MODERNA COVID-19 VACCINE

Indiana Department of Health

Division of **Immunization**

VACCINE SAFETY AND ADMINISTRATION **TOOLKIT**

DECEMBER 2020

Disclaimer

Please refer to the manufacturer, Moderna, www.modernatx.com, for most up-to-date information. This toolkit will be updated as the website and Fact Sheets are updated.

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Actualized: December 2020

MODERNA COVID-19 VACCINE

VACCINE SAFETY AND ADMINISTRATION TOOLKIT

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Introduction

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

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

.1 Moderna 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 Moderna COVID-19 Vaccine or their caregiver, information consistent with the "Fact Sheet for Recipients and Caregivers" prior to the individual receiving Moderna 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 "Moderna 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 Moderna COVID-19 Vaccine to recipients.

*Please refer to Fact Sheet for more information on known adverse events
Source: Moderna Fact Sheet For Healthcare Providers Administering Vaccine (Vaccination Providers). Revised December 2020. Retrieved from https://www.modernatx.com/covid19vaccine-eua/providers/

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 Moderna 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: Moderna. (2020). Fact Sheet For Healthcare Providers Administering Vaccine. Retrieved from https://www.modernatx.com/covid19vaccine-eua/providers/

Vaccine Safety and Administration Checklist

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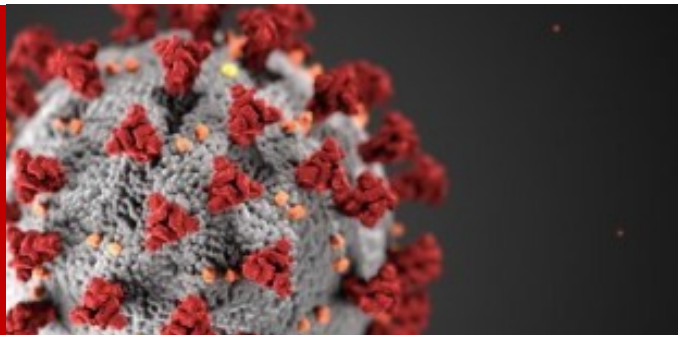
Steps to Take Before Moderna COVID-19 Vaccine Administration



1. REGISTER/CHECK IN PATIENT ON ZOTEC (PHASE 1A) OR ACCENTURE

- Zotec (Phase 1A) or Accenture is used to register patient's appointment and vaccination record documentation
- Patient search must be completed in Zotec (Phase 1A) or Accenture prior to COVID-19 vaccine administration. The data will automatically be entered into CHIRP, our state immunization registry.
- Patient search in Zotec (Phase 1A) or Accenture is critical for second dose patients to ensure the same COVID-19 vaccine product is used for the second dose. 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 Moderna Provider and Recipient Fact Sheets can be found on www.modernatx.com.
- This also serves as an opportunity to educate the patient and address any questions or concerns patients may have. Refer to the **Patient Education section** or www.modernatx.com for more information.

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 Moderna COVID-19 Vaccine website is located at www.modernatx.com.
- Refer to the **Screening the Patient section** for more guidance.

Steps to Take During Moderna COVID-19 Vaccine Administration

1. CHECKING VIAL EXPIRATION DATE

- You can confirm the vial expiration date by looking up the lot number at https://www.modernatx.com/covid19vaccine-eua/providers/vial-lookup
- Refer to the **Preparing and Thawing the Vaccine section** for more information or visit www.modernatx.com

2. VACCINE PREPARATION (NO DILUTION REQUIRED)

- The Moderna COVID-19 Vaccine does not require dilution.
- Thaw vaccine at room temperature or in refrigerated conditions
- After thawing, let vial stand at room temperature for 15 minutes before administering. After thawing, do not refreeze the vial(s)
- Record the date and time for first use on the Moderna COVID-19 Vaccine vial label. Discard vial after 6 hours
- Refer to the **Preparing and Thawing the Vaccine section** for more information on thawing and room temperature exposure time restrictions or www.modernatx.com

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 at first visit.
- Use appropriate gauge needle for body type (23-25 gauge).
- Administer intramuscularly in the deltoid muscle.
- Refer to the **Administering the Vaccine section** or www.modernatx.com for more information.

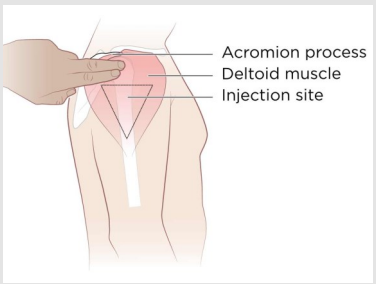
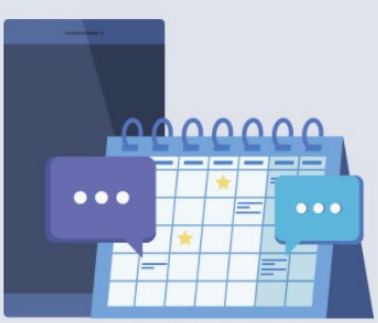


Image source: Intramuscular Injection Sites. Healthline. Medically reviewed by Deborah Weatherspoon, Ph.D., R.N., CRNA. Written by Jacquelyn Cafasso. Updated on March 7, 2019. Retrieved from https://www.healthline.com/health/intramuscular-injection

Steps to Take After Moderna 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.
- Using the COVID-19 vaccination record card provided in the ancillary kit, please record the time and day for second-dose appointment.
- The second dose is administered 28 days later and it must be Moderna COVID-19 vaccine; 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 (PHASE 1A) OR ACCENTURE

- Each COVID-19 dose administered must be entered into Zotec (Phase 1A) or Accenture 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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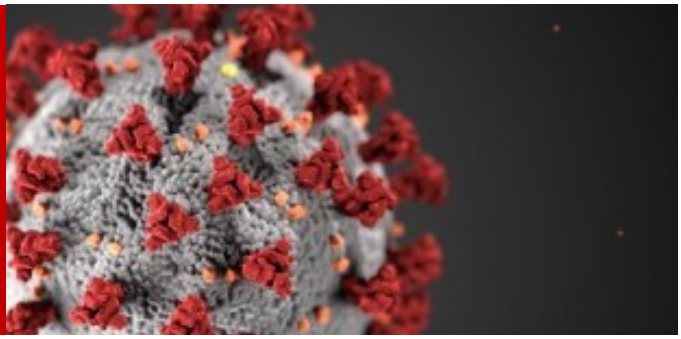
Infection Control During the COVID-19 Pandemic



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 (October 2020). General Practices for the Safe Delivery of Vaccination Services. Retrieved from https://www.cdc.gov/vaccines/pandemic-guidance/index.html

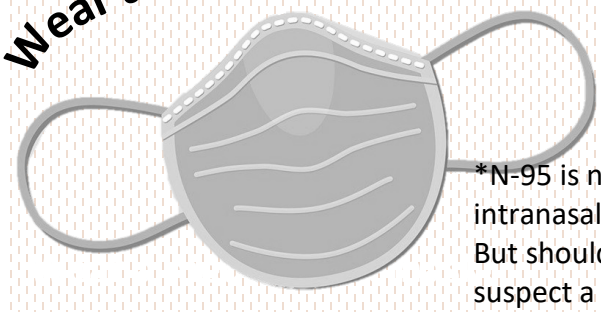
Vaccinating during COVID-19

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 vaccine patients. These range from wearing personal protective equipment (PPE) to hand hygiene.

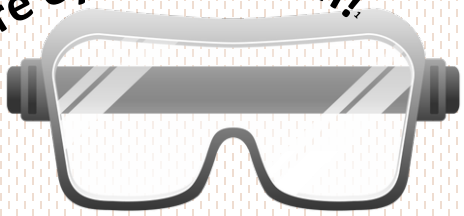
Take the necessary actions to protect you and your community!

Wear a medical facemask![2]



*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![1]



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

Change gloves between patients![1]

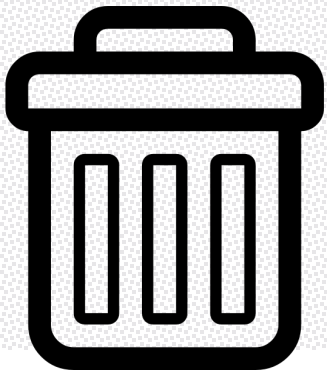
*Wearing gloves is not a substitute for hand hygiene!
*Gloves should be utilized[1] when giving the following vaccinations:

- Intranasal
- Oral

Practice hand hygiene![1]

*Wash your hands before and after patient contact.[1]

Throw PPE waste in a trash can![2]



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

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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) Dilute with 21 gauge or smaller needle and draw up and administer with appropriate gauge needle
5) Remove any air bubbles in the syringe, for safety needle of appropriate size
6) Ensure the proper size needle/gauge is being used for injection
7) Maintain aseptic technique throughout, clean rubber stopper on vial if prior to piercing the seal
8) Identify landmarks for proper placement (deltoid, anterolateral thigh, etc.).
9) 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 (Phase 1A) or Accenture.

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.

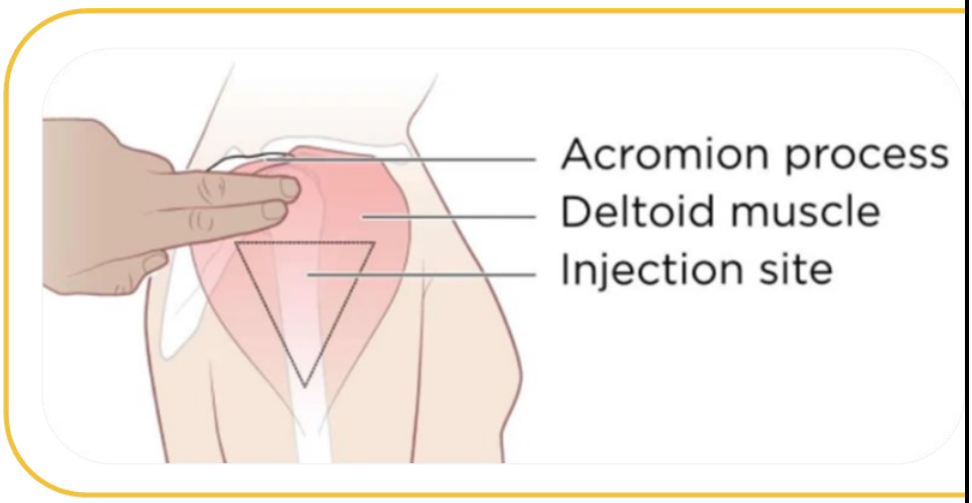

Image source: Intramuscular Injection Sites. Healthline. Medically reviewed by Deborah Weatherspoon, Ph.D., R.N., CRNA. Written by Jacquelyn Cafasso. Updated on March 7, 2019. Retrieved from https://www.healthline.com/health/intramuscular-injection

Source: CDC. (2020). 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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DECEMBER 2020

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 had 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 licenses vaccines, and detect unexpected or unusual patterns in adverse event reports.

Source: CDC. (2020). 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:
• Missing work • Being unable to preform normal daily activities • Getting care from a doctor or other health professional	• 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 ModernaTX Inc. at the contact information provided below.

Email	Fax Number	Telephone Number
ModernaPV@modernatx.com	1-866-599-1342	1-866-663-3762

Source: CDC. (2020). 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	**Option 2:** Download a Writable PDF Form and Upload at https://vaers.hhs.gov/uploadFile/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.	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)
- Patient ID can be retrieved from CHIRP or email request to Immunize@isdh.in.gov
- 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.

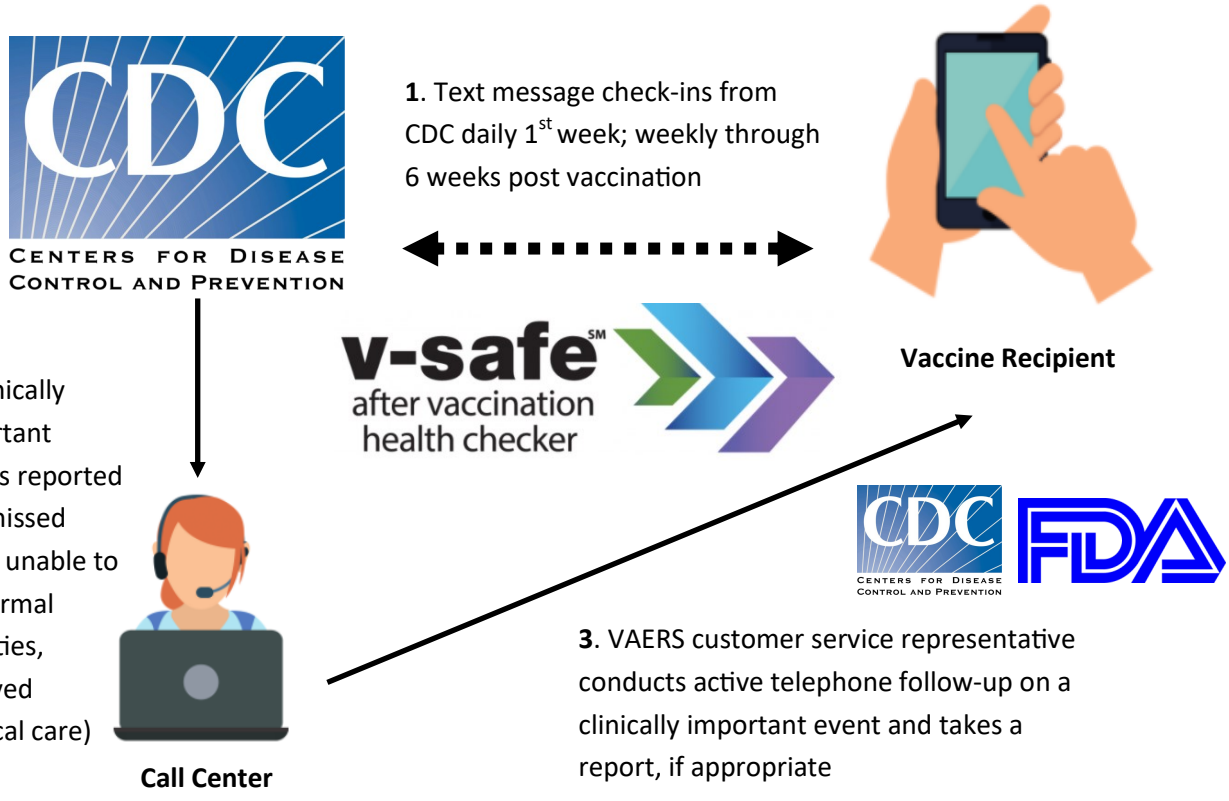
Source: CDC. (2020). Vaccine Adverse Reporting System (VAERS). Retrieved from https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vaers/index.html

V-safe 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. (2020). V-safe After Vaccination Health Checker. Retrieved fromhttps://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. (2020). V-safe After Vaccination Health Checker. Retrieved fromhttps://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html

Before COVID-19 Vaccine Administration

Indiana Department of Health

Division of **Immunization**

VACCINE SAFETY AND ADMINISTRATION **TOOLKIT**

DECEMBER 2020

Indiana Department of Health and ZOTEC - Quick Reference Guide

Gaining User Access to Zotec (for Facilities)

What is ZOTEC?

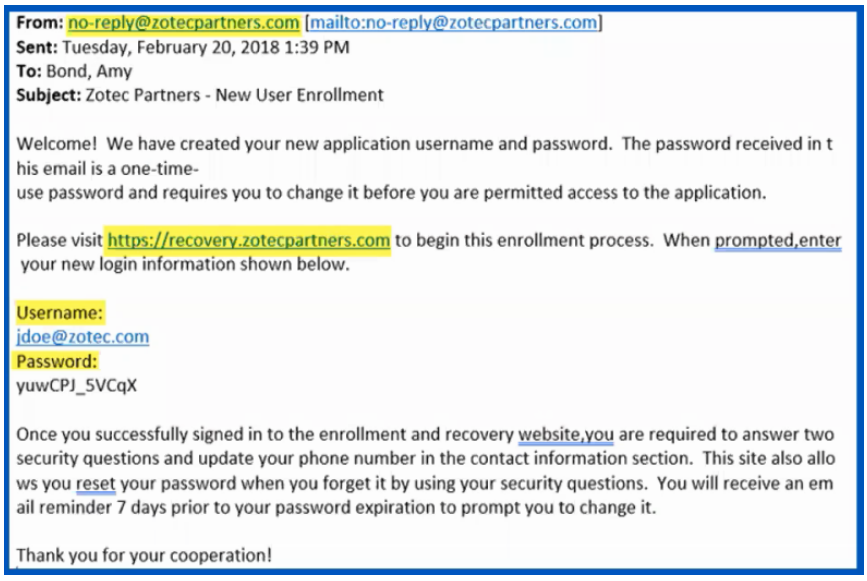
The Indiana Department of Health (IDOH) has partnered with Zotec during Phase 1A of COVID-19 vaccination efforts. Zotec has the available features needed to collect important data on patient demographics. You will document vaccine administration for your facility's patients using Zotec.

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 with the subject line New User Enrollment.



From: no-reply@zotecpartners.com [mailto:no-reply@zotecpartners.com]
Sent: Tuesday, February 20, 2018 1:39 PM
To: Bond, Amy
Subject: Zotec Partners - New User Enrollment

Welcome! We have created your new application username and password. The password received in t his email is a one-time-
use password and requires you to change it before you are permitted access to the application.

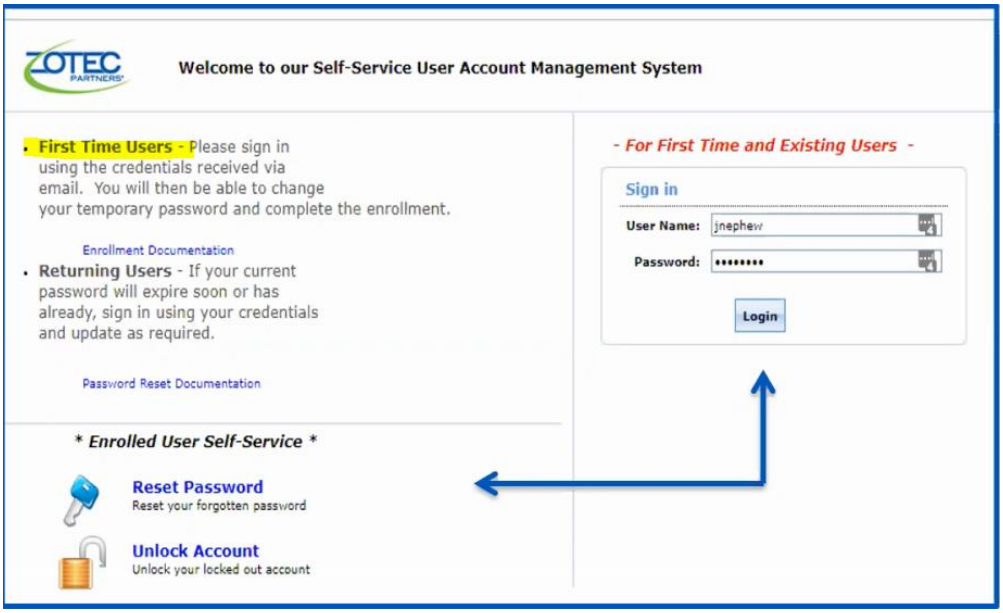
Please visit https://recovery.zotecpartners.com to begin this enrollment process. When prompted,enter your new login information shown below.

Username:
jdoe@zotec.com
Password:
yuwCPJ_5VCqX

Once you successfully signed in to the enrollment and recovery website,you are required to answer two security questions and update your phone number in the contact information section. This site also allo ws you reset your password when you forget it by using your security questions. You will receive an em ail reminder 7 days prior to your password expiration to prompt you to change it.

Thank you for your cooperation!

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: jnephew
Password:
Login

Indiana Department of Health and ZOTEC - Quick Reference Guide

Registering and Checking In Patients in Zotec

What is ZOTEC?

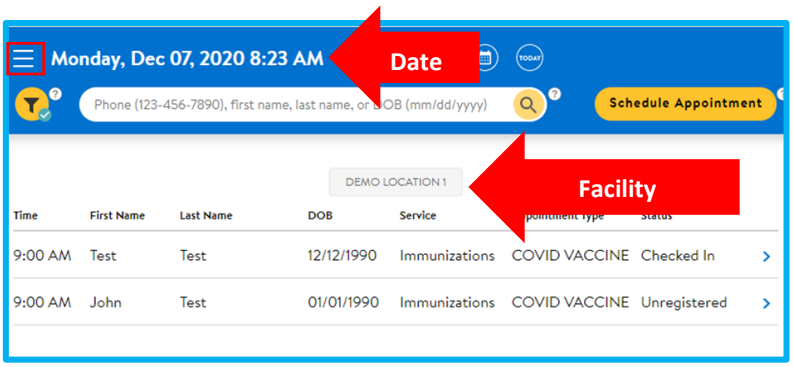
The Indiana Department of Health (IDOH) has partnered with Zotec during Phase 1A of COVID-19 vaccination efforts. Zotec has the available features needed to collect important data on patient demographics. You will document vaccine administration for your facility's patients using Zotec.

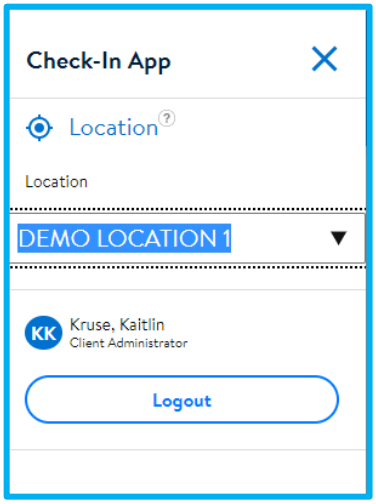
Questions? Please Contact our IDOH Help Desk Portal (https://eportal.isdh.in.gov/C19VaxHelpDeskCustomer)

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

Registering Patients

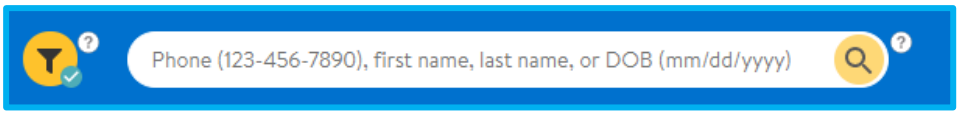
1. Login on https://checkin.coronavirus.in.gov using your credentials. If you do not have user access to Zotec, please refer to the **Gaining Access to Zotec (for Facilities)** Quick Reference Guide.
2. Once you have logged in you will need to confirm your location and current date is correct. If the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





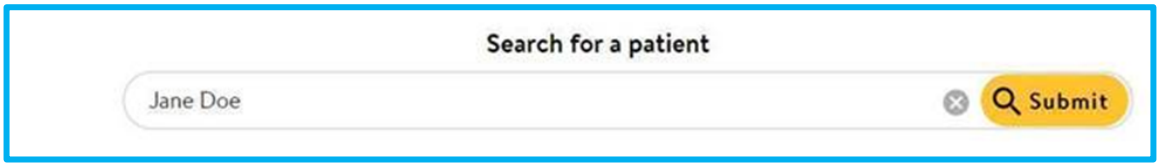
Indiana Department of Health | Division of Immunization

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)



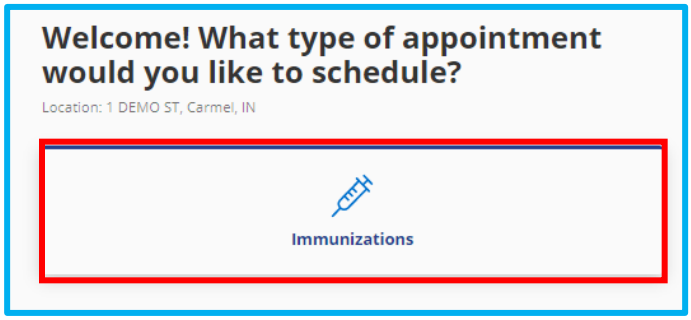
4. If you cannot find the patient, you can create a new patient by clicking the yellow **Scheduling Appointment** button on the upper right-hand corner.

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

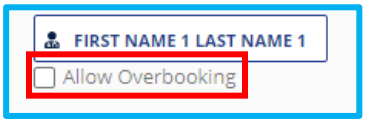


6. Click the **Continue as New** button on the bottom of the page.

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.

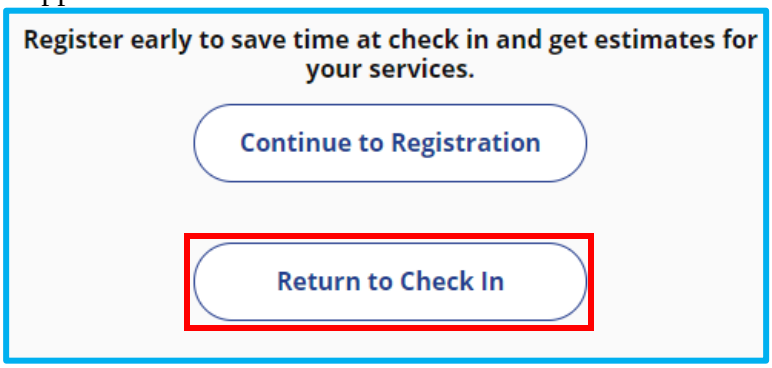


9. The next page will ask for recipient information (First name, last name, date of birth, sex, contact information) **For residents, please enter your facility email and phone number**.

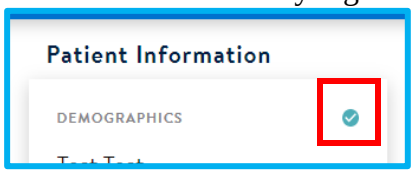
10. After you have verified that all the information is correct, click **Confirm Appointment.**

Checking In Patients

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



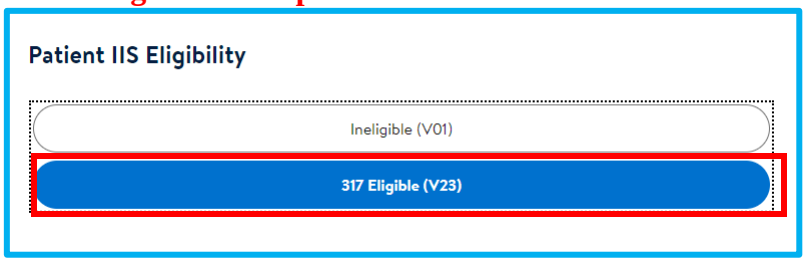
12. You will be redirected to the main screen main screen where you should see the patient listed next to their time lot. Select that patient and EDIT **the demographic areas until you have a green check mark** to successfully register a patient for testing.



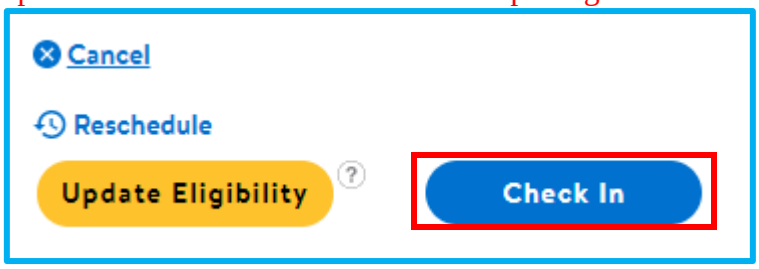
13. Make sure you edit each section on the main screen
    a. Demographics
    b. Additional Demographics
    c. Fill out the insurance information so the facility can bill insurance for the administration. (The patient will not be charged for this visit)
    d. Consents - choose **Collect Manually** 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.**



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.



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 and Operation Warp Speed

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. Moderna 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 Moderna's Fact Sheet For Recipients and Caregivers.

Source: FDA. (2020). Emergency Use Authorization for Vaccines Explained. Retrieved from https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained

Source: HHS. (2020). Fact Sheet: Explaining Operation Warp Speed. Retrieved from https://www.hhs.gov/coronavirus/explaining-operation-warp-speed/

Operation War Speed's goal is to make a safe and effective COVID-19 vaccine widely available as soon as possible. In traditional vaccine development timelines, manufacturing steps are carried out in a sequential basis, however, with Operation Warp Speed manufacturing steps are carried out simultaneously. This increases the financial risk, but does not compromise the safety of the vaccine. Please refer to this educational video from FDA on "What is an EUA?".

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 Moderna COVID-19 Vaccine and provide the following:

- FDA has authorized the emergency use of the Moderna COVID-19 Vaccine, which is not an FDA-approved vaccine.
- The recipient or their caregiver has the option to accept or refuse the Moderna COVID-19 Vaccine.
- The significant known and potential risks and benefits of the Moderna 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: ModernaTX. (2020). Clinical Trials. Retrieved from https://www.modernatx.com/covid19vaccine-eua/eua-fact-sheet-providers.pdf

Adverse Reactions or Side Effects

Side effects that have been reported with the Moderna 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
- swollen lymph nodes (lymphadenopathy)

There is a remote chance that the Moderna 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 Moderna 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 Moderna COVID-19 Vaccine. Serious and unexpected side effects may occur. Moderna 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.

Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Moderna 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 Moderna COVID-19 Vaccine	
Included Pain at the Injection Site	92.0%
Fatigue	70.0%
Headache	64.7%
Muscle Pain	61.5%
Joint Pain	46.4%
Chills	45.4%
Nausea	23.0%
Axillary Swelling/ tenderness	19.8%
Fever	15.5%
Injection Site Swelling	14.7%
Injection Site Erythema	10.0%
Lymphadenopathy	1.1%

Clinical Trail Data

*Available data on Moderna 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 Moderna COVID-19 Vaccine on the breastfed infant or on milk production/excretion

Source: ModernaTX. (2020). Fact Sheet For Healthcare Providers Administering Vaccine. Retrieved from hhttps://www.modernatx.com/covid19vaccine-eua/eua-fact-sheet-providers.pdf

COVID-19 Vaccine Hesitancy

What is Vaccine Hesitancy?

Vaccine hesitancy is the reluctance or refusal to vaccinate despite the availability of vaccines. Many patients may feel reluctant about getting the COVID-19 Vaccine. Often this reluctance stems from lack of information or misinformation about the vaccine. As a healthcare provider, your recommendation plays a significant role in a patient's decision to vaccinate.

Resources

- CDC COVID-19 Communications Toolkit
- Answering Patients' Questions
- Emergency Use Authorization Explained
- V-Safe Monitoring System
- Moderna Factsheet for Recipients & Caregivers

Building Vaccine Confidence

Start Conversations About the COVID-19 Vaccine Early	♦ Set expectations about vaccine availability. ♦ The goal is that the vaccine will be available for everyone, however, not everyone will be able to get vaccinated right away.
Give a Strong Recommendation	♦ Patients rank healthcare providers as their most trusted source for vaccine information. Your strong recommendations is critical for vaccine acceptance.
Use Empathy and Understanding	♦ Acknowledge the disruptions that COVID-19 has caused in all of our lives.
Listen and Respond to Patient Questions	♦ Make it clear that you want to answer questions patients' questions so that they feel confident choosing to get vaccinated. ♦ Address patients' concerns and answer questions in a way they can understand it.
Continue the Conversation	♦ Just because a patient refuses the vaccine at one appointment does not mean they will refuse it at future appoints. ♦ Encourage patients to read additional information that you give them about the COVID-19 Vaccine. ♦ Continue to remind patients about the importance of getting a COVID-19 vaccine during future routine visits.

COVID-19 Vaccine FAQ for Providers

Indiana Department of Health

What is an EUA?

An Emergency Use Authorization is allowed in instances where a public health threat is identified and there is no approved or adequate existing products. The Food and Drug Administration (FDA) carefully reviews all safety data from clinical trials and an authorizes emergency vaccine use only when the expected benefits outweigh potential risks. For more information about EUAs visit https://www.youtube.com/watch?v=iGkwaESsGBQ.

Source: FDA. (2020). Emergency Use Authorization for Vaccine Explained. Retrieved from https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained

What is Operation Warp Speed?

Operation War Speed's goal is to make a safe and effective COVID-19 vaccine widely available as soon as possible. In traditional vaccine development timelines, manufacturing steps are carried out in a sequential basis, however, with Operation Warp Speed manufacturing steps are carried out simultaneously. This increases the financial risk, but does not compromise the safety of the vaccine.

Source: HHS. (2020). Fact Sheet: Explaining Operation Warp Speed. Retrieved from https://www.hhs.gov/coronavirus/explaining-operation-warp-speed/index.html

Is Natural Immunity better than vaccine-induced immunity? Am I better off getting COVID-19 instead of getting the vaccine?

Natural immunity comes from fighting off a virus, however, COVID-19 can have serious, life-threatening complications, there is no way to know how COVID-19 will affect a person. There are potential serious long-term health issues after recovering from COVID-19. It is not known whether getting COVID-19 protects you from getting the virus again in the future, 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. (2020). Answering Patients' Questions. Retrieved from https://www.cdc.gov/vaccines/covid-19/hcp/answering-questions.html

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

While the vaccine greatly reducing your risk of contracting COVID-19, it is not a perfect fix, you will still need to practice precautions like wearing a mask, social distancing, and other hygiene measures until public health experts say otherwise.

Source: CDC. (2020). Answering Patients' Questions. Retrieved from https://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 the monitor the safety of the vaccine, to identify any possible long-term side effects. The ACIP 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 adverse reaction to the vaccine.

Source: CDC. (2020). Answering Patients' Questions. Retrieved from https://www.cdc.gov/vaccines/covid-19/hcp/answering-questions.html

COVID-19 Vaccine FAQ for Providers

Indiana Department of Health

Moderna COVID-19 Vaccine

What is mRNA?

The Moderna COVID-19 Vaccine is an mRNA vaccine. mRNA vaccines are not made up of the actual pathogen, they are made up of genetic information and not parts of the virus. The mRNA must be taken up into the body's cells, and the cells are then able to produce the protein that stimulates the immune response. mRNA vaccines train the body to identify and attack the coronavirus protein. Receiving an mRNA vaccine will not affect your DNA.

Source: HHS. (2020). Fact Sheet: Explaining Operation Warp Speed. Retrieved from https://www.acsh.org/news/2020/10/21/how-pfizers-rna-vaccine-works-15104

Will the vaccine make you sick?

The vaccine cannot give someone COVID-19 because it does not contain the live virus. Side effects can occur with any vaccine, as 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 patients should know when to should seek medical care if their symptoms do not go away.

Source: CDC. (2020). Answering Patients' Questions. Retrieved from https://www.cdc.gov/vaccines/covid-19/hcp/answering-questions.html

Is the Moderna COVID-19 Vaccine safe?

The Food and Drug Administration (FDA) and Advisory Committee on Immunization Practices (ACIP) carefully review all safety data from clinical trials before authorizing emergency vaccine 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 vaccine. There is a reporting system in place to identify any possible side effects or adverse events.

Source: CDC. (2020). Answering Patients' Questions. Retrieved from https://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 instances of vaccine adverse events. Healthcare personal 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 massaging and web surveys to provide daily health check-ins with COVID-19 vaccine recipients and will provide telephone follow up to anyone who reports medically important adverse events. A VAERS report will be taken during telephone follow up, if appropriate.

Source: CDC. (2020). Ensuring the Safety of COVID-19 Vaccines in the United States. Retrieved from https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety.html

COVID-19 Vaccine FAQ for Providers

Indiana Department of Health

Moderna COVID-19 Vaccine

How is the Moderna COVID-19 Vaccine administered?

The Moderna COVID-19 Vaccine is administered intramuscularly in a series of two injections, with a waiting period of 28 days between the injections. After administration, the person receiving the vaccine will be monitored for 15 minutes by vaccination staff.

Source: Moderna. (2020). Fact Sheet for Healthcare Providers. Retrieved from http://www.modernatx.com/covid19vaccine-eua/eua-fact-sheet-providers.pdf.

What are the ingredients in the Moderna COVID-19 Vaccine?

The Moderna COVID-19 Vaccine contains: a total lipid content of 1.93 mg (SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), 0.31 mg tromethamine, 1.18 mg tromethamine hydrochloride, 0.043 mg acetic acid, 0.12 mg sodium acetate, and 43.5 mg sucrose.

Source: Moderna. (2020). Fact Sheet for Healthcare Providers. Retrieved from http://www.modernatx.com/covid19vaccine-eua/eua-fact-sheet-providers.pdf.

What are the potential risks and side effects of the Moderna COVID-19 Vaccine?

Side effects that have been reported with the Moderna COVID-19 Vaccine include: Injection site reactions, pain, tenderness and swelling of the lymph nodes in the same arm of the injection, swelling (hardness), and redness. General side effects include fatigue, headache, muscle pain, joint pain, chills, nausea and vomiting, and fever.

There is a remote chance that the Moderna 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 Moderna COVID-19 Vaccine. For this reason, your vaccination provider may ask you to stay at the place where you received your vaccine for monitoring after vaccination.

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 Moderna COVID-19 Vaccine. Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Moderna COVID-19 Vaccine.

Source: Moderna. (2020). Fact Sheet for Healthcare Providers. Retrieved from http://www.modernatx.com/covid19vaccine-eua/eua-fact-sheet-providers.pdf.

If I have an allergic reaction to the first dose of Moderna COVID-19 Vaccine can I get the second dose?

If you have an allergic reaction to the first dose of the Moderna COVID-19 Vaccine it is not recommended that you get the second dose of the vaccine.

Source: Moderna. (2020). Fact Sheet for Recipients and Caregivers. Retrieved from http://www.modernatx.com/covid19vaccine-eua/eua-fact-sheet-providers.pdf.

COVID-19 Vaccine FAQ for Providers

Indiana Department of Health

Moderna COVID-19 Vaccine

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

If you have had a previous COVID-19 infection, you are still able to receive the COVID-19 Vaccine. People with a known current COVID-19 infection should wait until they have recovered from the acute illness and criteria have been met to end the isolation period. 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 interval between infection and vaccination.

Source CDC. (2020). 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

Can I get the COVID-19 Vaccine if I'm pregnant or breast feeding?

There are currently no available data on the safety of COVID-19 Vaccines in pregnant individuals. However studies are ongoing and expected to be available soon. The mRNA in the vaccine is degraded quickly in the body by normal cell processes, and experts believe that mRNA vaccines are unlikely to pose a risk for people who are pregnant. However, pregnant people who develop a COVID-19 infection are at increased risk of adverse pregnancy outcomes. Pregnant people may choose to be vaccinated. A conversation between the patient and their doctor may assist with decisions of whether or not to vaccinate. When making a decision pregnant people should consider their level of COVID-19 community transmission, their own level of exposure to COVID-19, the side effects of the vaccine, and the risks of a COVID-19 infection to the patient and potential risk to the fetus.

There are no data on the safety of COVID-19 vaccines in lactating people. mRNA vaccines are not though to be a risk to the breastfeeding infant. A lactating person may choose to be vaccinated.

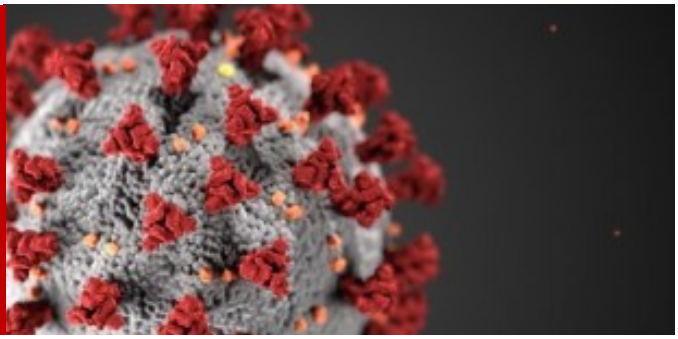
Source CDC. (2020). Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States. Retrieved from: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html

Can I get the vaccine if I have had food/bee 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 Moderna COVID-19 Vaccination. A 30 minute observation period following vaccination is recommended for anyone with a history of a severe allergic reaction.

Source CDC. (2020). 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

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 Moderna COVID-19 Vaccine Provider Fact Sheet.

Reviewing Moderna COVID-19 Vaccine Contraindications

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

Reviewing the Moderna COVID-19 Vaccine Ingredients

Each 0.5 mL dose of the Moderna COVID-19 Vaccine contains 100 mcg of a nucleoside-modified messenger RNA encoding the viral spike (S) glycoprotein of SARS-CoV-2. Each dose of the Moderna COVID-19 Vaccine also includes the following ingredients: lipids (SM-102; 1,2-dimyristoyl-rac-glycero-3-methoxypolyethylene glycol-2000 [PEG2000-DMG]; cholesterol; and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), tromethamine, tromethamine hydrochloride, acetic acid, sodium acetate, and sucrose.

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 Moderna COVID-19
Altered Immunocompetence	Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Moderna COVID-
Limitation of Effectiveness	The Moderna COVID-19 Vaccine may not protect all vaccine recipients

Source: ModernaTX: . (2020). Fact Sheet For Healthcare Providers Administering Vaccine. Retrieved from https://www.modernatx.com/covid19vaccine-eua/eua-fact-sheet-providers.pdf

Appendix B: Triage of persons presenting for mRNA COVID-19 vaccination

	MAY PROCEED WITH VACCINATION	PRECAUTION TO VACCINATION	CONTRAINDICATION TO VACCINATION
CONDITIONS	**CONDITIONS** • Immunocompromising conditions • Pregnancy • Lactation **ACTIONS** • Additional information provided* • 15 minute observation period	**CONDITIONS** • Moderate/severe acute illness **ACTIONS** • Risk assessment • Potential deferral of vaccination • 15 minute observation period if vaccinated	**CONDITIONS** • None **ACTIONS** • N/A
ALLERGIES	**ALLERGIES** • History of food, pet, insect, venom, environmental, latex, or other allergies not related to vaccines or injectable therapies • History of allergy to oral medications (including the oral equivalent of an injectable medication) • Non-serious allergy to vaccines or other injectables (e.g., no anaphylaxis) • Family history of anaphylaxis • Any other history of anaphylaxis that is not related to a vaccine or injectable therapy **ACTIONS** • 30 minute observation period: Persons with a history of severe allergic reaction (e.g., anaphylaxis) due to any cause • 15 minute observation period: Persons with allergic reaction, but not anaphylaxis	**ALLERGIES** • History of severe allergic reaction (e.g., anaphylaxis) to another vaccine (not including mRNA COVID-19 vaccines†) • History of severe allergic reaction (e.g., anaphylaxis) to an injectable therapy **ACTIONS:** • Risk assessment • Potential deferral of vaccination • 30 minute observation period if vaccinated	**ALLERGIES** • History of severe allergic reaction (e.g., anaphylaxis) to any component of an mRNA COVID-19 vaccine† **ACTIONS** • Do not vaccinate

* See Special Populations section for information on patient counseling in these groups

† Refers only to mRNA COVID-19 vaccines currently authorized in the United States (i.e., Pfizer-BioNTech, Moderna COVID-19 vaccines)

Page last reviewed: December 20, 2020
Content source: National Center for Immunization and Respiratory Diseases

Review Important Safety Information

- Do not administer Moderna COVID-19 Vaccine to individuals with known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Moderna 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 Moderna COVID-19 Vaccine
- Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Moderna COVID-19 Vaccine
- The Moderna 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 (92.0%), fatigue (70.0%), headache (64.7%), myalgia (61.5%), arthralgia (46.4%), chills (45.4%), nausea/vomiting (23.0%), axillary swelling/tenderness (19.8%), fever (15.5%), swelling at the injection site (14.7%), and erythema at the injection site (10.0%).
- Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Moderna COVID-19 Vaccine.
- Available data on Moderna 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 Moderna COVID-19 Vaccine on the breastfed infant or on milk production/excretion
- There are no data available on the interchangeability of the Moderna COVID-19 Vaccine with other COVID-19 vaccines to complete the vaccination series. Individuals who have received one dose of Moderna COVID-19 Vaccine should receive a second dose of Moderna COVID-19 Vaccine 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 “Moderna 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 Moderna COVID-19 Vaccine Dosing and Administration website.

Source: ModernaTX. (December 2020). Dosing and Administration. Retrieved from: https://www.modernatx.com/covid19vaccine-eua/

During COVID-19 Vaccine Administration

Indiana Department of Health

Division of **Immunization**

VACCINE SAFETY AND ADMINISTRATION **TOOLKIT**

DECEMBER 2020

Preparing and Thawing 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 VTrckS. For centrally distributed vaccines, each kit will contain supplies to administer 975 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. (2020). 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

- 10 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 Moderna 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 Moderna COVID-19 Vaccine. All kits are configured for 100 doses with 5% surplus. Examples include:

Needle and Syringe Sizes for Moderna 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 (December 4, 2020). Product Information Guide for COVID-19 Vaccines and Associated Products. https://www.in.gov/isdh/files/Product%20information%20guide_12.04.20_CLEAN.pdf

Room Temperature Exposure Restrictions During Vaccine Thawing

When you are ready to thaw or use the vaccine please keep the following room temperature restrictions in mind:

1. Open punctured, the vial must be discarded after 6 hours.
2. Once a vial is thawed in the fridge or at room temperature, it should not be returned to storage
3. No more than 12 hours at room temperature
4. ***Do not*** refreeze thawed vials

Thawing the Vaccine Options

The amount of time needed for thawing will vary depending on when you need the vaccine. Refer to the table and diagram below to determine how the vaccine should thaw. The vaccine should be completely thawed before administering and should sit an additional 15 minutes at room temperature. Record the date and time of first use on the vial label.

For more information related to thawing please visit the Moderna Dosing and Administration website.

Option 1: For Later Use	Option 2: For Immediate Use
• Transfer frozen vials immediately to refrigerator, and thaw for 2.5 hours at 2°C to 8°C (36°F to 46°F) and an additional 15 minutes at room temperature. • Vials may be stored up to 30 days in refrigerator at 2°C to 8°C .	• Vials needed for immediate can be thawed at room temperature for 1 hour. • Unopened vials can be stored at room temperature for up to 12 hours. • Punctured vials can be stored for up to 6 hours.

Checking Vial Expiration

You can confirm vaccine expiration date by looking up the lot number at https://www.modernatx.com/covid19vaccine-eua/providers/vial-lookup.

Source: ModernaTX. (December 2020). Dosing and Administration. Retrieved from: https://www.modernatx.com/covid19vaccine-eua/providers/dosing-administration

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 Moderna 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 white to off-white in color in both vial and syringe
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.

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

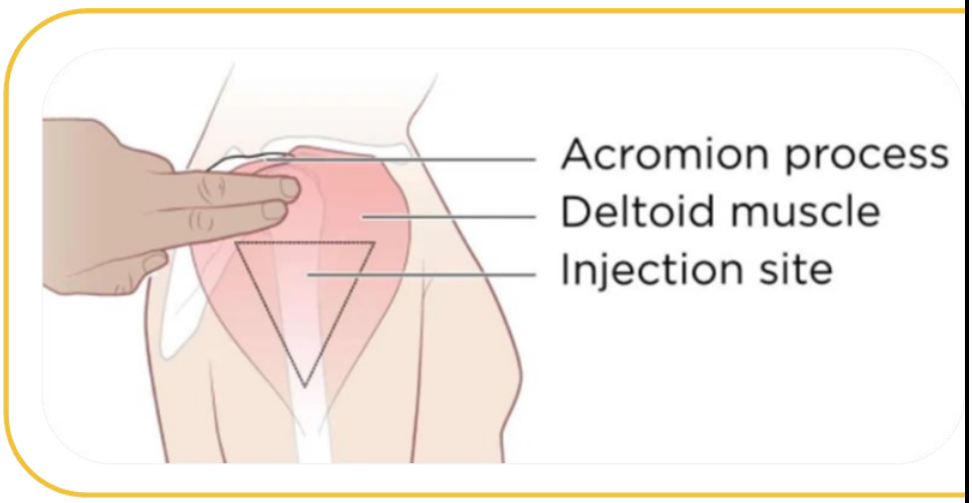


Image source: Intramuscular Injection Sites. Healthline. Medically reviewed by Deborah Weatherspoon, Ph.D., R.N., CRNA. Written by Jacquelyn Cafasso. Updated on March 7, 2019. Retrieved from https://www.healthline.com/health/intramuscular-injection

Source: CDC. (December 2020). You Call the Shots. https://www.cdc.gov/vaccines/hcp/admin/downloads/vaccine-administration-needle-length.pdf

After COVID-19 Vaccine Administration

Indiana Department of Health

Division of **Immunization**

VACCINE SAFETY AND ADMINISTRATION **TOOLKIT**

DECEMBER 2020

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, Date 2nd Dose Administered
- Healthcare Professional or Facilty where doses were administered

The Moderna COVID-19 Vaccine is administered as a series of 2 doses one month apart (28 days). The first and second dose are (0.5 mL) 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. They must bring the card to their second dose visit. The reminder on the back is also available in Spanish.

The second dose must be Moderna COVID-19 vaccine; it is not interchangeable with other COVID-19 vaccines. Since the Moderna COVID-19 Vaccine is a two does series, Vaccine Finder will be useful for patients to locate where they can get their second dose. Please refer to the next page for more information.

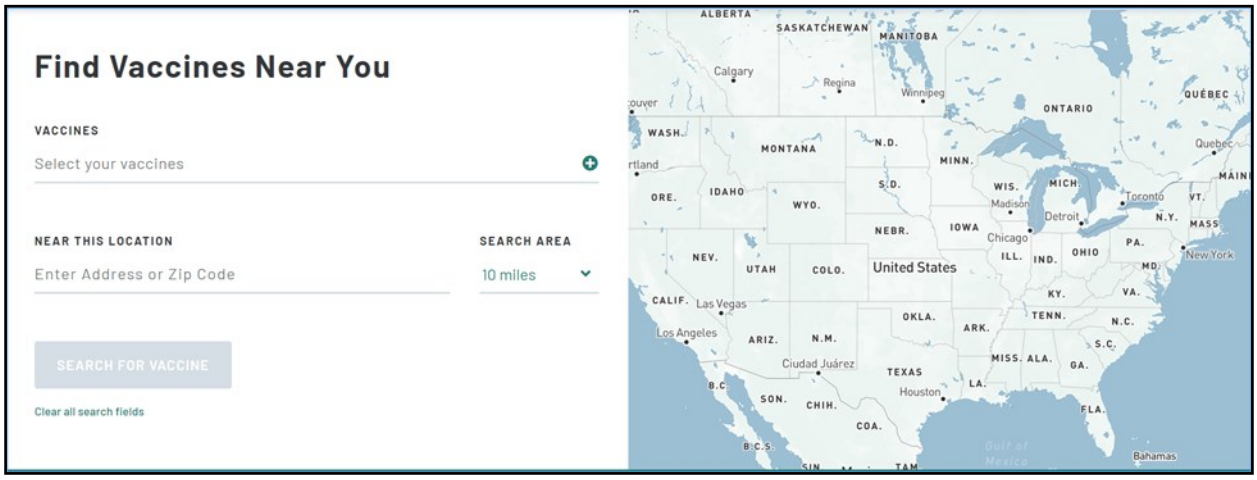
Vaccine Finder

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. Since the Moderna COVID-19 Vaccine is a two does series, this will be useful for patients to locate where they can get their second dose.

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. (2020). 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) (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. The reports should include the words "Moderna COVID-19 Vaccine EUA" in the description section of the report[1]. In addition, you can report side effects to Moderna. at the contact information provided below.

Website	Fax Number	Telephone Number
ModernaPV@modernatx.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 Moderna 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
- swollen lymph nodes (lymphadenopathy)

[1]Source: Moderna. (December 2020). Fact Sheet for Recipients and Caregivers. Retrieved from: https://www.modernatx.com/covid19vaccine-eua/

There is a remote chance that the Moderna 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 Moderna 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 Moderna COVID-19 Vaccine. Serious and unexpected side effects may occur. Moderna 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 Moderna 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.

[1]Source: ModernaTX. (December 2020). Fact Sheet for Recipients and Caregivers. Retrieved from: https://www.modernatx.com/covid19vaccine-eua/eua-fact-sheet-recipients.pdf

Indiana Department of Health and ZOTEC - Quick Reference Guide

Documenting Vaccination

What is ZOTEC?

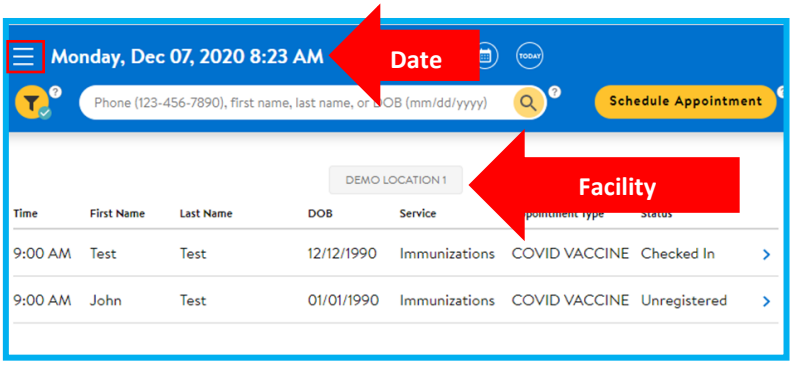
The Indiana Department of Health (IDOH) has partnered with Zotec during Phase 1A of COVID-19 vaccination efforts. Zotec has the available features needed to collect important data on patient demographics. You will document vaccine administration for your facility's patients using Zotec.

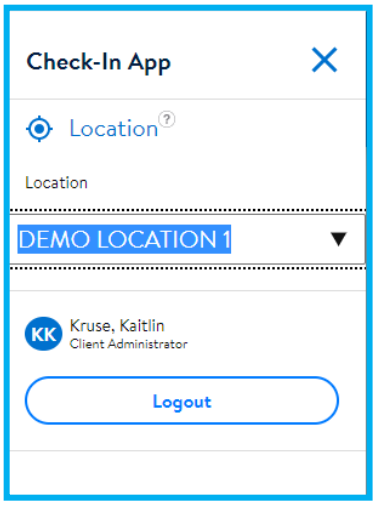
Questions? Please Contact our IDOH Help Desk Portal (https://eportal.isdh.in.gov/C19VaxHelpDeskCustomer)

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.





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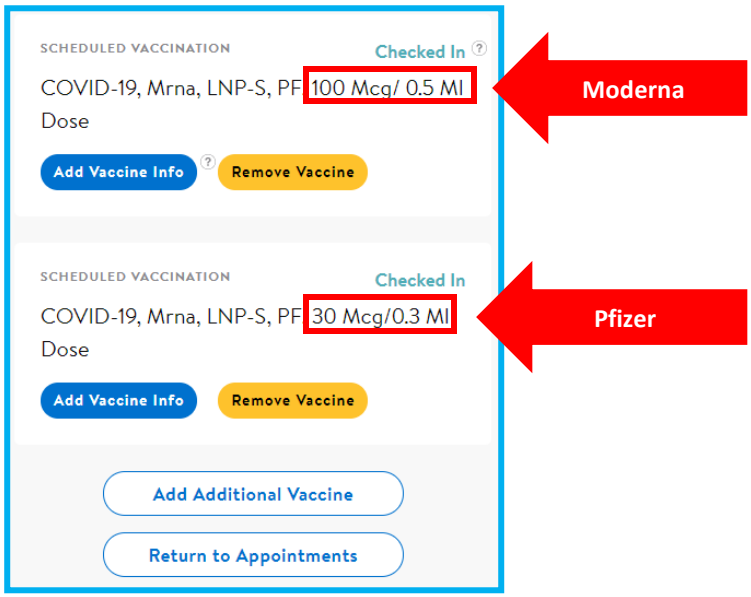
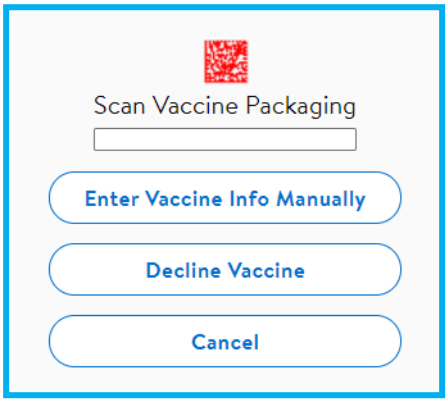
3. Once you have selected the correct patient you will be taken to the demographics page. There will be 2 different brands of COVID-19 Vaccine to choose from.

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

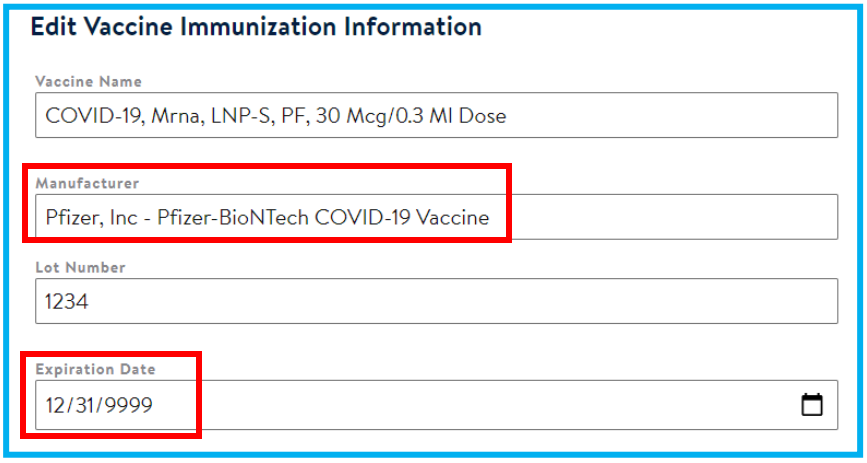


4. When you select **Add Vaccine Info** you will have the option to scan the vaccine information or to enter the information manually.

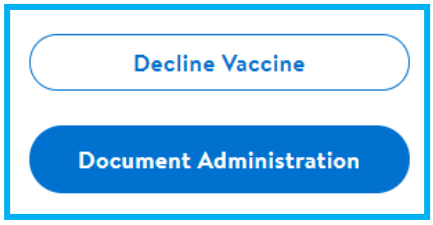


Tip: Only vaccine administrators will have login access to add vaccine information.

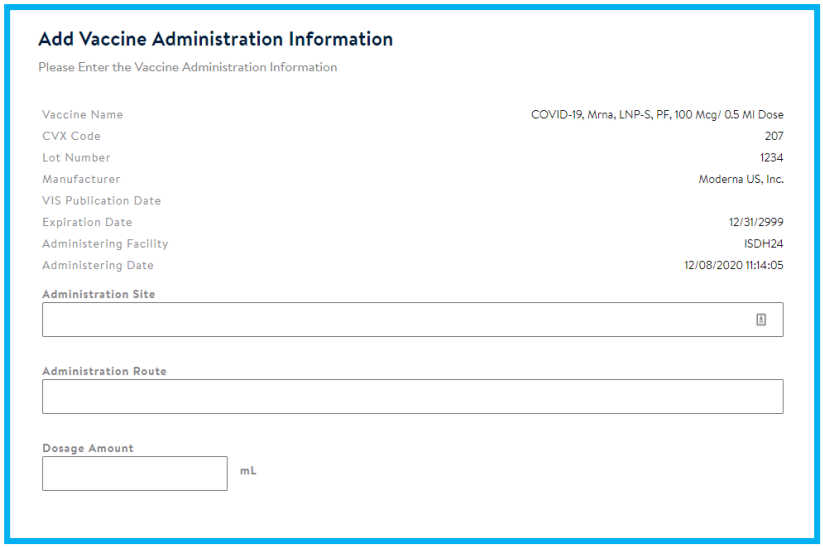
5. The name and manufacturer will be prepopulated when you open the vaccine info. **Make sure you are checking a second time to see if the manufacturer is correct.** You will input the vaccine info and provide the **temporary expiration date as 12/31/9999.**



6. 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.

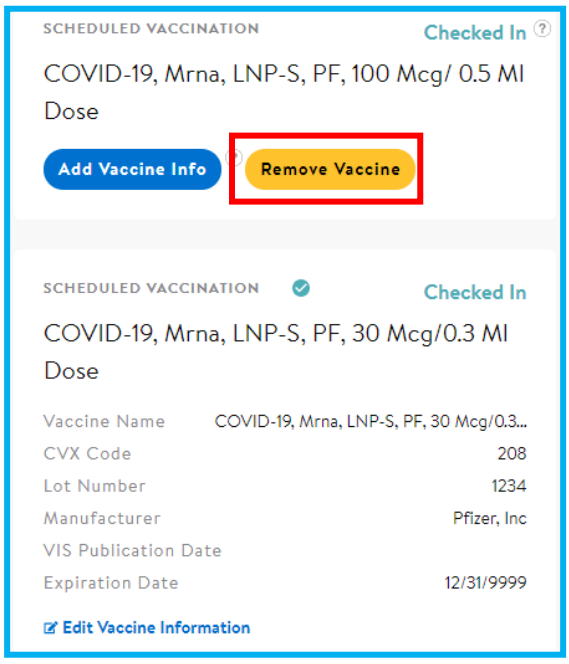


7. You will need to verify that all the vaccine information listed at the top is correct. When entering the administration site and route the selections available will appear after you start typing.

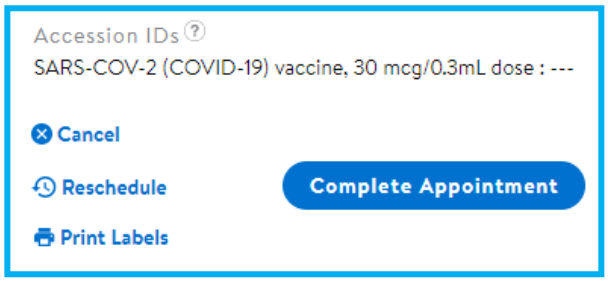


Indiana Department of Health | Division of Immunization

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.



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



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?

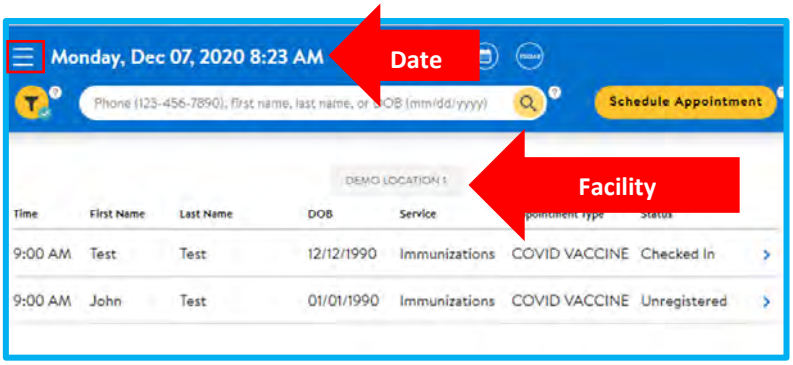
The Indiana Department of Health (IDOH) has partnered with Zotec during Phase 1A of COVID-19 vaccination efforts. Zotec has the available features needed to collect important data on patient demographics. You will document vaccine administration for your facility's patients using Zotec.

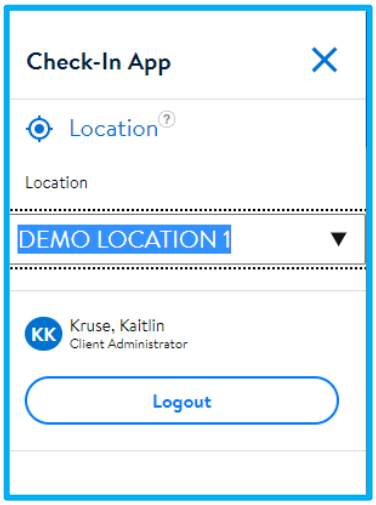
Questions? Please Contact our IDOH Help Desk Portal (https://eportal.isdh.in.gov/C19VaxHelpDeskCustomer)

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

Checking Out

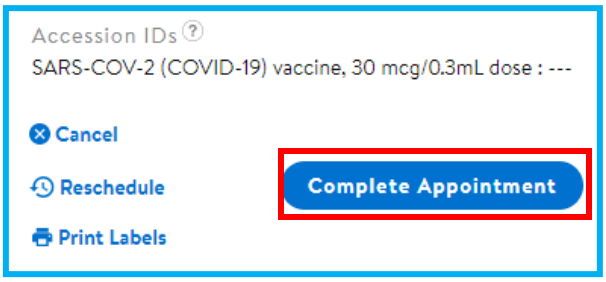
1. Login on https://checkin.coronavirus.in.gov using your credentials. If you do not have user access to Zotec, please refer to the **Gaining Access to Zotec (for Facilities)** Quick Reference Guide.
2. Once you have logged in you will need to confirm your location and current date is correct. If the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



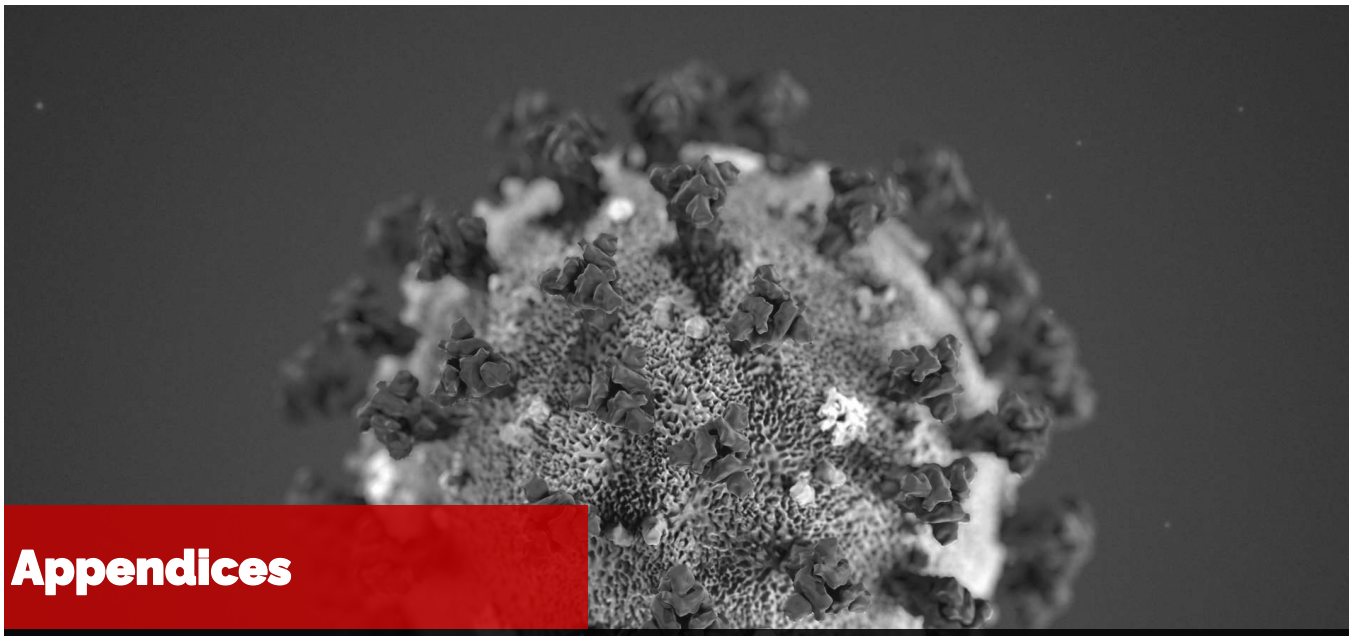


Indiana Department of Health | Division of Immunization

3. The patient can then be checked out by registration or a vaccinator that has duel 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

Indiana Department of Health

Division of **Immunization**

VACCINE SAFETY AND ADMINISTRATION **TOOLKIT**

DECEMBER 2020

Steps to Take Before, During, and After Administration Checklist

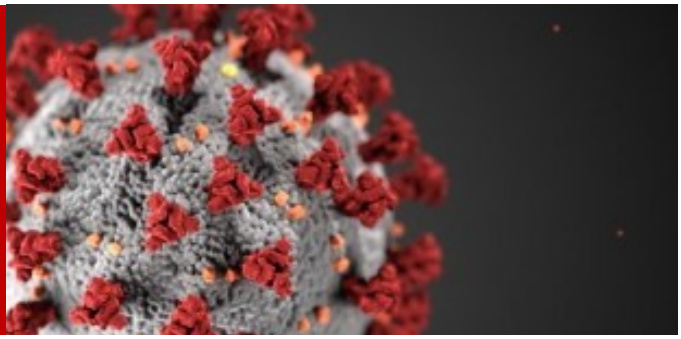
Indiana Department of Health

Division of **Immunization**

VACCINE SAFETY AND ADMINISTRATION **TOOLKIT**

DECEMBER 2020

Steps to Take Before Moderna COVID-19 Vaccine Administration



1. REGISTER/CHECK IN PATIENT ON ZOTEC (PHASE 1A) OR ACCENTURE

- Zotec (Phase 1A) or Accenture is used to register patient's appointment and vaccination record documentation
- Patient search must be completed in Zotec (Phase 1A) or Accenture prior to COVID-19 vaccine administration. The data will automatically be entered into CHIRP, our state immunization registry.
- Patient search in Zotec (Phase 1A) or Accenture is critical for second dose patients to ensure the same COVID-19 vaccine product is used for the second dose. 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 Moderna Provider and Recipient Fact Sheets can be found on www.modernatx.com.
- This also serves as an opportunity to educate the patient and address any questions or concerns patients may have. Refer to the **Patient Education section** or www.modernatx.com for more information.

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 Moderna COVID-19 Vaccine website is located at www.modernatx.com.
- Refer to the **Screening the Patient section** for more guidance.

Steps to Take During Moderna COVID-19 Vaccine Administration

1. CHECKING VIAL EXPIRATION DATE

- You can confirm the vial expiration date by looking up the lot number at https://www.modernatx.com/covid19vaccine-eua/providers/vial-lookup
- Refer to the **Preparing and Thawing the Vaccine section** for more information or visit www.modernatx.com

2. VACCINE PREPARATION (NO DILUTION REQUIRED)

- The Moderna COVID-19 Vaccine does not require dilution.
- Thaw vaccine at room temperature or in refrigerated conditions
- After thawing, let vial stand at room temperature for 15 minutes before administering. After thawing, do not refreeze the vial(s)
- Record the date and time for first use on the Moderna COVID-19 Vaccine vial label. Discard vial after 6 hours
- Refer to the **Preparing and Thawing the Vaccine section** for more information on thawing and room temperature exposure time restrictions or www.modernatx.com

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 at first visit.
- Use appropriate gauge needle for body type (23-25 gauge).
- Administer intramuscularly in the deltoid muscle.
- Refer to the **Administering the Vaccine section** or www.modernatx.com for more information.

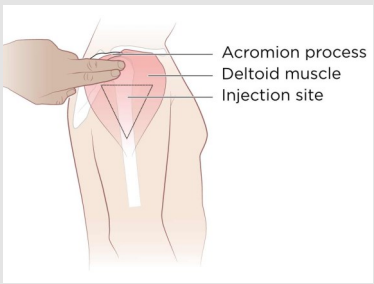
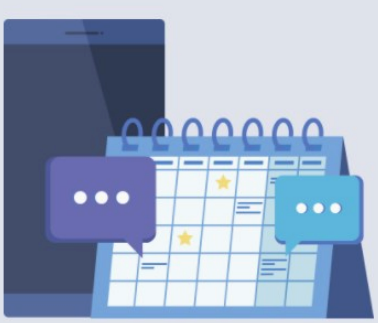


Image source: Intramuscular Injection Sites. Healthline. Medically reviewed by Deborah Weatherspoon, Ph.D., R.N., CRNA. Written by Jacquelyn Cafasso. Updated on March 7, 2019. Retrieved from https://www.healthline.com/health/intramuscular-injection

Steps to Take After Moderna 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.
- Using the COVID-19 vaccination record card provided in the ancillary kit, please record the time and day for second-dose appointment.
- The second dose is administered 21 days later and it must be Moderna COVID-19 vaccine; 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 (PHASE 1A) OR ACCENTURE

- Each COVID-19 dose administered must be entered into Zotec (Phase 1A) or Accenture 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

Indiana Department of Health

Division of **Immunization**

VACCINE SAFETY AND ADMINISTRATION **TOOLKIT**

DECEMBER 2020

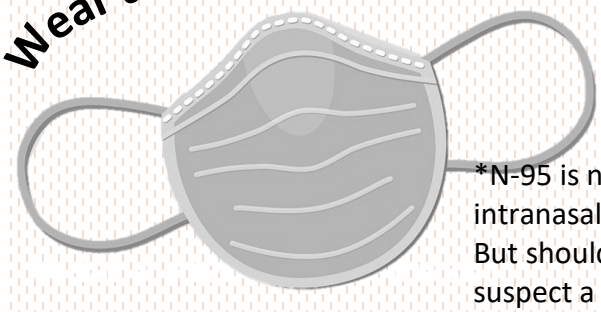
Vaccinating during COVID-19

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 vaccine patients. These range from wearing personal protective equipment (PPE) to hand hygiene.

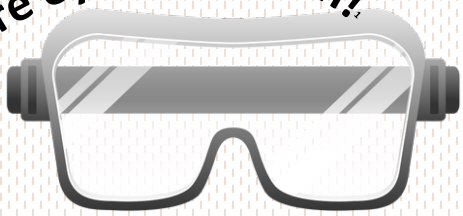
Take the necessary actions to protect you and your community!

Wear a medical facemask![2]



*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![1]



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

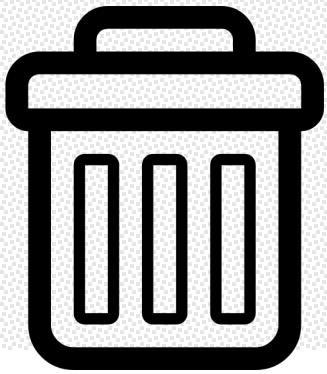
Change gloves between patients![1]

*Wearing gloves is not a substitute for hand hygiene!
*Gloves should be utilized[1] when giving the following vaccinations:
- Intranasal
- Oral

Practice hand hygiene![1]

*Wash your hands before and after patient contact.[1]

Throw PPE waste in a trash can![2]



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

Indiana Department of Health

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

COVID-19 Vaccine Hesitancy Packet for Providers

Indiana Department of Health

Division of **Immunization**

VACCINE SAFETY AND ADMINISTRATION **TOOLKIT**

DECEMBER 2020

COVID-19 Vaccine Hesitancy

What is Vaccine Hesitancy?

Vaccine hesitancy is the reluctance or refusal to vaccinate despite the availability of vaccines. Many patients may feel reluctant about getting the COVID-19 Vaccine. Often this reluctance stems from lack of information or misinformation about the vaccine. As a healthcare provider, your recommendation plays a significant role in a patient's decision to vaccinate.

Resources

- CDC COVID-19 Communications Toolkit
- Answering Patients' Questions
- Emergency Use Authorization Explained
- V-Safe Monitoring System
- Moderna Factsheet for Recipients & Caregivers

Building Vaccine Confidence

Start Conversations About the COVID-19 Vaccine Early	♦ Set expectations about vaccine availability. ♦ The goal is that the vaccine will be available for everyone, however, not everyone will be able to get vaccinated right away.
Give a Strong Recommendation	♦ Patients rank healthcare providers as their most trusted source for vaccine information. Your strong recommendations is critical for vaccine acceptance.
Use Empathy and Understanding	♦ Acknowledge the disruptions that COVID-19 has caused in all of our lives.
Listen and Respond to Patient Questions	♦ Make it clear that you want to answer questions patients' questions so that they feel confident choosing to get vaccinated. ♦ Address patients' concerns and answer questions in a way they can understand it.
Continue the Conversation	♦ Just because a patient refuses the vaccine at one appointment does not mean they will refuse it at future appoints. ♦ Encourage patients to read additional information that you give them about the COVID-19 Vaccine. ♦ Continue to remind patients about the importance of getting a COVID-19 vaccine during future routine visits.

COVID-19 Vaccine FAQ for Providers

Indiana Department of Health

What is an EUA?

An Emergency Use Authorization is allowed in instances where a public health threat is identified and there is no approved or adequate existing products. The Food and Drug Administration (FDA) carefully reviews all safety data from clinical trials and an authorizes emergency vaccine use only when the expected benefits outweigh potential risks. For more information about EUAs visit https://www.youtube.com/watch?v=iGkwaESsGBQ.

Source: FDA. (2020). Emergency Use Authorization for Vaccine Explained. Retrieved from https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained

What is Operation Warp Speed?

Operation War Speed's goal is to make a safe and effective COVID-19 vaccine widely available as soon as possible. In traditional vaccine development timelines, manufacturing steps are carried out in a sequential basis, however, with Operation Warp Speed manufacturing steps are carried out simultaneously. This increases the financial risk, but does not compromise the safety of the vaccine.

Source: HHS. (2020). Fact Sheet: Explaining Operation Warp Speed. Retrieved from https://www.hhs.gov/coronavirus/explaining-operation-warp-speed/index.html

Is Natural Immunity better than vaccine-induced immunity? Am I better off getting COVID-19 instead of getting the vaccine?

Natural immunity comes from fighting off a virus, however, COVID-19 can have serious, life-threatening complications, there is no way to know how COVID-19 will affect a person. There are potential serious long-term health issues after recovering from COVID-19. It is not known whether getting COVID-19 protects you from getting the virus again in the future, 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. (2020). Answering Patients' Questions. Retrieved from https://www.cdc.gov/vaccines/covid-19/hcp/answering-questions.html

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

While the vaccine greatly reducing your risk of contracting COVID-19, it is not a perfect fix, you will still need to practice precautions like wearing a mask, social distancing, and other hygiene measures until public health experts say otherwise.

Source: CDC. (2020). Answering Patients' Questions. Retrieved from https://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 the monitor the safety of the vaccine, to identify any possible long-term side effects. The ACIP 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 adverse reaction to the vaccine.

Source: CDC. (2020). Answering Patients' Questions. Retrieved from https://www.cdc.gov/vaccines/covid-19/hcp/answering-questions.html

COVID-19 Vaccine FAQ for Providers

Indiana Department of Health

Moderna COVID-19 Vaccine

What is mRNA?

The Moderna COVID-19 Vaccine is an mRNA vaccine. mRNA vaccines are not made up of the actual pathogen, they are made up of genetic information and not parts of the virus. The mRNA must be taken up into the body's cells, and the cells are then able to produce the protein that stimulates the immune response. mRNA vaccines train the body to identify and attack the coronavirus protein. Receiving an mRNA vaccine will not affect your DNA.

Source: HHS. (2020). Fact Sheet: Explaining Operation Warp Speed. Retrieved from https://www.acsh.org/news/2020/10/21/how-pfizers-rna-vaccine-works-15104

Will the vaccine make you sick?

The vaccine cannot give someone COVID-19 because it does not contain the live virus. Side effects can occur with any vaccine, as 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 patients should know when to should seek medical care if their symptoms do not go away.

Source: CDC. (2020). Answering Patients' Questions. Retrieved from https://www.cdc.gov/vaccines/covid-19/hcp/answering-questions.html

Is the Moderna COVID-19 Vaccine safe?

The Food and Drug Administration (FDA) and Advisory Committee on Immunization Practices (ACIP) carefully review all safety data from clinical trials before authorizing emergency vaccine 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 vaccine. There is a reporting system in place to identify any possible side effects or adverse events.

Source: CDC. (2020). Answering Patients' Questions. Retrieved from https://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 instances of vaccine adverse events. Healthcare personal 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 massaging and web surveys to provide daily health check-ins with COVID-19 vaccine recipients and will provide telephone follow up to anyone who reports medically important adverse events. A VAERS report will be taken during telephone follow up, if appropriate.

Source: CDC. (2020). Ensuring the Safety of COVID-19 Vaccines in the United States. Retrieved from https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety.html

COVID-19 Vaccine FAQ for Providers

Indiana Department of Health

Moderna COVID-19 Vaccine

How is the Moderna COVID-19 Vaccine administered?

The Moderna COVID-19 Vaccine is administered intramuscularly in a series of two injections, with a waiting period of 28 days between the injections. After administration, the person receiving the vaccine will be monitored for 15 minutes by vaccination staff.

Source: Moderna. (2020). Fact Sheet for Healthcare Providers. Retrieved from http://www.modernatx.com/covid19vaccine-eua/eua-fact-sheet-providers.pdf.

What are the ingredients in the Moderna COVID-19 Vaccine?

The Moderna COVID-19 Vaccine contains: a total lipid content of 1.93 mg (SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), 0.31 mg tromethamine, 1.18 mg tromethamine hydrochloride, 0.043 mg acetic acid, 0.12 mg sodium acetate, and 43.5 mg sucrose.

Source: Moderna. (2020). Fact Sheet for Healthcare Providers. Retrieved from http://www.modernatx.com/covid19vaccine-eua/eua-fact-sheet-providers.pdf.

What are the potential risks and side effects of the Moderna COVID-19 Vaccine?

Side effects that have been reported with the Moderna COVID-19 Vaccine include: Injection site reactions, pain, tenderness and swelling of the lymph nodes in the same arm of the injection, swelling (hardness), and redness. General side effects include fatigue, headache, muscle pain, joint pain, chills, nausea and vomiting, and fever.

There is a remote chance that the Moderna 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 Moderna COVID-19 Vaccine. For this reason, your vaccination provider may ask you to stay at the place where you received your vaccine for monitoring after vaccination.

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 Moderna COVID-19 Vaccine. Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Moderna COVID-19 Vaccine.

Source: Moderna. (2020). Fact Sheet for Healthcare Providers. Retrieved from http://www.modernatx.com/covid19vaccine-eua/eua-fact-sheet-providers.pdf.

If I have an allergic reaction to the first dose of Moderna COVID-19 Vaccine can I get the second dose?

If you have an allergic reaction to the first dose of the Moderna COVID-19 Vaccine it is not recommended that you get the second dose of the vaccine.

Source: Moderna. (2020). Fact Sheet for Recipients and Caregivers. Retrieved from http://www.modernatx.com/covid19vaccine-eua/eua-fact-sheet-providers.pdf.

COVID-19 Vaccine FAQ for Providers

Indiana Department of Health

Moderna COVID-19 Vaccine

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

If you have had a previous COVID-19 infection, you are still able to receive the COVID-19 Vaccine. People with a known current COVID-19 infection should wait until they have recovered from the acute illness and criteria have been met to end the isolation period. 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 interval between infection and vaccination.

Source CDC. (2020). 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

Can I get the COVID-19 Vaccine if I'm pregnant or breast feeding?

There are currently no available data on the safety of COVID-19 Vaccines in pregnant individuals. However studies are ongoing and expected to be available soon. The mRNA in the vaccine is degraded quickly in the body by normal cell processes, and experts believe that mRNA vaccines are unlikely to pose a risk for people who are pregnant. However, pregnant people who develop a COVID-19 infection are at increased risk of adverse pregnancy outcomes. Pregnant people may choose to be vaccinated. A conversation between the patient and their doctor may assist with decisions of whether or not to vaccinate. When making a decision pregnant people should consider their level of COVID-19 community transmission, their own level of exposure to COVID-19, the side effects of the vaccine, and the risks of a COVID-19 infection to the patient and potential risk to the fetus.

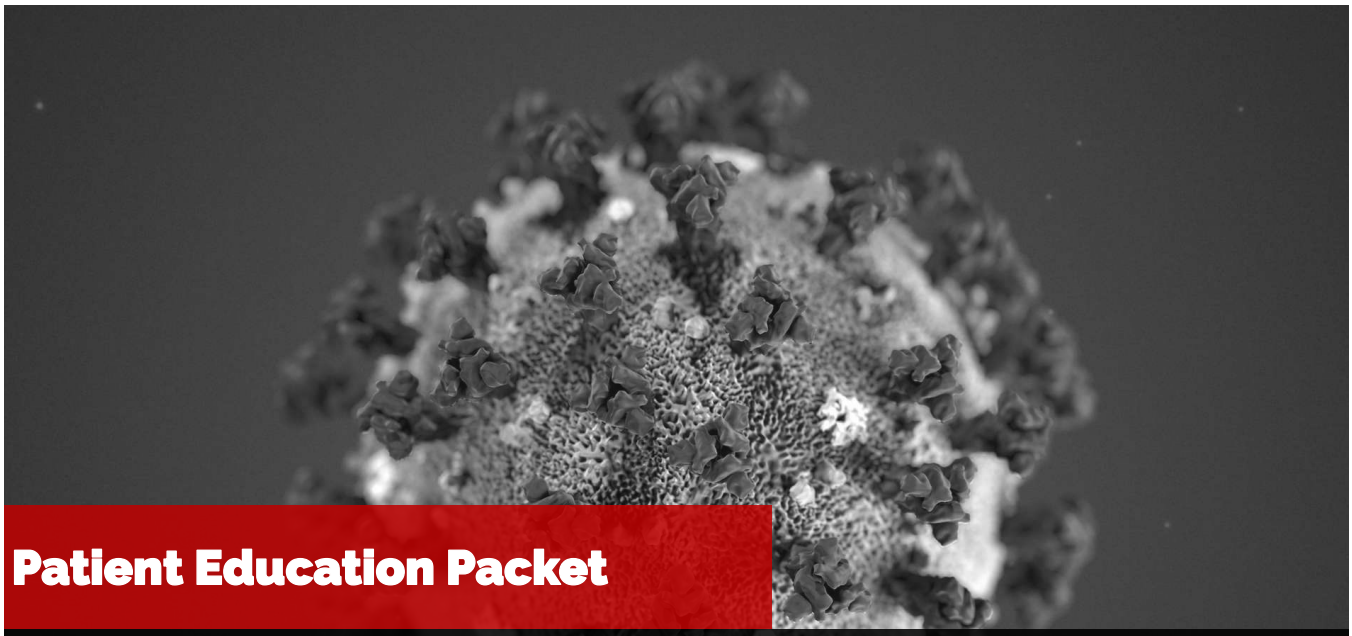
There are no data on the safety of COVID-19 vaccines in lactating people. mRNA vaccines are not though to be a risk to the breastfeeding infant. A lactating person may choose to be vaccinated.

Source CDC. (2020). 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

Can I get the vaccine if I have had food/bee 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 Moderna COVID-19 Vaccination. A 30 minute observation period following vaccination is recommended for anyone with a history of a severe allergic reaction.

Source CDC. (2020). 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



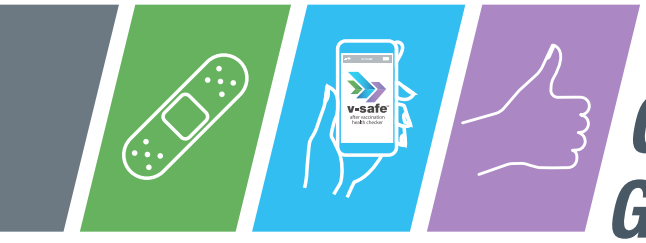
Patient Education Packet

Indiana Department of Health

Division of **Immunization**

VACCINE SAFETY AND ADMINISTRATION **TOOLKIT**

DECEMBER 2020



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.

v-safe℠
after vaccination health checker

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

12/01/20

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:

Use your smartphone's browser to go to

vsafe.cdc.gov

OR

Aim your smartphone's camera at this code

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

COVID-19 Vaccine FAQ for Patients

Indiana Department of Health

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Source: CDC. (2020). Answering Patients' Questions. Retrieved from https://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 the monitor the safety of the vaccine, to identify any possible long-term side effects. The ACIP 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 adverse reaction to the vaccine.

Source: CDC. (2020). Answering Patients' Questions. Retrieved from https://www.cdc.gov/vaccines/covid-19/hcp/answering-questions.html

COVID-19 Vaccine FAQ for Patients

Indiana Department of Health

Moderna COVID-19 Vaccine

What is mRNA?

The Moderna COVID-19 Vaccine is an mRNA vaccine. mRNA vaccines are not made up of the actual pathogen, they are made up of genetic information and not parts of the virus. The mRNA must be taken up into the body's cells, and the cells are then able to produce the protein that stimulates the immune response. mRNA vaccines train the body to identify and attack the coronavirus protein. Receiving an mRNA vaccine will not affect your DNA.

Source: HHS. (2020). Fact Sheet: Explaining Operation Warp Speed. Retrieved from https://www.acsh.org/news/2020/10/21/how-pfizers-rna-vaccine-works-15104

Will the vaccine make you sick?

The vaccine cannot give someone COVID-19 because it does not contain the live virus. Side effects can occur with any vaccine, as 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 patients should know when to should seek medical care if their symptoms do not go away.

Source: CDC. (2020). Answering Patients' Questions. Retrieved from https://www.cdc.gov/vaccines/covid-19/hcp/answering-questions.html

Is the Moderna COVID-19 Vaccine safe?

The Food and Drug Administration (FDA) and Advisory Committee on Immunization Practices (ACIP) carefully review all safety data from clinical trials before authorizing emergency vaccine 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 vaccine. There is a reporting system in place to identify any possible side effects or adverse events.

Source: CDC. (2020). Answering Patients' Questions. Retrieved from https://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 instances of vaccine adverse events. Healthcare personal 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 massaging and web surveys to provide daily health check-ins with COVID-19 vaccine recipients and will provide telephone follow up to anyone who reports medically important adverse events. A VAERS report will be taken during telephone follow up, if appropriate.

Source: CDC. (2020). Ensuring the Safety of COVID-19 Vaccines in the United States. Retrieved from https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety.html

COVID-19 Vaccine FAQ for Patients

Indiana Department of Health

Moderna COVID-19 Vaccine

How is the Moderna COVID-19 Vaccine administered?

The Moderna COVID-19 Vaccine is administered intramuscularly in a series of two injections, with a waiting period of 28 days between the injections. After administration, the person receiving the vaccine will be monitored for 15 minutes by vaccination staff.

Source: Moderna. (2020). Fact Sheet for Healthcare Providers. Retrieved from http://www.modernatx.com/covid19vaccine-eua/eua-fact-sheet-providers.pdf.

What are the ingredients in the Moderna COVID-19 Vaccine?

The Moderna COVID-19 Vaccine contains: a total lipid content of 1.93 mg (SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), 0.31 mg tromethamine, 1.18 mg tromethamine hydrochloride, 0.043 mg acetic acid, 0.12 mg sodium acetate, and 43.5 mg sucrose.

Source: Moderna. (2020). Fact Sheet for Healthcare Providers. Retrieved from http://www.modernatx.com/covid19vaccine-eua/eua-fact-sheet-providers.pdf.

What are the potential risks and side effects of the Moderna COVID-19 Vaccine?

Side effects that have been reported with the Moderna COVID-19 Vaccine include: Injection site reactions, pain, tenderness and swelling of the lymph nodes in the same arm of the injection, swelling (hardness), and redness. General side effects include fatigue, headache, muscle pain, joint pain, chills, nausea and vomiting, and fever.

There is a remote chance that the Moderna 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 Moderna COVID-19 Vaccine. For this reason, your vaccination provider may ask you to stay at the place where you received your vaccine for monitoring after vaccination.

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 Moderna COVID-19 Vaccine. Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Moderna COVID-19 Vaccine.

Source: Moderna. (2020). Fact Sheet for Healthcare Providers. Retrieved from http://www.modernatx.com/covid19vaccine-eua/eua-fact-sheet-providers.pdf.

If I have an allergic reaction to the first dose of Moderna COVID-19 Vaccine can I get the second dose?

If you have an allergic reaction to the first dose of the Moderna COVID-19 Vaccine it is not recommended that you get the second dose of the vaccine.

Source: Moderna. (2020). Fact Sheet for Recipients and Caregivers. Retrieved from http://www.modernatx.com/covid19vaccine-eua/eua-fact-sheet-providers.pdf.

COVID-19 Vaccine FAQ for Patients

Moderna COVID-19 Vaccine

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

If you have had a previous COVID-19 infection, you are still able to receive the COVID-19 Vaccine. People with a known current COVID-19 infection should wait until they have recovered from the acute illness and criteria have been met to end the isolation period. 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 interval between infection and vaccination.

Source CDC. (2020). 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

Can I get the COVID-19 Vaccine if I'm pregnant or breast feeding?

There are currently no available data on the safety of COVID-19 Vaccines in pregnant individuals. However studies are ongoing and expected to be available soon. The mRNA in the vaccine is degraded quickly in the body by normal cell processes, and experts believe that mRNA vaccines are unlikely to pose a risk for people who are pregnant. However, pregnant people who develop a COVID-19 infection are at increased risk of adverse pregnancy outcomes. Pregnant people may choose to be vaccinated. A conversation between the patient and their doctor may assist with decisions of whether or not to vaccinate. When making a decision pregnant people should consider their level of COVID-19 community transmission, their own level of exposure to COVID-19, the side effects of the vaccine, and the risks of a COVID-19 infection to the patient and potential risk to the fetus.

There are no data on the safety of COVID-19 vaccines in lactating people. mRNA vaccines are not though to be a risk to the breastfeeding infant. A lactating person may choose to be vaccinated.

Source CDC. (2020). 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

Can I get the vaccine if I have had food/ bee 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 Moderna COVID-19 Vaccination. A 30 minute observation period following vaccination is recommended for anyone with a history of a severe allergic reaction.

Source CDC. (2020). 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

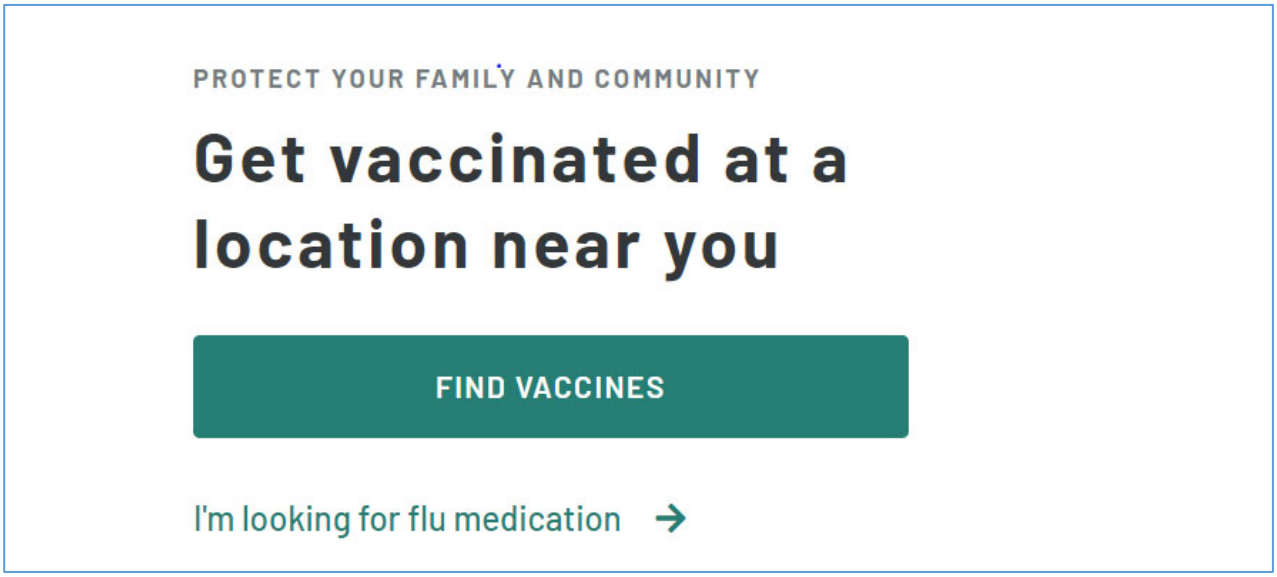
Vaccine Finder

What is Vaccine Finder?

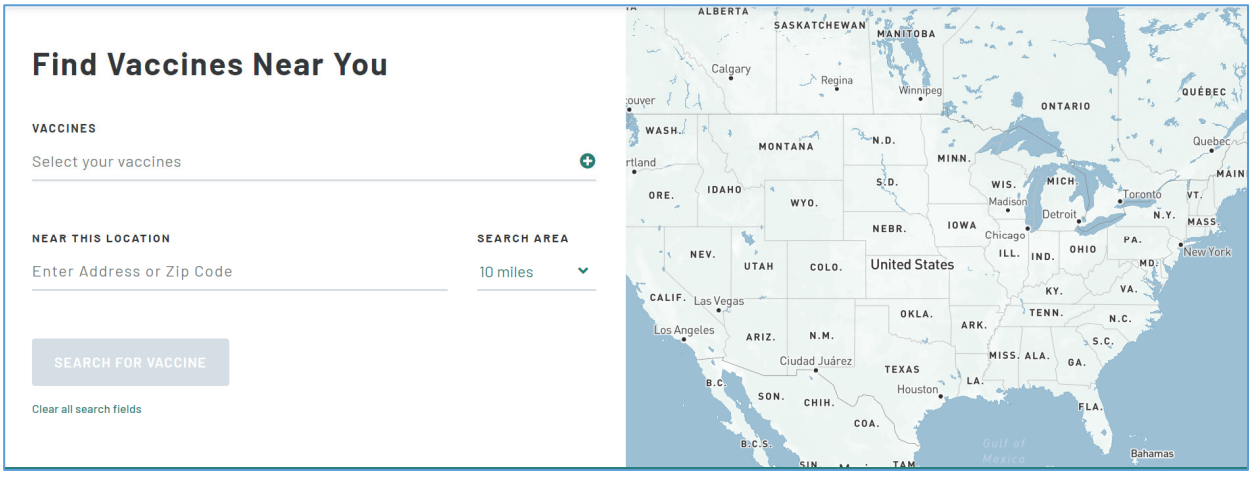
Vaccine Finder is an online database that uses geo-mapping to find healthcare providers in a given area that provide immunizations. The goal of the Vaccine Finder is to simplify the process of finding and choosing a vaccine provider, therefore increasing vaccine coverage. By entering a zip code, individuals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

How Do I Search for a Vaccine in Vaccine Finder?

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



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



Vaccine Safety and Administration Additional Resources

Indiana Department of Health

Division of **Immunization**

VACCINE SAFETY AND ADMINISTRATION **TOOLKIT**

DECEMBER 2020

Moderna and CDC/FDA/HHS Resources

Moderna 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: Moderna COVID-19 Vaccine Patient EUA and Provider Fact Sheet

Webpage: Moderna Dosing and Administration

Webpage: Moderna Safety Info

Webpage: Moderna Resources

Webpage: Moderna Q&A

CDC Resources

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

Webpage: Interim Clinical Considerations for Use of Moderna COVID-19 Vaccine

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: December 2020

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

PDF: V-safe for Patients Handout

Where to Find More Safety and Administration Resources

Webpage: Immunizations MMWR

Actualized: December 2020

Moderna Contact List

Moderna

[Moderna COVID-19 Vaccine Website]

	Phone Number	Hours	Email/Website	Help For
Shipment Issues/ General Product Inquiries	866-MODERNA	24 hours a day 7 days/week		
Adverse Event Reporting to VAERS and Moderna Inc.	Phone: 1-866-663-3762 Fax: 1-866-599-1342		ModernaPV@modernatx.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.htm

Actualized: December 2020