts. Additionally, when you become infected with the virus, you risk transmitting it to the people around you.

Source: CDC. (2021). Answering Patients' Questions. Retrieved from www.cdc.gov/vaccines/covid-19/hcp/answering-questions.html

Can I stop wearing a mask or social distancing after I get the vaccine?

While the vaccine greatly reduces your risk of contracting COVID-19, you will still need to practice precautions such as wearing a mask, social distancing, and other hygiene measures until public health experts say otherwise.

Source: CDC. (2021). Answering Patients' Questions. Retrieved from www.cdc.gov/vaccines/covid-19/hcp/answering-questions.html

Could the vaccine cause long-term side effects or other problems that we do not know about yet?

The FDA and CDC are continuing to monitor the safety of the vaccine to identify any possible long-term side effects. The CDC's committee charged with evaluating vaccine safety data will take action to address any safety issues that are identified. When you receive the vaccine, you will be provided with resources to report any bad reaction to the vaccine.

Source: CDC. (2021). Answering Patients' Questions. Retrieved from www.cdc.gov/vaccines/covid-19/hcp/answering-questions.html

What is the Vaccine Adverse Event Reporting System? What is the V-safe Monitoring System?

The Vaccine Adverse Event Reporting System (VAERS) is a national monitoring system that tracks people's physical reactions after getting the shot. Healthcare workers and vaccine manufacturers are required to report adverse events that occur after vaccination in VAERS. V-safe is a new smartphone-based health monitoring system for people who receive the COVID-19 vaccine. V-safe uses text messaging and web surveys to provide check-ins with COVID-19 vaccine recipients. They will call to follow-up with anyone who reports a significant bad reaction. A VAERS report will be taken during follow-up if appropriate.

Source: CDC. (2021). Ensuring the Safety of COVID-19 Vaccines in the United States. Retrieved from www.cdc.gov/coronavirus/2019-ncov/vaccines/safety.html

Johnson and Johnson (Janssen) COVID-19 Vaccine

How is the Johnson and Johnson (Janssen) COVID-19 vaccine different from the other two COVID-19 vaccines?

The Johnson and Johnson (Janssen) COVID-19 vaccine differs from other COVID-19 vaccines, because it uses an adenovirus instead of mRNA to stimulate the body's natural immune response. You might be familiar with adenoviruses if you've had the common cold. Adenovirus vaccines use a modified version of a different virus as a vector to deliver instructions for making the spike protein found on the surface of the COVID-19 virus. The genetic material delivered by the adenovirus does not enter the cell nucleus and does not integrate into a person's DNA. Viral vectors, such as adenoviruses, have been used in vaccines since the 1970s against a number of infectious diseases including influenza, Zika Virus, and Ebola.

Source: CDC. (2021). Understanding and Explaining Viral Vector COVID-19 Vaccines.. Retrieved from www.cdc.gov/vaccines/covid-19/hcp/viral-vector-vaccine-basics.html

Will the vaccine make you sick?

The vaccine cannot give someone COVID-19, because it does not contain the COVID-19 virus. Side effects can occur with any vaccine. They are a sign that the immune system is working to build up protection against a virus. Symptoms from the vaccine typically resolve within a week, but you should talk to your doctor about if your symptoms do not go away.

Source: CDC. (2021). Answering Patients' Questions. Retrieved from www.cdc.gov/vaccines/covid-19/hcp/answering-questions.html

Is the Johnson and Johnson (Janssen) COVID-19 vaccine safe?

The FDA and CDC's Advisory Committee on Immunization Practices (ACIP) carefully review all safety data from clinical trials before authorizing emergency vaccines and recommend the vaccine for use only when the expected benefits outweigh potential risks. The FDA and CDC will continue to monitor the safety of these vaccines. There is a reporting system in place to identify any possible side effects or adverse events.

Source: CDC. (2021). Answering Patients' Questions. Retrieved from www.cdc.gov/vaccines/covid-19/hcp/answering-questions.html

How is the Johnson and Johnson (Janssen) COVID-19 vaccine administered?

The Johnson and Johnson (Janssen) COVID-19 vaccine is administered intramuscularly with a single injection. After administration, the person receiving the vaccine will be monitored for 15 minutes by clinic staff.

Source: CDC. (2021). Answering Patients' Questions. Retrieved from www.cdc.gov/vaccines/covid-19/hcp/answering-questions.html

Johnson and Johnson (Janssen) COVID-19 Vaccine

What are the ingredients in the Johnson and Johnson (Janssen) COVID-19 vaccine?

The Johnson and Johnson (Janssen) COVID-19 vaccine contains: citric acid monohydrate (0.14 mg), trisodium citrate dihydrate (2.02 mg), ethanol (2.04 mg), 2-hydroxypropyl- β -cyclodextrin (HBCD) (25.50 mg), polysorbate-80 (0.16 mg), sodium chloride (2.19 mg).

Source: Janssen (2021). Fact Sheet for Healthcare Providers. Retrieved from www.janssenlabels.com/emergency-use-authorization/Janssen+COVID-19+Vaccine-HCP-fact-sheet.pdf.

What are the potential risks and side effects of the Johnson and Johnson (Janssen) COVID-19 Vaccine?

Side effects that have been reported with the Johnson and Johnson (Janssen) Vaccine include:

- Injection site pain
- Headache
- Fatigue
- Muscle aches
- Nausea

In very rare cases, the Johnson and Johnson (Janssen) COVID-19 vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the Johnson and Johnson (Janssen) COVID-19 vaccine. For this reason, your vaccination provider will ask you to stay at the clinic for 15 minutes after you receive the shot for monitoring.

Signs of a severe allergic reaction can include difficulty breathing, swelling of your face and throat, a fast heartbeat, a bad rash all over your body, dizziness, and weakness. These may not be all the possible side effects of the Johnson and Johnson (Janssen) COVID-19 vaccine. Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Johnson and Johnson (Janssen) COVID-19 vaccine.

Source: Janssen (2021). Fact Sheet for Healthcare Providers. Retrieved from www.janssenlabels.com/emergency-use-authorization/Janssen+COVID-19+Vaccine-HCP-fact-sheet.pdf.

If I have already had COVID-19, how long do I need to wait to get the COVID-19 Vaccine?

If you previously had a COVID-19 infection, you can receive the COVID-19 vaccine. People with a current COVID-19 infection should wait until they have recovered from the illness and their isolation period is over to get the vaccine. If you received monoclonal antibodies or convalescent plasma as part of COVID-19 treatment, it is recommended that you wait 90 days before vaccination. If you did not receive any of these treatments for a COVID-19 infection, there is no recommended minimum amount of time between infection and vaccination.

Source CDC. (2021). Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States. Retrieved from: www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html

Johnson and Johnson (Janssen) COVID-19 Vaccine

Can I get the Johnson and Johnson (Janssen) COVID-19 vaccine if I'm pregnant or breastfeeding?

There are currently no available data on the safety of the Johnson and Johnson (Janssen) COVID-19 vaccines in pregnant individuals. However, studies are ongoing and expected to be available soon. Pregnant people who develop a COVID-19 infection are at increased risk of poor pregnancy outcomes. Pregnant people may choose to be vaccinated. A conversation between the patient and their doctor may help with decisions of whether or not to vaccinate. When making a decision, pregnant people should consider their level of COVID-19 transmission in their community, their own level of exposure to COVID-19, the risks of a COVID-19 infection to the patient and potential risk to the fetus, and the side effects of the vaccine. There are no data on the safety of the Johnson and Johnson (Janssen) COVID-19 vaccine in lactating people. A lactating person may choose to be vaccinated.

Source CDC. (2021). Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States. Retrieved from: [cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html](https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html)

Can I get the vaccine if I have had food or other allergy?

If you have a history of food, pet, insect, venom, environmental, latex, or other allergies not related to vaccines or injectable therapies you can still receive the Johnson and Johnson (Janssen) COVID-19 vaccine. A 30 minute observation period following vaccination is recommended for anyone with a history of a severe allergic reactions.

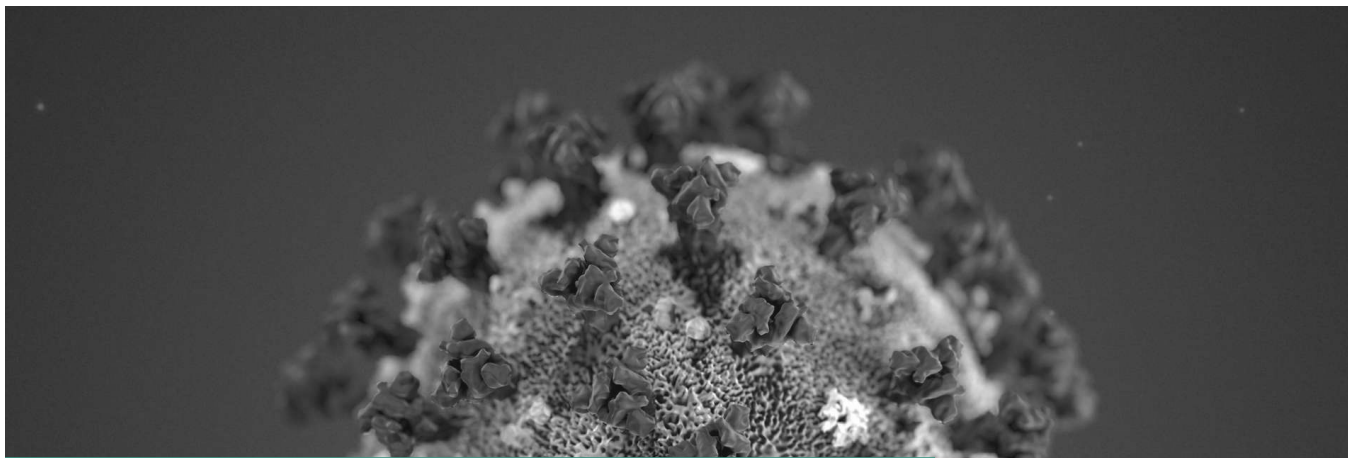
Source CDC. (2021). Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States. Retrieved from: [cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html](https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html)



Point your smartphone's camera at this QR code to see the complete Johnson & Johnson fact sheet.

For additional information visit:
ourshot.in.gov





Vaccine Safety and Administration Additional Resources



Indiana
Department
of
Health

Division of
Immunization

VACCINE SAFETY AND ADMINISTRATION TOOLKIT

MARCH 2021



Johnson and Johnson (Janssen) and CDC/FDA/HHS Resources



Johnson and Johnson (Janssen) COVID-19 Website

The manufacturer website contains the most recent patient EUA and provider fact sheet. The fact sheet contains information on storage and handling, safety and administration, and vaccine preparation.

[Webpage: Janssen COVID-19 Vaccine Patient EUA and Provider Fact Sheet](#)

[Webpage: Janssen Dosing and Administration](#)

[Webpage: Janssen Resources](#)

[Webpage: Janssen Q&A](#)

CDC Resources

Find information for COVID-19 vaccination administration, storage and handling, reporting, and patient education for each specific vaccine.

[Webpage: Interim Clinical Considerations for Use of COVID-19 Vaccines](#)

[Webpage: COVID-19 Vaccination Clinical Resources for Each COVID-19 Vaccine](#)

[Webpage: COVID-19 Vaccine Training: General Overview of Immunization Best Practices for Healthcare Providers](#)

[Webpage: Vaccine Adverse Event Reporting System](#)

[Webpage: V-Safe After Vaccination Health Checker](#)

[PDF: Product Information Guide for COVID-19 Vaccines and Associated Products](#)

[PDF: Needle Gauge and Length Chart](#)

Actualized: March 2021

Vaccine Safety and Administration Links and Other Trainings



Vaccine Safety and Administration Resources

Vaccine Safety

[Webpage: CDC COVID-19 Vaccines](#)

[Webpage: V-safe & Ensuring the Safety of COVID-19 Vaccines in the United States](#)

[Vaccine Adverse Event Reporting System](#)

[Webpage: Vaccination Guidance During a Pandemic: Interim guidance for immunization services during COVID-19](#)

[Video: FDA What is an EUA?](#)

Vaccine Administration

[Webpage: CDC You Call the Shots – Vaccine Administration](#)

[Webpage: COVID-19 Vaccine Training: General Overview of Immunization Best Practices for Healthcare Providers](#)

[PDF: Skills Checklist for Vaccine Administration Module](#)

[PDF: How to Administer Intramuscular Injections](#)

[PDF: Product Information Guide for COVID-19 Vaccines and Associated Products](#)

Patient Education Resources

[Webpage: CDC COVID-19 Vaccination Communication Toolkit](#)

[Webpage: Answering Patients' Questions](#)

[Webpage: Emergency Use Authorization](#)

Where to Find More Safety and Administration Resources

[Webpage: Immunizations MMWR](#)

Updated: March 2021

Johnson and Johnson (Janssen) Contact List



Johnson and Johnson (Janssen)

[Janssen COVID-19 Vaccine Website](#)

	Phone Number	Email/Website	Help For
Shipment Issues/ General Product Inquiries	1-800-565-4008	www.janssencovid19vaccine.com	General Questions
Adverse Event Reporting to VAERS and Johnson and Johnson Inc.	Phone: 1-800-565-4008 Fax: 1-215-293-9955	JNJvaccineAE@its.jnj.com	Additional reporting of side effects related to COVID-19 vaccine

IDOH Contact List



IDOH

[IDOH COVID-19 Vaccine Training Website](#)

[IDOH Immunization Division COVID-19 Vaccine Training on LMS:INvest](#)

[IDOH Vaccinator Questions Portal](#)

	Phone Number	Hours	Email/Website
IDOH Epidemiology Resource Center	877-826-0011	8:00AM-5:00PM	https:// www.coronavirus.in.gov/2397.ht m

Updated: March 2021