

BILH Patient Vaccination Manual

Updated as of February 11, 2021

This training deck will be updated to reflect any new or changing information.

Table of Contents

Site Preparation	3
Infection Control	3
Clinic Supplies	3
Vaccine Clinic Emergency Response Bag Contents.....	4
PPE for Clinic Staff.....	4
Security	5
Overview of Clinic Roles.....	5
Start of Clinic Day	6
Vaccine Storage, Preparation, and Handling	6
Receiving Vaccine.....	6
Refrigeration Temperature Log for COVID-19 Vaccine.....	7
Pfizer COVID-19 Vaccination Information Guide	10
Moderna COVID-19 Vaccination Information Guide	11
Patient Vaccination Site Visit: Overview	12
IT Scheduling Tool	12
Logging into the COVAX Tool for the First Time	12
Navigating the Dashboard	13
Check-In Process (Greeter Role)	14
Check-In Process	14
Check-In Process: COVAX Tool	15
COVID Screening Questions	16
Patient Handouts	17
Patient Guidance for Isolation vs. Quarantine.....	20
Unplanned Patient Arrivals	21
Vaccination Process (Vaccinator Role).....	21
Pre-Receipt Assessment of Contraindications / Precautions.....	21
Vaccinator Role	22
Preventing Needle-Stick Injuries.....	23
Documenting the Patient's Vaccination in the COVAX Tool	24
Vaccination Process – Observer.....	25

Vaccination Process – Emergency Response	25
Vaccination Process – Vaccine Clinic: Reaction Response Form	26
Vaccination Process – Anaphylaxis at a Glance	28
Vaccination Process – Administration of EpiPen	29
Vaccination Process – Adverse Reactions: Reporting and Documentation.....	29
Post-Vaccine Administration and Check-Out.....	30
Check-Out Process	30
Staff Schedules Patient’s Second Dose in COVAX Tool	30
End of Day	31
BILH Interim COVID-19 Vaccine Clinics Guideline for Allocating Extra Doses Prior to Closure	32
Documentation of Vaccinator and Observer Competencies	32
Reference Materials.....	34
1. BILH Vaccine Clinic Playbook	34
2. BILH Pharmacy Standard Operating Procedures for Vaccine Clinics	34
3. BIDMC Training Materials	34
4. Patient Facing Clinic Materials	34
BILH Standing Order for Medical Management of Vaccine Reactions in COVID-19 Vaccination Clinics.....	34
BILH Vaccine Clinic Emergency Response SOP	37
Characteristics of Reactions and Vaccine Side Effects Following mRNA COVID-19 Vaccination.....	43
COVID-19 mRNA Vaccine (Moderna & Pfizer Bio-NTech) Management of Potential Post-Vaccination Side Effects.....	44

Site Preparation

Infection Control

(Source: Adapted from BILH Vaccine Clinic Playbook)

- ☐ All staff must be knowledgeable regarding infection control practices.
- ☐ Furniture should all be cleanable using approved agents.
- ☐ Vaccine administration stations and observation areas are approximately 6 feet apart and should be disinfected every hour (as per CDC recommendations), or if visibly soiled, using an approved germicidal wipe.
- ☐ Cleaning and disinfection is performed by the vaccinator or room assistant or other role designated on-site.
- ☐ High-touch surfaces (workstations, keyboards, telephones, and doorknobs at check in area and in observation areas are cleaned and disinfected using an approved germicidal wipe following the stated wet contact time at least every hour between shifts and at the end of the clinic day.
- ☐ Surgical masks should be available at entry/check-in to give to each vaccine recipient and essential escort. Individuals should wear the BILH-provided surgical mask in place of the mask (or face covering) they arrive with, over their own mask (or face covering), or if they arrive with no mask/face covering.
- ☐ Hand hygiene stations are available at vaccination, observation and entry/check-in areas and should be checked at least twice a day to ensure they have sufficient product; refill as necessary.
- ☐ Eating or drinking is not allowed outside of the designated break/lunchroom.
- ☐ All clinics are cleaned at end of day by staff, or local cleaning contract and should include the following areas and actions:
 - Door handles, Bathrooms, Check in and check out tables, Vaccine station tables, Vaccine station chairs, Observation chairs, Clean and mop all hard surfaces, Vacuum rugs within observation area, Empty all trash

Clinic Supplies

(Source: Adapted from BILH Vaccine Clinic Playbook)

- ☐ Chux/disposable pads
- ☐ Disinfectant wipes
- ☐ Paper towels
- ☐ 2-3 Emergency kits (see next slide)
 - Epinephrine, autoinjector
- ☐ Band-aids and gauze pads
- ☐ Blood pressure measuring device
- ☐ Vaccine station # signs
- ☐ One station for every vaccinator with 2 chairs (avoid fabric and ensure cleanable arms), wastebasket, sharps containers, alcohol-based hand sanitizer dispenser
- ☐ Enough chairs in observation space, set up 6 feet apart from each other
- ☐ Screens to allow for disrobing: 1 per clinic
- ☐ BILH-provided vaccination information/documents
- ☐ Laptops with chargers (one per vaccination station)
- ☐ Hand sanitizer locations
- ☐ Entry and exit to clinic and observation space
- ☐ Every vaccination station
- ☐ Workstations
- ☐ BILH-approved signage

- Physical distancing markings on floor to stand 6 ft apart
 - “Not feeling well signs:” procedures to follow if onsite and have symptoms
 - Any signs referencing the operator of the site should include the name of the sponsoring hospital
- ☐ Surgical masks
- ☐ Reusable eye protection and brown paper bags (for PPE storage during breaks, between shifts)

Vaccine Clinic Emergency Response Bag Contents

(Source: BILH Standing Order Vaccine Reactions for COVID-19 Clinics)

Medications for Managing Vaccine Reactions:

Medication Box		
Medication	Strength	Number present
EpiPen Auto-injector	0.3 mg/0.3 mL	4
Glucose gel (pending confirmation)	15 gm/30 mL	2
Albuterol (Pro-Air) Metered-Dose Inhaler (MDI) 8.5 gm	200 inhalations/ canister	2
Diphenhydramine 50 mg vial (pending confirmation)	50 mg/mL	2
Diphenhydramine oral	25 mg capsule	10
Loratadine oral (pending confirmation)	10 mg tablets	2
Hydroxyzine (pending confirmation)	pending	pending

Supplies for Managing Vaccine Reactions:

Other Supplies in Med Box (from Distribution services)		
Item	PeopleSoft #	Number present
Retracting 3 mL syringe (IM) (pending confirmation)	35038	3
Blunt fill needle (pending confirmation)	30547	2
Alcohol wipes	41364	10
Medication Labels	MC1480	6
Other Supplies in Bag – (from Distribution services)		
Item	PeopleSoft #	Number present
Roll of tape	129517	2
4x4 gauze	130709	10
Band-Aids	40563	10
Kerlex	2793	1
Ice Pak	3316	2
Gloves	3542(L)/3541(M)	2 boxes (1 L, 1M)
Reusable Stethoscope (pending confirmation)	41504	1
Flashlight (pending confirmation)	40150	1

PPE for Clinic Staff

(Source: Adapted from BILH Vaccine Clinic Playbook)

Staff must wear:

- ☐ Surgical Masks

- ☐ Eye protection

Eye Protection: per the BILH PPE Guidance, all vaccine clinic staff must wear approved eye protection (goggles, eye shield or face shield) for all patient contact or work in a patient care/vaccination area. Face shields are preferred

Gloves: not required per CDC and OSHA for high throughput vaccination clinics but will be available on-site. Whether or not gloves are worn, staff should continue to practice proper hand hygiene and handwashing procedures

Gowns: gowns do not need to be worn by staff

**Patients should be masked at all times when at the vaccination site*

Security

(Source: Adapted from BILH Vaccine Clinic Playbook)

- ☐ Badge access granted to all necessary staff, including Pharmacy, Vaccinators, Observers, Clinic Operations & Administration.
- ☐ Police & Security should be aware of security needs. Each site will need to include their local Security team in their operational staffing plans.
- ☐ Ensure site-based Security knows the clinic's location and hours of operation, including the time for setup and breakdown of the clinic.
- ☐ During check-in, employee/vaccinator provides proof of ID with employee badge.
- ☐ BILH Pharmacy will remove vaccine product nightly from each clinic and return to appropriate storage facility.
- ☐ All clinic doors will be locked after clinic closes so laptops and supplies are secured.
- ☐ Identify other security concerns that need to be addressed at identified clinic sites.

Overview of Clinic Roles

(Source: Adapted from BILH Vaccine Clinic Playbook)

Role	Duties
Executive Operational Director	Oversight of all vaccine operations
Medical Director	Oversight of medical operations at vaccine site
Site Operations Lead	Supports Executive Director in overseeing all vaccine operations, including Pharmacy
Pharmacy Officer	Pharmacy Oversight
Facilities Lead	Facility Oversight
Support contact local hardware / network	IT Oversight
On-Site Vaccine Clinic Manager	Manages day to day operations of clinic site and elevates issue to leads and directors as necessary
Greeter/Check-In:	<ul style="list-style-type: none"> Responsible for greeting, checking-in and directing patients to vaccination station Answers questions and manages traffic flow. Notifies on-site Vaccine Clinic Manager if an individual has a question the Greeter cannot answer

Room Assistant / Table Wiper:	Cleans and disinfects each vaccination station table between individuals with a hospital-approved germicidal wipe or at the scheduled hourly cleaning time.
Vaccinator	Vaccinators can be MAs if certified in vaccine administration (see MA DPH Circular Letter DCP 17-8-102 from August 2017), LPNs, RNs, NPs and MDs, PAs, PA students, Medical students, Pharmacists, pharmacist interns, pharmacy students: sites should work with their Chief Pharmacy Officer to determine feasibility of leveraging Interns, Graduate nurse (completed course work- pending NCLEX) and CNI's (completed course work, graduated and passed NCLEX)
Observer	Required credentials/skillset: Certified MA, LPN, RN, or NP.
Staff Scheduler (may be combined with other roles depending on site)	<ul style="list-style-type: none"> Schedules appropriate clinic staff with appropriate staffing mix (Vaccinators & Observers). Works with Human Resources Talent Acquisition to identify staffing gaps Requests appropriate IT access for defined staff Communicates staff issues to Manager (e.g., no shows, substantially late for shift)
Appointment Scheduler/Check-Out Staff	Checks-out individuals and schedules patients for their 2 nd dose appointment through COVID-19 scheduling tool.

Start of Clinic Day

(Source: Adapted from BILH Vaccine Clinic Playbook)

On-Site Vaccine Clinic Manager:

1. Call security if needed to open door to site
2. Write names and roles on the white board, including Administrator on Call (with their phone number)
3. Ensure laptops are powered on and charged.
4. Review clinic schedule. Ensure enough vaccine doses provided by Pharmacy.
5. Ensure vaccine preparations have been stored separately.
6. It is recommended once a clinic has mixed product (e.g., Pfizer & Moderna) vaccination stations be manufacturer specific as a safety precaution and to decrease likelihood of error.
7. Set up Vaccination Station tables (with table #s) and training materials.
8. Welcome staff, introduce yourself, match staff to your list, assign to roles and vaccination stations.
9. Ok to re-assign staff based on when individuals arrive and your discretion
10. Remind any non-exempt staff that they need to clock in and out
11. Orient staff to restrooms, safe lunch/break space
12. All snacks or lunches to be eaten in a safe eating location

Vaccine Storage, Preparation, and Handling

Receiving Vaccine

(Source: Adapted from BILH Pharmacy Standard Operating Procedures)

1. Vaccine will be delivered to site by courier from the BILH Westwood Pharmacy at least half hour prior to the first scheduled patient. Amount of vaccine delivered daily will be limited to the amount needed to immunize anticipated/scheduled patient volume.

2. Vaccines will be delivered in a thermal shipper that will maintain temperatures between 2°C and 8°C for up to 96 hours. Any remaining unopen vials will need to be placed back in thermal shipper at the end of the day and returned to BILH Westwood Pharmacy by pre-arranged courier service.
3. Thermal shipper will have continuous temperature monitoring device attached to the outside of the shipper. It is important that shipper is always securely closed and temperature inside cooler is maintained between 2°C and 8°C at all times. Upon morning delivery:
 - a. Confirm that current temperature monitor reading is within range (2°C and 8°C) and that the “MIN” and “MAX” readings are also within range. Notify site administrator or corresponding hospital pharmacy contact for any out-of-range temperature readings.
 - b. Sign attached “Vaccine Chain of Custody Received” form acknowledging receipt and chain of custody.
 - c. Inspect onsite refrigerator ensuring temperature ranges are within 2°C and 8°C. Notify site administrator if refrigerator out of range.
 - d. Immediately transfer all vaccines from thermal shipper to refrigerator. Thermal shipper must only be opened once in the morning to remove all vaccine and once a night to repack any leftover vaccine (as needed).
 - e. Close and secure thermal shipper to ensure cold chain integrity and store in a safe place away from any heat source.
4. Vaccines are transported under refrigerated conditions but may arrive on site still frozen or partially thawed (see next slides).
5. Vaccines will be delivered bagged and labeled according to:
 - a. Manufacturer
 - b. “Use by” date
6. Pay particular attention to the use by date and always rotate stock so that product with the shortest expiration date is always administered first in order to minimize wastage. ****Note**** Do not use any product after the “use by date”, notify clinic manager of any expired/wasted/unusable product.
7. Place vaccine thermal shipper aside and away from any heat source for repackaging and shipment back to pharmacy at the end of day.
8. If there are no vaccines left to send back to the pharmacy via the courier, please still send back the empty box.
9. Only un-punctured vials should be returned to the pharmacy at the end of the day.

Refrigeration Temperature Log for COVID-19 Vaccine

(Source: BILH Pharmacy Standard Operating Procedures)

Vaccination Site: _____ **Site Administrator:** _____

Refrigeration Temperature Log For COVID-19 Vaccine

Month/Year: _____/2021

Instructions:

1. **When vaccine clinic Opens:** Upon morning delivery of vaccine, record refrigeration temperature under “AM Temp”. Place your initials in the box next to the reading. If reading is out of range document under “OOR” and contact site administrator.
2. **When Vaccine clinic closes:** Remove any remaining vaccines and place in vaccine transport container and return as directed. Record evening temp under “PM Temp” and initial.
3. **During the day:** Should the temp alarm activate contact the site administrator immediately and wait for instructions. Check off “OOR” and document on page 2.

Temperature must remain between 2°C and 8°C for REFRIGERATOR

If Out of Range Temp – check off OOR, and follow instructions below - document on page 2

Day	AM Temp.	Initials	PM Temp.	Initials	OOR
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					
17					
18					
19					
20					
21					
22					
23					
24					
25					
26					
27					
28					
29					
30					
31					

Unacceptable refrigerator temp. ranges are defined as the following: falls below 2°C or is above 8°C. If the temperature is out of range (OOR), please **(1) Contact site administrator immediately (2) identify the problem (see back), (3) attempt to correct problem and document (see back) (4) recheck the temperature after 30 minutes to confirm resolution and (5) Store the vaccine under proper conditions as quickly as possible if problem does not resolve.**

❖ If after 30 minutes the intervention did not result in a temperature between 2°C and 8°C:

1. Contact site administrator or corresponding hospital partner
2. Corresponding hospital partner will attempt to troubleshoot problem and provide further directions AND
3. If not resolved, place signage on the refrigerator door indicating the situation and identifying where the refrigerated medications are temporarily stored.

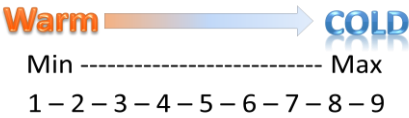
Important: Notify the local Site Administrator ASAP!

Procedure: Document in ALL fields below for Out Of Range (OOR) temperature

Date /Day	Time	Current Temperature	Identify Problem A-F (See below)	Document Action 1-6 (See below)	Comments	Record the 1hr recheck temp	Time of re-check	Problem resolved	Contacted Pharmacy and Facilities	Initials
-----------	------	---------------------	----------------------------------	---------------------------------	----------	-----------------------------	------------------	------------------	-----------------------------------	----------

								Y N	Y N	
								Y N	Y N	
								Y N	Y N	
								Y N	Y N	
								Y N	Y N	
								Y N	Y N	

Key: Identifying problem and corrective actions

Problem Identified	Corrective Action Taken
A. Recent frequent use or door ajar	1. Physically confirm door is closed. Problem will likely be resolved at 1 hour temp re-check
B. Temperature probe improperly positioned	2. Make sure probe is inside refrigerator. Probe should not be touching any side of the fridge or any product. Some probes are sealed in polyglycol solution, and this whole unit should also not be touching other areas.
C. Temperature probe is out of calibration	3. Each probe has an expiration date for current calibration. If product is out of date replace probe and/or monitor.
D. Thermometer display needs new batteries	4. Erratic readings, faint display, or no display are signs that the batteries should be replaced. One AA battery is required for replacement.
E. Refrigerator is too cold	5. a - The fridge may need to be defrosted if you see ice build-up. Please contact site administrator if this occurs. b - If temperature has been trending too cold, adjust the temperature dial to a warmer setting. The dial may be on the outside/back of the refrigerator.
F. Refrigerator is too warm	6. If the temperature has been trending too warm, adjust the temperature dial to a higher setting. <div style="text-align: center;">  <p>Warm COLD</p> <p>Min ----- Max</p> <p>1 - 2 - 3 - 4 - 5 - 6 - 7 - 8 - 9</p> </div>

This guidance describes the steps in safe administration of COVID-19 vaccine administration and post-vaccination monitoring as well as emergency response.

Pfizer COVID-19 Vaccination Information Guide

(Source: BILH Pharmacy Standard Operating Procedures)

Pfizer COVID-19 Vaccine Information Guide

(For patient vaccination clinics without overnight storage)

Storage

- Pfizer vaccine will arrive under refrigeration but may still be frozen*, see thawing instructions below prior to dilution and use
- Undiluted vials stored in refrigerator at 2 to 8 °C must be used within 5 days, always label/verify with expiration sticker accordingly and rotate stock to prevent waste.
- **Diluted product must be used within 6 hours from the time of dilution, store at room temperature between 2°C to 25°C (35.6° to 77°F).**
- Undiluted vials may be held at room temperature for no more than 2 hours.
- Vials must be transported un-diluted. Do not transport vials after dilution.

*Note: Pfizer vaccine is removed from ultra-cold storage and placed in refrigerated thermal shipper the morning of clinic. Some vials may still be frozen/partially frozen upon arrival at clinic.

PREPARATION AND ADMINISTRATION

Preparation (Thawing)	How Supplied	Route & Dose	Stability	Misc.
Thaw before dilution- for immediate use leave at room temperature [up to 25°C (77°F)] for 30 minutes or will require 2-3 hours to thaw under refrigeration	Solution in 6 dose vial; dilute with 1.8ml NS	0.3mL IM to deltoid muscle of the non-dominant arm; 2 doses given 21 days apart	Use within ≤ 6 hours at room temperature (20-25°C) after dilution	Once vial is at room temperature, it cannot be returned to storage.

Preparation

- Once vials are thawed, gently invert the vial 10 times prior to dilution. **Do not shake.**
- Dilute 6 dose vial with 1.8ml PF NaCl 0.9% solution for injection using a 21 gauge or narrower needle and aseptic technique.
- Equalize the pressure before removing needle from the vial by withdrawing 1.8ml of air.
- Gently invert the vial 10 times again. **Do not shake.**
- Diluted vaccines should be off-white with no visible particles.
- Mark vial with new discard date and time. Vials must be used within 6 hours after dilution.

Administration

- Remove 0.3 mL of diluted vaccine into a sterile 1mM luer lock syringe using aseptic technique.
- Use the same needle to withdraw and administer the vaccine if possible.
- Use a new syringe and needle for each dose.
- Administer vaccine intramuscularly in the deltoid muscle of the non-dominant arm.

Moderna COVID-19 Vaccination Information Guide

(Source: BILH Pharmacy Standard Operating Procedures)

Moderna COVID-19 Vaccine Information Guide

(For patient vaccination clinics without overnight storage)

Storage

- Moderna vaccine will arrive under refrigeration but may still be frozen*, see thawing instructions below prior to use
- Vials stored in refrigerator at 2 to 8 °C must be used within 30 days, always label/verify with expiration sticker accordingly and rotate stock to prevent waste.
- **Vials must be used within 6 hours after withdrawal of the first dose. Store punctured vials at temperatures between 2°C to 25°C (35.6° to 77°F).**

*Note: Moderna vaccine is removed from freezer and placed in refrigerated thermal shipper the morning of clinic. Some vials may still be frozen/partially frozen upon arrival at clinic.

PREPARATION AND ADMINISTRATION

Preparation (Thawing)	How Supplied	Route & Dose	Stability	Misc.
Thaw - for immediate use leave at room temperature [up to 25°C (77°F)] for 1 hour, or 2.5 hours to thaw under refrigeration.	Solution in 10 dose vial; no dilution is required	0.5mL IM to deltoid muscle of the non-dominant arm; 2 doses given 28 days apart	Use within ≤ 6 hours at temperatures 2 - 25°C	Once vial is at room temperature, it cannot be returned to storage.

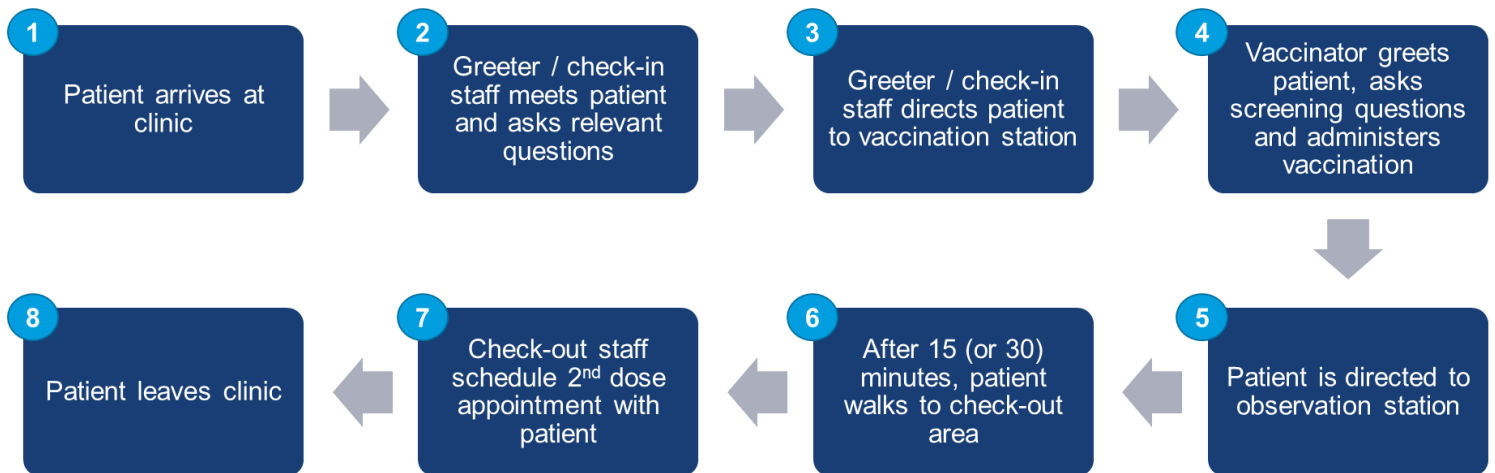
Preparation

- Dilution is not required for the Moderna vaccine
- Swirl vial gently after thawing and between each withdrawal; do NOT shake
- Vaccines should be off-white with no visible particles.
- Mark vial with new discard date and time. Vials must be used within 6 hours of first draw.

Administration

- Remove 0.5 mL of vaccine into a sterile 1mM luer lock syringe using aseptic technique.
- Use the same needle to withdraw and administer the vaccine if possible.
- Use a new syringe and needle for each dose.
- Administer vaccine intramuscularly in the deltoid muscle of the non-dominant arm.

Patient Vaccination Site Visit: Overview



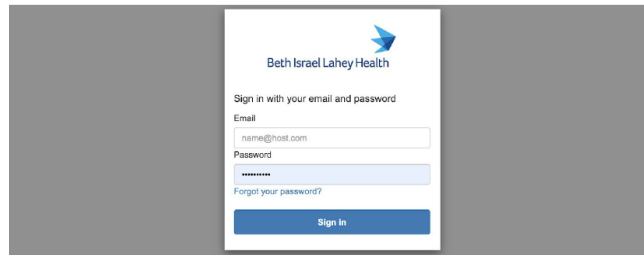
IT Scheduling Tool

Logging into the COVAX Tool for the First Time

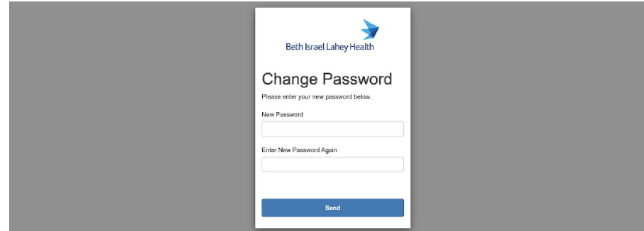
(Source: Adapted from BIDMC COVID-19 Vaccine Administration Training Materials)

Logging In for the First Time

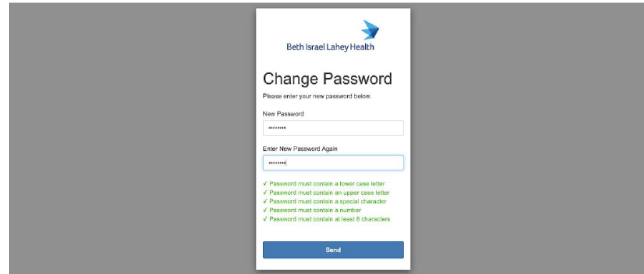
1. Staff will receive an email from C19VaccinePatientITSupport@bilh.org with a link to the Patient Vaccine Administration Tool, and a temporary password. Your primary email is your username. When you click the link you will see the login page as below.

The image shows the login page for Beth Israel Lahey Health. It features the organization's logo at the top. Below the logo, the text "Sign in with your email and password" is displayed. There are two input fields: "Email" with the placeholder "name@host.com" and "Password" with a masked password "*****". A link "Forgot your password?" is located below the password field. A blue "Sign In" button is at the bottom.

2. When you log in for the first time, enter your email address and the temporary password. Upon successful login, you will be prompted to set a new password.

The image shows the "Change Password" page for Beth Israel Lahey Health. It prompts the user to "Please enter your new password below." There are two input fields: "New Password" and "Enter New Password Again". A blue "Save" button is at the bottom.

3. Enter your new password ensuring it meets security requirements and click "Save".

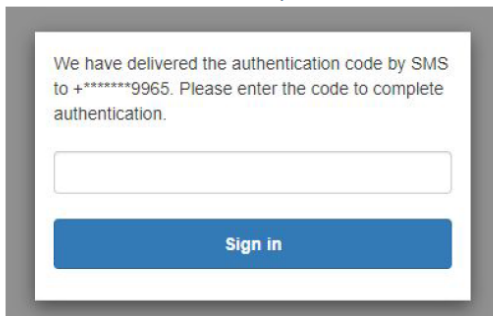
This image shows the "Change Password" page with the security requirements for the new password. The "New Password" and "Enter New Password Again" fields are now filled with masked text. Below the fields, there are five green checkmarks indicating the password meets the following criteria: "Password must contain at least one letter", "Password must contain an upper case letter", "Password must contain a special character", "Password must contain a number", and "Password must contain at least 8 characters". A blue "Save" button is at the bottom.

4. For all future logins, use your email address and your new password.

Two-Factor Authentication

As an important added layer of security, each time you log into the tool, as described above, you will also be prompted to enter an **authentication code**, which will be sent via **text** to your cell phone. **Note:** It is important that you have your cell phone with you at all times while using this tool, as this two-factor authentication process will occur every time you sign in.

1. Enter the code that you receive via text message into the field and click "Sign In."

The image shows a screen for two-factor authentication. It displays the message: "We have delivered the authentication code by SMS to +*****9965. Please enter the code to complete authentication." Below the message is a text input field and a blue "Sign In" button.

Text Message
Today 1:06 PM

**BILH COVAX Vaccination
Dashboard: Your
authentication code is 474168**

Navigating the Dashboard

(Source: Adapted from BIDMC COVID-19 Vaccine Administration Training Materials)

Navigating the Dashboard

Log into the dashboard via this link: [COVID-19 Patient Vaccination Administration Tool](#)

Detailed information will display in the Dashboard related to the patient's 1st and 2nd vaccinations.

A. Filter Options:

- Filter by **Vaccination Site** and **Date**.
- Other filter options include **Vaccine Status** and **Check-In Status**.
- You can search for the patient by **name, phone number or email address**.

B. Patient Information:

- Review/confirm information related to the patient receiving the vaccination (**Name, DOB, Sex**)
- Click on the column headers to sort on the fly.

C. Dose 1 and Dose 2 Information:

- Two separate sections will display for **Dose 1** and **Dose 2**.
- **Site** will indicate the site where the employee was scheduled.
- You will see the date and time of their **scheduled** appointment
- **Brand** will display the vaccine brand recorded at the time of vaccination.
- **Clock icon** indicates the days since the 1st dose was administered.
- **Vaccinated** will display the date of check-in for each dose.
- Click on the column headers to sort on the fly (ie. click on the **Scheduled** column to sort across 1st and 2nd doses to provide a comprehensive view of the day's schedule. If you want to filter down to just 1st or 2nd doses, use the **Status** filter as well.

A

COVID-19 Vaccine Check-In Dashboard

Welcome Rachel Osholin | Sign out

Vaccination Site: All

Date: 1/22/2021

Phase: All

Status: All

Checked In?: All

Search Patient:

Patient Name	DOB	Age	Sex	Phase	Dose 1: Site	Scheduled	Checked In	Vaccinated	Brand	Dose 2: Site	Scheduled	Checked In	Vaccinated
		37Y	F		Beverly VRP - Beth Israel Lahey Health Primary Care ...		Yes						
		89Y	M				Yes	1/23/2021	Moderna	3			
		78Y	M				Yes	1/16/2021	Pfizer	20			

B

C

Check-In Process (Greeter Role)

Check-In Process

(Source: Adapted from BILH Vaccine Clinic Playbook and BIDMC COVID-19 Vaccine Administration Training Materials)

Greeter / Check-In Staff

1. Patients need to wear a surgical mask at all times while on site
2. Asks individual to use alcohol-based hand sanitizer
3. Verify the patient has an appointment via the check-in tool, check-in patient, and check identification (see next slide)
4. Ensure the patient has an escort only if they are physically unable to proceed without one. Escorts must also wear a surgical mask at all times while on site and be asked the COVID screening questions
5. New surgical masks should be available at entry/check-in for vaccine recipients arriving wearing a cloth mask, bandana/gaiter mask, a mask with exhalation valve, a mask that is torn or visibly soiled, or if the patient is not wearing any face covering


6. Ask patient whether they have received another vaccine in the past 14 days. If the patient says yes, note the name of the vaccine and notify the clinic manager
7. Ask patient COVID screening questions (see upcoming slide). Response do not have to be recorded
8. Ask patient “Have you had a history of a severe allergic reaction (e.g., anaphylaxis) after a previous dose of mRNA COVID-19 vaccine, or any of its components (including polyethylene glycol or polysorbate)?” **AND** “Have you received a monoclonal antibody for COVID-19 treatment or prevention in the past 90 days?” If yes to either question, the patient cannot receive the vaccine at that visit. Ask a vaccinator or the clinic manager to speak with the patient.
9. If patient receiving 2nd dose, confirm which manufacturer (e.g., Pfizer, Moderna) the patient received for the first dose.
10. Make sure patient is prepared to wait 15 minutes after administration, hand paperwork to patient to review
 - a. BILH “What to Expect Today”
 - b. CDC’s “What to Expect after Getting a COVID-19 Vaccine”
 - c. EITHER Pfizer—BioNtech OR Moderna Emergency Use Authorization Fact Sheet for Recipients and Caregivers
 - d. Patient Information Sheet
11. Direct patient to vaccination station

Check-In Process: COVAX Tool

(Source: BIDMC COVID-19 Vaccine Administration Training Materials)

Checking-in a Patient

1. Log in to the **Patient Vaccine Administration Dashboard**.
2. Use the two-factor authentication process outlined above to get through the second layer of security.



Sign in with your email and password

Email

Password

[Forgot your password?](#)

Sign in

We have delivered the authentication code by SMS to +*****9965. Please enter the code to complete authentication.

Sign in

3. Select the **Vaccination Site** and **Date** to display the day’s schedule.

COVID-19 Vaccine Check-In Dashboard			
Vaccination Site: Beverly VRP - Beth Israel Lahe	Date: 1 /27/2021	Phase: All	Status: All

- Click on the patient to open the check-in window.
- Confirm the patient's **name and DOB** with them.
- On the left-hand side, under **Dose 1**, check the box next to **Checked-In**
- Click **Save Dose 1**.
- The patient's status of **Checked In** will appear on the dashboard.

(DOB:)

Home Address

Cell Phone

Email

Demographic Information

Ethnicity: Not Hispanic or Latino

Race: White

Language

English

Medical Record Numbers

EPIC-MACIPA:

Dose 1 [Update Schedule](#)

☐ Checked in
 ☐ Walk-in

Save Dose 1

Dose 2 [Update Schedule](#)

☐ Checked in
 ☐ Walk-in

Save Dose 2

Cancel

COVID Screening Questions

COVID-19 Vaccine Clinic – Screening Patients & Essential Escorts		
Your care and safety is a top priority. For your protection and the safety of other patients and staff, please read the questions below and point to your answers for staff to review.		
1. Have you been diagnosed with COVID-19 in the last 20 days?		YES NO
Actions for Staff: If yes, instruct the patient to reschedule vaccine appointment after end of isolation period (if not already completed per their history). 10 days from positive test result/diagnosis if mild illness and 20 days if severe infection or unknown. If no, continue to next question		
2. Are you experiencing any of the following symptoms?		YES NO
Fever (>100.3 deg F) or feeling feverish Chills Body aches Sore throat	Cough (new or worsening) Shortness of breath (new or worsening) Diarrhea (new or worsening) Loss of smell or taste	
Actions for Staff: If yes to at least one symptom, instruct patient to reschedule their vaccination after discussion with their PCP and COVID-19 testing has been performed. Refer to BILH COVID-19 testing site, if needed. If no, continue to next question		
3. Have you been in contact with anyone who has confirmed COVID-19 in the last 14 days?		YES NO
Actions for Staff: If yes, instruct patient to reschedule their appointment in 2 weeks and contact their PCP for COVID-19 testing or refer to BILH COVID-19 testing site, if needed. If no, offer patient/essential escort a surgical mask and proceed to vaccination.		

1. [Moderna EUA Fact Sheet](#)
2. [Pfizer EUA Fact Sheet](#)
3. BILH What to Expect Today

Your COVID-19 Vaccination Appointment

What to Expect Today

Beth Israel
Lahey Health

Congratulations!

You are about to receive your COVID-19 vaccination.

There are a few parts to your appointment and some important things you should know before you leave. Before you get started, you will be screened for COVID-19 symptoms or exposure.

Review the information below and let your caregivers know if you have any questions.

Please Remember

 Wear a mask at all times

 No food or drink

 No visitors, unless providing necessary assistance

Your Vaccination Appointment

Check In

You will provide your name and date of birth to confirm your vaccination appointment.



Vaccination

You'll receive a shot in your upper arm and receive a vaccination card, stating the details of the vaccine you received.



Observation

We will monitor you for any severe reactions, which are very rare. Please sit in the observation area for 15-30 minutes.



Before You Leave

- ☐ Book your second appointment. You'll need to bring your vaccination card.
- ☐ Take a picture of your card in case you forget it next time
- ☐ Review your paperwork
- ☐ Continue safety measures



Become a vaccine ambassador



Open the camera on your mobile phone and hold it up to the QR code to share your reason for getting the COVID-19 vaccine.

4. CDC What to Expect

What to Expect after Getting a COVID-19 Vaccine

Accessible version: <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/expect/after.html>

COVID-19 vaccination will help protect you from getting COVID-19. You may have some side effects, which are normal signs that your body is building protection. These side effects **may feel like flu** and **may even affect your ability** to do daily activities, but they should go away in a few days.

Common side effects

On the arm where you got the shot:

- Pain
- Swelling

Throughout the rest of your body:

- Fever
- Tiredness
- Chills
- Headache

Helpful tips

If you have pain or discomfort, talk to your doctor about taking an over-the-counter medicine, such as ibuprofen or acetaminophen.

To reduce pain and discomfort where you got the shot:

- Apply a clean, cool, wet washcloth over the area.
- Use or exercise your arm.

To reduce discomfort from fever:

- Drink plenty of fluids.
- Dress lightly.



Ask your healthcare provider about getting started with v-safe

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 dose.

Learn more about **v-safe**.
www.cdc.gov/vsafe

When to call the doctor

In most cases, discomfort from fever or pain is normal. Contact your doctor or healthcare provider:

- If the redness or tenderness where you got the shot increases after 24 hours
- If your side effects are worrying you or do not seem to be going away after a few days

Remember

- Side effects may feel like flu and even affect your ability to do daily activities, but they should go away in a few days.
- With most COVID-19 vaccines, you will need 2 shots in order for them to work. Get the second shot even if you have side effects after the first one, unless a vaccination provider or your doctor tells you not to get a second shot.
- It takes time for your body to build protection after any vaccination. COVID-19 vaccines that require 2 shots may not protect you until a week or two after your second shot.
- It's important for everyone to continue using all the tools available to help stop this pandemic as we learn more about how COVID-19 vaccines work in real-world conditions. Cover your mouth and nose with a mask when around others, stay at least 6 feet away from others, avoid crowds, and wash your hands often.

HEALTHCARE PROVIDER, PLEASE FILL IN THE INFORMATION BELOW:

If your temperature is ____°F or ____°C or higher or if you have questions, call your healthcare provider.

Tell your healthcare provider about: _____

Healthcare provider phone number: _____

Medication (if needed):

Take _____ every _____ hours as needed.
(type and dose or amount)



cdc.gov/coronavirus

CS 321466-A 12/13/2020

5. Patient Information Sheet mRNA (Pfizer BioN-Tech & Moderna) COVID-19 Vaccines

Patient Information Sheet mRNA (Pfizer BioN-Tech & Moderna) COVID-19 Vaccines

The purpose of COVID-19 vaccination is to reduce the risk of becoming sick from the virus that causes Coronavirus Disease 2019 (COVID-19).

There are currently two COVID-19 mRNA vaccines (Pfizer/BioN-Tech and Moderna (collectively the "EUA Vaccines")) approved by the Food and Drug Administration ("FDA") through Emergency Use Authorization ("EUA"). Both are recommended equally for use. We will be offering either EUA Vaccine based on their immediate availability and are not able to accommodate individual preferences. The FDA may issue an EUA based on a declaration by the Secretary of the Department of Health and Human Resources that circumstances justify the emergency use of drugs and biological products during the COVID-19 pandemic if certain criteria are met. The criteria are explained in more detail in the EUA Fact Sheets linked below.

Please review the Emergency Use Authorization (EUA) Fact Sheet for Recipients and Caregivers online for complete details on the vaccine and possible side effects.

Moderna Fact Sheet - <https://www.modernatx.com/covid19vaccine-eua/eua-fact-sheet-recipients.pdf>

Pfizer BioN-Tech Fact Sheet - <https://www.fda.gov/media/144414/download>

Reasons to Delay Vaccination:

- **If you have a history of severe allergy (anaphylaxis) or immediate reaction of any kind (e.g., anaphylaxis, difficulty breathing, hives, swelling around the mouth, throat or eyes) to a prior dose of a COVID-19 mRNA vaccine (or any of its components), you should not receive this vaccine.**
- If you have a fever (temperature of 100.4 degrees or higher), chills or any symptoms of COVID-19 infection, you should contact your primary health care provider to consider testing for COVID-19 prior to vaccination.
- If you were recently diagnosed with COVID-19 or are on quarantine due to an exposure, you should wait until your primary health care provider recommends ending isolation or quarantine prior to vaccination.
- If you have received (or may have received in a clinical trial) any of the following for COVID-19 treatment or prevention: a monoclonal antibody (such as Regeneron or Bamlanivimab) or convalescent plasma, you should wait 90 days after the treatment date before getting vaccinated so that the vaccine will be as effective as possible.

Other Considerations Prior to Vaccination:

- If you are pregnant, lactating (breast-feeding) or planning to become pregnant, we recommend that you have a conversation with your primary health care provider about whether vaccination is right for you.
- **If you have a history of immediate allergic reaction (such as anaphylaxis, difficulty breathing, hives, swelling around the mouth, throat or eyes) to any vaccine or injectable (intramuscular, intravenous or subcutaneous) medication in the past, we ask that you consult with your primary health care provider to determine if you can safely receive the COVID-19 vaccine and inform us so that the appropriate longer post-vaccination monitoring (30 minutes) may be performed.**

Patient Information Sheet mRNA (Pfizer BioN-Tech & Moderna) COVID-19 Vaccines

Required Post-Vaccination Observation Period:

You will be monitored for any signs of an allergic reaction immediately after the vaccination (minimum 15 minutes, 30 minutes if prior severe allergic reaction). Some symptoms of allergic reaction are rash, wheezing, difficulty breathing, dizziness and fainting, swelling around the mouth, throat, or eyes. This is not an exhaustive list. Please notify us immediately if you notice any of these symptoms or have any other concerns.

What to Expect After Your COVID-19 Vaccination:

The vaccines may cause side effects in some people, like sore muscles, feeling tired, or mild fever. These reactions mean the vaccine is working to help teach your body how to fight COVID-19 if you are exposed. For most people, these side effects will last no longer than a day or two. **Having these types of side effects does NOT mean that you have COVID-19.** If you have questions about your health after your vaccination, call your primary health care provider. As with any medicine, it is rare but possible to have a serious reaction, such as not being able to breathe. It is very unlikely that this will happen, but if it does, call 911 or go to the nearest emergency room.

Please report all vaccine side effects to the FDA/CDC Vaccine Adverse Event Reporting System (VAERS) online, <https://vaers.hhs.gov/reportevent.html>, or the VAERS toll-free number (1-800-822-7967). You may also report to the CDC v-safe online tool (<https://vsafe.cdc.gov>).

What to Do After Your COVID-19 Vaccination:

Even after you get your vaccine, you will need to keep wearing a mask that covers your nose and mouth, cleaning your hands often, and staying at least 6 feet away from other people you do not live with. This gives you and others the best protection from catching the virus.

Make sure that you schedule and return for your 2nd Dose of Vaccine:

- Pfizer BioN-Tech – 2nd dose is due in 21 days (Earliest may be scheduled is Day 17)
- Moderna – 2nd dose is due in 28 days (Earliest may be scheduled is Day 24)

Reminder - The vaccine you receive will be listed on a vaccination card provided to you. Please keep this card for your COVID-19 Vaccination Record and bring it to your second vaccination appointment.

Consider enrolling in the CDC v-safe Tool (<https://vsafe.cdc.gov>) – a smartphone after vaccination health checker for people who receive COVID-19 vaccines. This tool will provide a symptoms check-in as well as 2nd dose vaccination reminders.

Please avoid other non-urgent vaccinations until 14 days after you've completed your COVID-19 vaccine series.

If you have any questions about side effects and whether you should not receive your 2nd dose of the vaccine, please consult with your primary health care provider.

COVID-19 Vaccination Record Card

Please keep this record card, which includes medical information about the vaccines you have received.

Por favor, guarde esta tarjeta de registro, que incluye información médica sobre las vacunas que ha recibido.

Last Name: _____ First Name: _____ SS: _____

Date of Birth: _____ Patient number (medical record or ID record number): _____

Vaccine	Product Name/Manufacturer	Date	Healthcare Professional or Clinic Site
1 st Dose COVID-19	Lot Number: _____	mm / dd / yy	
2 nd Dose COVID-19	Lot Number: _____	mm / dd / yy	
Other	Lot Number: _____	mm / dd / yy	
Other	Lot Number: _____	mm / dd / yy	

As of 1/19/21

Beth Israel Lahey Health 

Patient Guidance for Isolation vs. Quarantine

ISOLATION:

For a person diagnosed with COVID (either with a test or diagnosed by your healthcare provider based on your symptoms). Isolation means complete separation from all others, ideally in a separate dwelling but not always possible.

You can discontinue isolation:

If MILD illness: after 10 days from onset of symptoms (or from positive test) if symptoms significantly improved and fever free (without using Tylenol or ibuprofen) for 24+ hours OR after 10 days from a positive test (even with no symptoms) if you remain without symptoms.

SEVERE illness or severely immunocompromised: after 20 days from onset of symptoms if symptoms significantly improved and fever free (without using Tylenol or ibuprofen) for 24+ hours.

QUARANTINE:

For *close contacts* of known or presumed positive cases.

Stay home! Only leave for urgent medical care.

You can discontinue quarantine:

At least 10 days from last exposure if you have remained without symptoms. You should monitor closely for development of any concerning symptoms from day 11-14.

OR

At least 7 days from last exposure if you remain without symptoms and have had a negative COVID test (PCR test) on day 5-7. You should monitor closely for development of any concerning symptoms from day 11-14.

OR

At least 14 days from last exposure, as long as you remain without symptoms

If you develop symptoms concerning for possible COVID at any time, you must be retested and begin ISOLATION until test is resulted.

Unplanned Patient Arrivals

Patient walk-ins or patient does not have an appointment:

- We will not be able to vaccinate patients who do not have an appointment

Patient arrives late:

- We encourage sites to vaccinate the patient, if possible and leave it up to the sites to manage session flow and supply

Patient is not able or willing to wait 15 minutes (or 30 minutes, if applicable) after their vaccination:


- We will not be able to vaccinate the patient – they must reschedule their appointment to a time when they can wait 15 minutes (or 30 minutes, if applicable)

Vaccination Process (Vaccinator Role)

Pre-Receipt Assessment of Contraindications / Precautions

(Source: BILH Pre-Receipt Assessment for Contraindications/Precautions)

1. The vaccinator **MUST** review allergy history and determine if a strict contraindication is present that precludes vaccination onsite. All other patients will be observed for a 15 min duration.



Screening Questions:		Action if Patient Response = Yes:	
A) Contraindications	1) Have you had a history of a severe allergic reaction (e.g. anaphylaxis) after a previous dose of mRNA COVID-19 vaccine? 2) Have you had an immediate allergic reaction ¹ of any severity to a previous dose of an mRNA COVID-19 vaccine or any of its components (including polyethylene glycol or polysorbate)? 3) Have you received a monoclonal antibody for COVID-19 treatment or prevention in the past 90 days?	Do Not Vaccinate	<ul style="list-style-type: none"> If history of severe allergic reaction: Consider referral to Allergist-immunologist or Primary Care provider to discuss alternate vaccination options or whether they can safely receive the vaccine in a setting with advanced medical care available If history of monoclonal antibody therapy, reschedule for 90 days after receipt of therapy
B) Precautions	1) Do you have a history of immediate allergic reaction ¹ to any vaccine? 2) Do you have a history of immediate allergic reaction ¹ to any injectable (intravenous, intramuscular, or subcutaneous) medication? 3) Do you have a history of anaphylaxis for any reason?	Offer deferral of vaccination and referral to PCP or allergist-immunologist for discussion 30 min mandatory observation period, if vaccinated	<ul style="list-style-type: none"> 30 min observation period will be required for 2nd dose even if no reactions
C) Considerations	1) Are you pregnant or lactating (breast-feeding) or planning to become pregnant?	Proceed with Vaccination 15 min mandatory observation period	<ul style="list-style-type: none"> Instruct patient to contact primary provider if any questions prior to receipt of vaccine

Immediate Allergic Reaction – defined as any hypersensitivity-related signs or symptoms consistent with urticarial, angioedema, respiratory distress (e.g. wheezing, stridor) or anaphylaxis that occur within 4 hours following administration.

References:

[CDC Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines](#)

[Medications that contain PEG and/or polysorbate Review](#)

Vaccinator Role

(Source: Adapted BILH Vaccine Clinic Playbook and BIDMC Standard Operating Procedure for COVID-19 Vaccine Administration)

1. Confirm name, DOB, and whether this is 1st or 2nd dose (if 2nd dose, confirm manufacturer of 1st dose by checking CDC card, COVAX tool, asking patient)
2. The vaccinator **MUST** review allergy history and determine if a strict contraindication is present that precludes vaccination onsite. All other patients will be observed for a 15 min duration.
3. Review the defined Emergency Use Authorization (EUA) information sheet and determine if the individual has any concerns or questions
4. Vaccination will be performed per standard vaccination procedure (see right hand box)
5. After administration, vaccine recipients will be provided a CDC COVID-19 Vaccination Record Card with the vaccination product name/manufacturer, vaccine lot#, date and vaccinator name/site completed. In addition, the time of vaccination should be documented below the date (completed by Vaccinator).
6. Vaccinator enters information into COVAX tool (see next slide)
7. On "What to Expect After Getting COVID-19 Vaccine" sheet, write vaccination site location name

Vaccination Procedure

CDC video on IM injection technique: <https://www.youtube.com/watch?v=PqSuCPnPeYE>

1. Determine which arm will receive the vaccine based on individual's dominant hand, contraindications to injection in an arm (e.g., mastectomy with lymphedema), and individual's preference
2. Have the individual roll up their sleeve to the top of their arm. If unable to do so, can unbutton the top of the shirt and pull it down from the collar. If unable to get to the upper arm, have the individual partially disrobe.
3. Choose correct needle size based on patient size. Needle size chart is included as part of the vaccine standing order
4. Use a separate needle and syringe for each injection.
5. Check the expiration dates on the vaccine, syringe, needle. Note: the expiration date may not be visible to the vaccinator
6. Only administer vaccines clinical provider has prepared. This is a medication administration best practice standard.
7. Perform hand hygiene (hand washing with soap & water for at least 2 minutes or use approved hand sanitizer), disinfect injection site with alcohol wipe and allow to air dry. Then, inject vaccine intramuscularly into the individual's arm
8. Document the vaccination in COVID-19 online tool.
9. Document the vaccination on the CDC card provided by manufacturer and give to the individual. If the patient does not already have them, provide the following: handout on post-vaccination reactions, FDA EUA required handout, v-safe handout.
 - a. What to Expect After Getting COVID-19 Vaccine
 - b. Pfizer—BioNtech Emergency Use Authorization Fact Sheet for Recipients and Caregivers
 - c. Moderna Emergency Use Authorization Fact Sheet for Recipients and Caregivers
 - d. Patient Information Sheet
10. Direct individual to observation area

Preventing Needle-Stick Injuries

Sharps Safety: Be Prepared, Be Aware, and Dispose with Care

- Injuries occur because of the following:
 - Passing or transferring equipment
 - Recapping contaminated needles
 - Colliding with coworkers
 - Decontaminating/processing used equipment
- **Contact Employee Health if needle-stick injury occurs**

Be Prepared

- Organize equipment at the point of use
- Make sure workspace has adequate lighting
- Keep sharps pointed away from the user
- Locate a sharps disposal container, or have one nearby
- Assess the patient's ability to cooperate
- Get help if necessary
- Ask the patient to avoid sudden movement

Be Aware

- Do not hand pass exposed sharps from one person to another

- Use predetermined neutral zone for placing/retrieving sharps
- Alert others when sharps are being passed
- Activate safety feature of devices with engineered sharps injury prevention features as soon as procedure is completed
- Observe audible or visual cues that confirm the feature is locked in place

Dispose with Care

- Check procedure trays, waste materials, and bedding for exposed sharps before handling
- Look for sharps/equipment left behind inadvertently
- Transport reusable sharps in a closed container
- Secure the container to prevent spillage and Inspect container
- Keep hands behind sharps, never put hands or fingers into sharps container
- Visually inspect sharps container for overfilling
- Replace containers before they become overfilled
- Keep filled containers for disposal in a secure area

Documenting the Patient's Vaccination in the COVAX Tool

(Source: Adapted from BIDMC COVID-19 Vaccine Administration Training Materials)

Staff completing the documentation for patients' vaccination will also be using this tool. Follow the same steps outlined above for signing into the tool, navigating the dashboard, and sorting/searching for patients.

1. Click on the patient to open the check-in window.
2. Enter the appropriate information for **vaccine name, date, route, body site, lot # and expiration date, vaccinator name and title.**
NOTE: You must complete all of these fields in order to save.
3. Click **Save Dose 1**.

4. The dashboard will now show the patient's vaccination information.

Dose 1: Site	Scheduled	Checked In	Vaccinated	Brand	
Beverly VRP - Beth Israel Lahey Health Primary Care ...	1/27/2021 9:30 AM	Yes	1/26/2021	Moderna	0
<< < 1 > >>					

Vaccination Process – Observer

(Source: Adapted BILH Vaccine Clinic Playbook)

1. When the patient exits the vaccination area, the designated observer should verify the time of vaccine administration has been documented, the duration of required observation period, and direct the vaccine recipient to sit in a socially distant chair in designated vaccine observation area.
2. Observe individual for 15 minutes following their vaccine administration if no history of allergy. Observe individual for 30 minutes if history of immediate allergic reaction to another vaccine or to intramuscular, intravenous, or subcutaneous medication, or a history of anaphylaxis for any reason.
3. Patients may be allowed to leave upon completing 15 or 30 minutes of observation (as directed) if they do not have any symptoms or signs of hypersensitivity reaction (flushing, fever, generalized rash, urticaria, lightheadedness, shortness of breath, etc.)

Vaccination Process – Emergency Response

(Source: BILH Vaccine Clinic Emergency Response SOP)

1. If patients report feeling unwell during their observation period:
 - a. Check vital signs (BP, HR, Temp, SpO2) and notify APP
 - b. Document the vital signs on a provided Vaccine Clinic Response form (Appendix A)
2. If patients are not recovering after treatment, call 911 for transfer to the ED:
 - a. Call 911
 - b. Stay with the patient, checking VS, noting if there is any reported change in how they are feeling
 - c. If patient becomes unresponsive or becomes acutely unwell; proceed with emergency response
 - d. Clear area of others in vaccination area (towards reception desk)
3. If patients become unresponsive, labored breathing, appear anaphylactic (i.e. sudden or gradual onset of generalized itching, erythema (redness), urticaria (hives), angioedema (swelling of the lips, face, or throat), severe bronchospasm (wheezing), shortness of breath, shock, abdominal cramping, or cardiovascular collapse):
 - a. Administer an EpiPen
 - b. Call 911
 - c. Stay with the patient
4. If Patient is unresponsive:
 - a. Activate an emergency response – Call 911
 - b. Check the carotid for no longer than 10 seconds
 - c. Simultaneously look for chest rise/listen for breaths
 - d. *If no pulse:*
 - i. Call for help, and start compressions (on the lower half of the breastbone)
 - ii. Ensure manual compressions are at a rate of 100-120/minute
 - e. Ask someone to bring the Emergency Equipment to the patient
 - f. Defibrillate (if indicated) as soon as the AED is available
 - i. Turn on AED
 - ii. Apply combi-pads immediately
 - iii. Follow the AED prompts
 1. Shock (as indicated) followed by IMMEDIATE CPR
 2. Remember to reassess the patient, pulse and rhythm every 2 minutes/5 cycles and rotate compressors (following prompts)
 - g. Document/Record findings
 - i. Document the event on a Vaccine Clinic Reaction Response Form
 1. Forms should be delivered to the medical director of the vaccine clinic

Vaccination Process – Vaccine Clinic: Reaction Response Form

VACCINE CLINIC – REACTION RESPONSE

Complete for each medical emergency response except cardiac arrest

Date: ____/____/____	Time (24 hour): ____ ____	Clinic Location:
-----------------------------	----------------------------------	-------------------------

Patient Type: <input type="checkbox"/> Employee <input type="checkbox"/> Out Patient		Gender: <input type="checkbox"/> Male <input type="checkbox"/> Female Transgender: <input type="checkbox"/> M-T-F <input type="checkbox"/> F-T-M																					
Allergies: <input type="checkbox"/> NKA																							
Medical Emergency: <input type="checkbox"/> Allergic Reaction <input type="checkbox"/> Hypoglycemia <input type="checkbox"/> Seizure <input type="checkbox"/> Intoxication <input type="checkbox"/> Stroke like / Weakness <input type="checkbox"/> Cardiac Symptoms <input type="checkbox"/> Other: _____																							
LIP: _____ Witness: _____		Observer: _____																					
PMHx:																							
<table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 15%;">Vital Signs:</td> <td style="width: 20%;">Time (24 hour): _____</td> <td style="width: 20%;">HR: _____</td> <td style="width: 20%;">BP: _____</td> <td style="width: 25%;">RR: _____</td> </tr> <tr> <td></td> <td>Time (24 hour): _____</td> <td>HR: _____</td> <td>BP: _____</td> <td>RR: _____</td> </tr> <tr> <td></td> <td>Time (24 hour): _____</td> <td>HR: _____</td> <td>BP: _____</td> <td>RR: _____</td> </tr> <tr> <td></td> <td>Time (24 hour): _____</td> <td>HR: _____</td> <td>BP: _____</td> <td>RR: _____</td> </tr> </table>				Vital Signs:	Time (24 hour): _____	HR: _____	BP: _____	RR: _____		Time (24 hour): _____	HR: _____	BP: _____	RR: _____		Time (24 hour): _____	HR: _____	BP: _____	RR: _____		Time (24 hour): _____	HR: _____	BP: _____	RR: _____
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	Time (24 hour): _____	HR: _____	BP: _____	RR: _____																			
Other Findings:																							
Communications: <input type="checkbox"/> ED <input type="checkbox"/> Other:																							
Treatment / Medications: <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <input type="checkbox"/> Diphenhydramine hydrochloride 25 mg PO <input type="checkbox"/> Diphenhydramine hydrochloride 50 mg IM <input type="checkbox"/> Bandage <input type="checkbox"/> Other: _____ </div> <div style="width: 45%;"> <input type="checkbox"/> Epinephrine 0.3 mg IM via EpiPen® <input type="checkbox"/> Oral Glucose gel 15 grams <input type="checkbox"/> Albuterol 17 grams (2 puffs meter dosed inhaler) </div> </div>			Comments:																				
Disposition: <input type="checkbox"/> ED <input type="checkbox"/> Other: _____			Time (24 hour): ____ ____ ____ ____																				
Mode of Transport:																							

X _____ / ____ / ____ ____
 Recorder Signature & Credentials Print Name Date Time (24 hour)

X _____ / ____ / ____ ____
 Provider Signature & Credentials Print Name Date Time (24 hour)

Patient Refusal of Care or Transport (Provide complete demographic information in patient ID box):

[HOSPITAL NAME] has offered me further evaluation and care including transportation to the Emergency Department. They have explained the possible risks if I refuse such treatment. I understand that my refusal may result in making my condition worse. I understand the risks as explained to me, and I refuse any further evaluation, care, or transportation.

X			<u>OR</u>
	Patient's Signature	Print Name	
X			and
	Signature of Person authorized to sign for patient	Print Name	Relationship to patient
Date: ____/____/____ Time: ____ : ____ <input type="radio"/> a.m. <input type="radio"/> p.m.			
X			
	Witness Signature	Print Name	Date Time (24 hour)

Distribution: **White** = Medical Records ■ **Canary** = EOHS (employee) or PCP (outpatient) ■ **Pink** = Patient / EMT

Vaccination Process – Anaphylaxis at a Glance

Anaphylaxis At a Glance

Anaphylaxis is a life-threatening allergic reaction that affects more than one organ system.



Allergens that can set off anaphylaxis

FOOD



- Peanuts
- Tree nuts: almonds, pecans, cashews, walnuts
- Shellfish
- Cow's milk products
- Hen's eggs
- Fish
- Soy
- Wheat

VENOM



- Yellow jackets
- Wasps and hornets
- Honeybees
- Fire ants
- Spiders

LATEX



- Balloons
- Rubber gloves
- Condoms
- Elastic bands (i.e., physical therapy bands/rubber bands)
- Dental dams

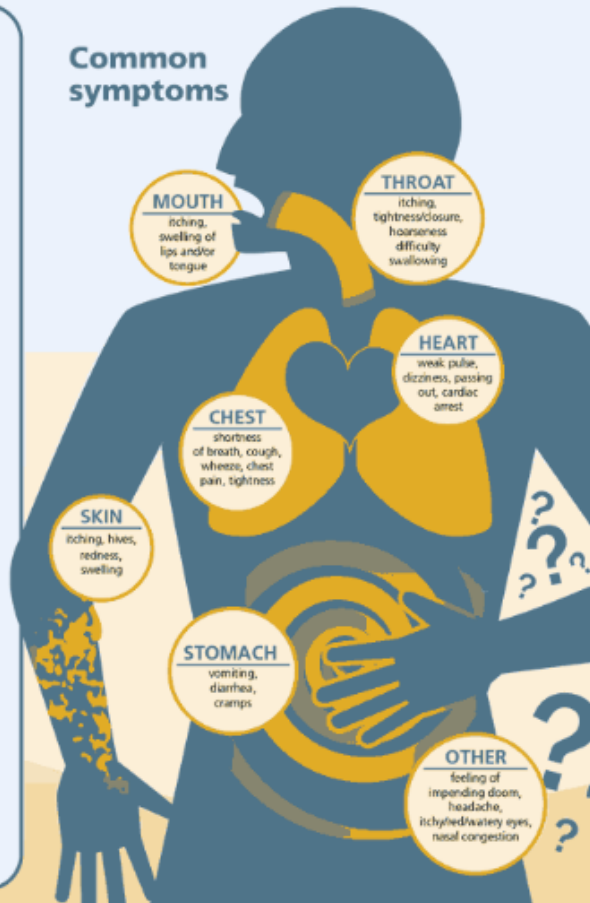
Foods with cross-reactive proteins to natural rubber: banana, avocado, chestnut and kiwi

MEDICATION



- Penicillin
- Aspirin, ibuprofen and other NSAID pain relievers

Common symptoms



Epi Everywhere! Every Day! Right Away!

RECOGNIZE THE SEVERITY



Anaphylaxis is life-threatening, unpredictable, presents in multiple ways and can progress quickly. If symptoms appear refer to your Emergency Care/Action Plan.

USE EPINEPHRINE IMMEDIATELY



Epinephrine is the **first line** of treatment to stop the progression of anaphylaxis. Use your epinephrine auto-injector at the **first sign of symptoms** – don't wait to see what happens!

CALL 911



Always call for emergency medical assistance and go to the emergency room for follow-up observation and treatment.

CARRY TWO AUTO-INJECTORS



Keep two epinephrine auto-injectors on hand, in case symptoms recur before emergency medical assistance is available. Up to 35% of people will require more than one dose.

FOLLOW UP



Consult a board-certified allergist for accurate diagnosis and prevention/treatment plan.

Vaccination Process – Administration of EpiPen

1. In adults, administer a 0.3 mg intramuscular dose using a premeasured or prefilled syringe, or an autoinjector in the mid-outer thigh.
2. The maximum adult dose is 0.5 mg per dose.
3. Epinephrine dose may be repeated every 5-15 minutes (or more often) as needed to control symptoms while waiting for emergency medical services.
4. Because of the acute, life-threatening nature of anaphylaxis, there are no contraindications to epinephrine administration.

Vaccination Process – Adverse Reactions: Reporting and Documentation

Vaccine Reaction:

1. Document any/all patient vaccine related events/reactions on a **BILH Vaccine Clinic Emergency Response Form**
 - a. On-Site Manager is responsible for ensuring completion of the form and collecting forms at end of day
2. Event must also be entered into the staff's applicable Incident/Safety Event Reporting System by the On-Site Manager
3. These vaccine adverse reactions are **required by law** to be reported online to Vaccine Adverse Event (AE) Reporting System (VAERS) here: <https://vaers.hhs.gov/esub/index.jsp>
 - a. Vaccine administration errors, whether or not associated with an adverse event (AE)
 - b. Serious AEs: anaphylaxis; death / life-threatening; requires intervention / hospital / "911" response (causality does not need to be established)

Any non-vaccine related event (worker, patient, visitor): e.g., worker injury, fall, security, fire, equip failure, registration error, non-vaccine related medical event, premises safety hazard etc.

1. **Must be entered into the applicable employee injury and Incident/Safety Event Reporting System** by the On-Site Manager

Note: Vaccination providers administering a COVID-19 vaccine that is under Emergency Use Authorization are required by the Food and Drug Administration to report:

- a. Vaccine administration errors
- b. Serious adverse events
- c. Cases of Multisystem Inflammatory Syndrome, and
- d. Cases of COVID-19 that result in hospitalization or death

Post-Vaccine Administration and Check-Out

Check-Out Process

(Source: Adapted from BIDMC Standard Operating Procedure for COVID-19 Vaccine Administration)

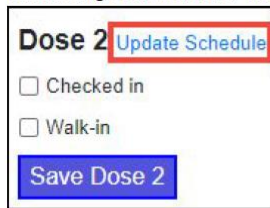
1. Check-out staff verifies which vaccine the patient received to ensure the patient is scheduled within the correct timeframe
2. Patients will receive a link to schedule the appointment themselves shortly after receiving the 1st dose. They may schedule their 2nd dose appointment while waiting in the observation area
3. Check-out staff should check with the patient to see if they self-scheduled their 2nd dose. If patient did not schedule a 2nd dose using the link that was sent to them, check-out staff should schedule the patient for their 2nd dose of vaccine, prior to the patient leaving the site, when possible (see next slide)
4. If 2nd dose appointment has been scheduled, write the appointment information on the CDC card and remind patient to bring the card to the 2nd dose appointment. Tell patient to take a picture of the CDC card in case they lose it (both sides).

Staff Schedules Patient's Second Dose in COVAX Tool

(Source: Adapted from BIDMC Standard Operating Procedure for COVID-19 Vaccine Administration)

Option 2: Staff schedules the patient's second dose

1. Click on the patient to open the check-in window.
2. On the right hand side, click **Update Schedule** next to Dose 2.



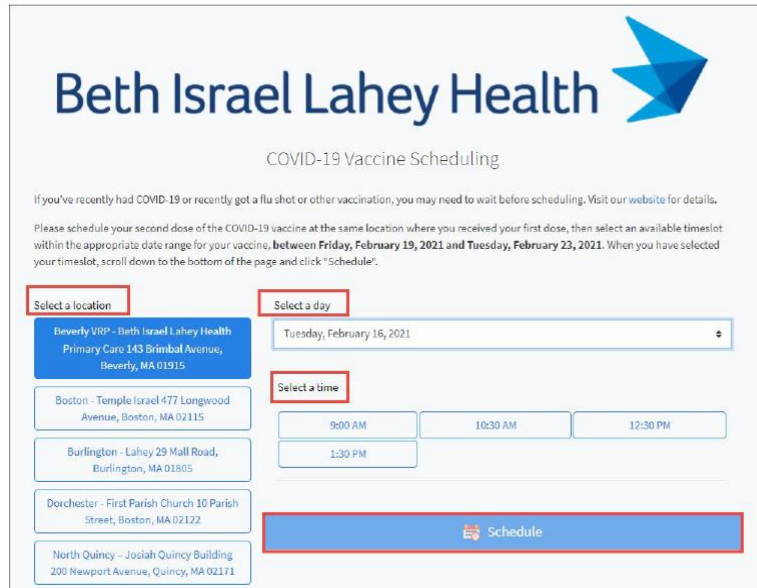
Dose 2 [Update Schedule](#)

☐ Checked in

☐ Walk-in

[Save Dose 2](#)

3. The link will open the patient's unique scheduling page for their 2nd dose.
4. Select the site of their 1st dose, as well as an available time slot within the date range for their vaccine type.
5. Click **Schedule**.



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COVID-19 Vaccine Scheduling

If you've recently had COVID-19 or recently got a flu shot or other vaccination, you may need to wait before scheduling. Visit our [website](#) for details.

Please schedule your second dose of the COVID-19 vaccine at the same location where you received your first dose, then select an available timeslot within the appropriate date range for your vaccine, **between Friday, February 19, 2021 and Tuesday, February 23, 2021**. When you have selected your timeslot, scroll down to the bottom of the page and click "Schedule".

Select a location

- Beverly VRP - Beth Israel Lahey Health
Primary Care 143 Brimbal Avenue,
Beverly, MA 01915
- Boston - Temple Israel 477 Longwood
Avenue, Boston, MA 02115
- Burlington - Lahey 29 Mall Road,
Burlington, MA 01805
- Dorchester - First Parish Church 10 Parish
Street, Boston, MA 02122
- North Quincy - Josiah Quincy Building
200 Newport Avenue, Quincy, MA 02171

Select a day

Tuesday, February 16, 2021

Select a time

- 9:00 AM
- 10:30 AM
- 12:30 PM
- 1:30 PM

[Schedule](#)

- The patient will receive a confirmation email and the check-in tool will be automatically updated with the vaccination 2nd dose schedule

End of Day

(Source: BILH Vaccine Clinic Playbook)

Pharmacy Lead:

1. Pharmacy ensures all remaining vials are couriered back to home pharmacy, report waste to site managers
2. Return all supplies to pharmacy
3. Pharmacy and check-in staff inform site managers of supplies that need to be replenished (a few days' notice), including both clinical and paperwork
4. Wipe down all high touch areas

On-Site Vaccine Clinic Manager:

1. Collect any BILH Vaccine Clinic Emergency Response forms at end of day and ensure adverse reaction reporting and documentation is complete
2. Straighten up vaccination stations and reception station
3. Ensure all areas are cleaned and disinfected through local protocol or a contracted service
4. Take inventory and replenish supplies

5. Order/coordinate supply needs for replenishment
6. Ensure workstations are wiped down, shutdown and plug in to charge
7. Send end-of-shift summary email to site Ops Leader with requested information (e.g. # of staff vaccinated, call out info, etc.)

BILH Interim COVID-19 Vaccine Clinics Guideline for Allocating Extra Doses Prior to Closure

<https://covid-19.bilh.org/wp-content/uploads/bilh-interim-guidelines-allocating-extra-covid-19-vaccine-doses.pdf>

Extra doses of COVID-19 vaccine may become available throughout the day due to patient cancellations or no-shows. Vaccine clinic staff must monitor patient cancellations and no-shows in real-time, in order to proactively manage extra doses throughout the day. Every possible measure should be taken to ensure **ZERO** waste of vaccine doses occurs prior to their expiration.

Process for the Allocation of Extra Vaccine Doses Prior To Clinic Closure:

- 1) Locations with access to BILH Employee Health (EOHS) vaccination sites should route all extra doses to their EOHS clinic for immediate use.
 - a. Applicable at:
 - i. BIDMC – Temple Israel
 - ii. LHMC – 29 Mall Road, Burlington
- 2) Review the COVAX 7 Day Appointment List for and outreach to patients with future appointments at your site.
 - a. Start with those patients who live in the same city/zip code as your clinic as they have the highest likelihood of being able to come with limited notice
- 3) In the rare instance where the above measures are unsuccessful, you can use your clinical judgement to administer the vaccine to a [person meeting criteria as closely as feasible to the current priority group being targeted for vaccination](#), in order to avoid vaccine waste. [Please review the Mass.gov FAQ for providers if any questions.](#)
 - a. Example of approach that may be taken:
 - i. While vaccinating individuals 75+, offer vaccine to an individual age 65+, if not feasible, offer vaccine to any caregiver or escort accompanying a patient
 - ii. Any person available including non-BILH patients or any on-site contracted clinic support staff who have not yet been vaccinated may be considered for this purpose
 - b. If the individual is not in the COVAX system, the Vaccine Clinic down-time form should be utilized for vaccine documentation purposes and discuss with your manager how to ensure 2nd appointment scheduling and MIIS reporting is completed.

Documentation of Vaccinator and Observer Competencies

- Clinical staff (vaccine handler, vaccinator and observer roles) will need to demonstrate and document clinical competencies
- A competency checklist has been adapted for use at the primary care vaccination sites

Reference Materials

(Note: Reference materials are included in separate zip file)

1. BILH Vaccine Clinic Playbook
2. BILH Pharmacy Standard Operating Procedures for Vaccine Clinics
3. BIDMC Training Materials
4. Patient Facing Clinic Materials

BILH Standing Order for Medical Management of Vaccine Reactions in COVID-19 Vaccination Clinics

{HOSPITAL NAME/VACCINE SITE} Standing Orders for the Medical Management of Vaccine Reactions in COVID-19 Vaccination Clinics

Purpose

To provide guidelines on the management of a patient presenting with signs & symptoms of a vaccine reaction following administration of COVID-19 vaccine.

Policy

Where allowed by state law, standing orders enable eligible nurses and other health care professionals (e.g., pharmacists) to assess the need for administration of medications and other therapies for adults who meet any of the criteria below.

Procedure

1. **Follow the COVID-19 Vaccination Prioritization and Screening protocols for contraindications and precautions per {Hospital Name/Vaccine Site} Standing Order Administering COVID-19 Vaccine to Adults**

Administering any medication, including vaccines, has the potential to cause an adverse reaction. To minimize the likelihood of an adverse event, screen patients for vaccine contraindications and precautions prior to vaccination.

2. **Assess the Type of Reaction:**

The reaction should be assessed, and determination made as to if it represents a localized response, anaphylaxis or alternate etiology such as fright, presyncope and syncope.

Table 1. Vaccine Related Reaction Types, Signs and Symptoms and Management:

Reaction Type	Signs and Symptoms	Management
Localized	Soreness, redness, itching, or swelling at the injection site	Apply a cold compress to the injection site. Consider giving an antipruritic (anti-itch) medication.
	Slight bleeding	Apply pressure and an adhesive compress over the injection site.

	Continuous bleeding	Place thick layer of gauze pads over site and maintain direct and firm pressure; raise the bleeding injection site (e.g., arm) above the level of the patient's heart.
Psychological fright, presyncope and syncope (fainting)	Fright before injection is given	Have patient sit or lie down (on their side, if nauseated) for the vaccination.
	Patient feels "faint" (e.g. light-headed, dizzy, weak, nauseated, or has visual disturbance)	Have patient lie flat. Loosen any tight clothing and maintain open airway. Apply cool, damp cloth to patient's face and neck. Keep them under close observation until full recovery.
	Fall without loss of consciousness	Examine the patient to determine if injury is present before attempting to move the patient. Place patient flat on back with feet elevated.
	Loss of consciousness	Call 911 if patient does not recover immediately. Check to determine if injury is present before attempting to move the patient. Place patient flat on back with feet elevated.
Anaphylaxis	Skin and mucosal symptoms such as generalized hives, itching, or flushing; swelling of lips, face, throat, or eyes. Respiratory symptoms such as nasal congestion, change in voice, sensation of throat closing, stridor, shortness of breath, wheeze, or cough. Gastrointestinal symptoms such as nausea, vomiting, diarrhea, cramping abdominal pain. Cardiovascular symptoms such as collapse, dizziness, tachycardia, hypotension.	See the emergency medical protocol for detailed steps to follow in treating anaphylaxis.

3. Management of localized reactions:

- a. For bleeding, put on gloves and apply pressure and an adhesive compress over injection site, if continuous apply thick layer of gauze pads over site and maintain direct pressure. Raise site above the level of the patient's head. Observe patient until stabilization of bleeding achieved.
- b. For itching and swelling confined to the injection site where the vaccination was given, observe patient closely for the development of generalized symptoms. Extend observation period for a minimum of 15 minutes and continue in increments of 15 minutes pending improvement/stability.
 - i. *Optional therapy* – Benadryl 25mg po x 1 or Loratadine 10mg po x 1 (if available) may be administered. Loratadine (if available) is preferred in patients age>65 due to potential sedating effects of Benadryl. Use of antihistamines should be avoided if any concern for progression to systemic reaction.

4. Management of psychological fright, presyncope and syncope (fainting)

- a. Follow general management strategies by vaccine reaction listed in Table 1.
- b. Glucose gel 15-30gm x1 may be administered if concern for hypoglycemia (e.g. diabetic patient feeling light-headed, dizzy, weak with symptoms consistent to prior hypoglycemic episodes). If glucose gel is administered, patient should be observed to ensure resolution of symptoms or need for additional evaluation.

5. Emergency medical protocol for management of anaphylactic reactions in adults:

- a. **If symptoms are generalized, call 911 to activate EMS immediately.** This should be done by a second person, while the primary healthcare professional assesses the airway, breathing, circulation, and level of consciousness of the patient. Vital signs should be monitored continuously. Notify the site medical director as soon as feasible based on the acute patient care needs.
- b. **Dug dosing information: The first line and most important therapy in anaphylaxis is epinephrine. There are NO absolute contraindications to epinephrine in the setting of anaphylaxis.**
 - i. **First-line treatment: Epinephrine (EpiPen) is the first-line treatment for anaphylaxis, and there is no known equivalent substitute.** Administer a 0.3 mg dose IM EpiPen via autoinjector in the mid-outer thigh. Epinephrine dose may be repeated 2 additional times every 5–15 minutes (or sooner as needed) while waiting for EMS to arrive.
 - ii. **Optional treatments:**
 1. **H₁ antihistamines** relieve itching and urticaria (hives). These medications DO NOT relieve upper or lower airway obstruction, hypotension, or shock. Consider giving diphenhydramine (e.g., Benadryl) for relief of itching and hives. Administer intramuscularly (IM) (if available) 1–2 mg/kg x1.
 2. **Albuterol MDI** - 2 inhalations every 20 minutes for a maximum of 3 doses – should be administered if wheezing is present while awaiting EMS arrival
- c. Monitor the patient closely until EMS arrives. Perform cardiopulmonary resuscitation (CPR), if necessary, while maintaining appropriate COVID-19 precautions including surgical mask and eye protection. Maintain hands-only CPR, manipulation of the airway is not recommended. Keep patient in recumbent position (flat on back) unless he or she is having breathing difficulty. If breathing is difficult, patient's head may be elevated, provided blood pressure is adequate to prevent loss of consciousness. If blood pressure is low, elevate legs. Monitor blood pressure and pulse every 5 minutes.
- d. Record the patient's reaction (e.g., hives, anaphylaxis) to the vaccine, all vital signs, medications administered to the patient, including the time, dosage, response, and the name of the medical personnel who administered the medication, and other relevant clinical information.
- e. The site medical director should report the incident in the Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov.

6. Medications for Managing Vaccine Reactions:

Medication Box		
Medication	Strength	Number present
EpiPen Auto-injector	0.3 mg/0.3 mL	4
Glucose gel (pending confirmation)	15 gm/30 mL	2
Albuterol (Pro-Air) Metered-Dose Inhaler (MDI) 8.5 gm	200 inhalations/ canister	2
Diphenhydramine 50 mg vial (pending confirmation)	50 mg/mL	2
Diphenhydramine oral	25 mg capsule	10
Loratadine oral (pending confirmation)	10 mg tablets	2
Hydroxyzine (pending confirmation)	pending	pending

7. Supplies for Managing Vaccine Reactions:

Other Supplies in Med Box (from Distribution services)		
Item	PeopleSoft #	Number present
Retracting 3 mL syringe (IM) (pending confirmation)	35038	3
Blunt fill needle (pending confirmation)	30547	2

Alcohol wipes	41364	10
Medication Labels	MC1480	6
Other Supplies in Bag – (from Distribution services)		
Item	PeopleSoft #	Number present
Roll of tape	129517	2
4x4 gauze	130709	10
Band-Aids	40563	10
Kerlex	2793	1
Ice Pak	3316	2
Gloves	3542(L)/3541(M)	2 boxes (1 L, 1M)
Reusable Stethoscope (pending confirmation)	41504	1
Flashlight (pending confirmation)	40150	1

Standing Orders Authorization:

This policy and procedure shall remain in effect for all patients vaccinated at patient COVID vaccination clinics sponsored by {INSERT HOSPITAL NAME/Vaccine Site} until rescinded.

Medical Director:

Signature date:

References: Immunization Action Coalition www.immunize.org, www.immunize.org/catg.d/p3082.pdf, Resuscitation Council UK

Approval Body:

Revisions:

Next Review Date:

BILH Vaccine Clinic Emergency Response SOP

{HOSPITAL NAME/VACCINE SITE} Standard Operating Procedure for COVID-19 Vaccine Administration and Emergency Response

This guidance describes the steps in safe administration of COVID-19 vaccine administration and post-vaccination monitoring as well as emergency response.

Daily- Open Unit

1. Check emergency equipment daily
 - a. AED:
 - i. Clinic staff is aware of the location and operation of the AED
 - ii. Ensure the AED is in “ready” mode
 - b. Vaccine Clinic Emergency Response Bag (contains medications and first aid items) is in a secure location
 - i. Check expiration dates on any syringes, fluids, lines and equipment, as noted on the Vaccine Clinic Emergency Response Bag Inventory List
 1. Expired items should be ordered and replaced ASAP (distribution for general items, pharmacy for medications).

- a. *All items with expiration date are good through the end of that month; for example, items expiring 6/21, would be good through 6/30/21.*

If Vaccine Clinic Emergency Response Bag is opened for 1 item (a medication or any other content), the items may be replaced. Pharmacy will exchange/refill used medications and/or first aid items.

2. Move all monitoring equipment and plug it into the outlet near the observation area
3. Wipe down all chairs with provided germicidal wipes

Vaccine Administration and Post-Vaccination Observation

Vaccine Administration:

1. The vaccinator MUST have reviewed and have available the {Enter Hospital Name/Vaccine Site} Standing Order for Administering COVID-19 Vaccine to Adults.
2. The vaccinator MUST review the vaccine recipient's allergy history and determine if a strict contraindication is present that precludes vaccination or a precaution is present which requires a 30 min observation period based upon an allergy algorithm provided to each vaccinator. All other patients will be observed for a 15 min duration. If a history of severe allergic reaction to any other (non-mRNA COVID-19) vaccine or injectable medication, or anaphylaxis for any reason, a 30 min observation must be used (see [Appendix B- BILH Patient Vaccination Screening](#))
3. Vaccine Recipients will be directed to the vaccine administration area and directed to a seated position
4. Vaccination will be performed per standard vaccination procedure
5. After administration, vaccine recipients will be provided a CDC COVID-19 Vaccination Record Card with the vaccination product name/manufacturer, vaccine lot#, date and vaccinator name/site completed. In addition, the time of vaccination should be documented below the date (completed by Vaccinator).
6. When the patient exits the vaccination area and enters the observation area, the designated vaccination observer should verify the time of vaccine administration has been documented, the duration of required observation period, and direct the vaccine recipient to sit in a socially distant chair in designated vaccine observation area.
 - a. Recipients will be provided with the time their observation is complete.
 - b. Recipients requiring a 30-minute observation period should be easily identifiable by sitting in a designated section or through an alternate system for identification (e.g. a specific sticker noting extended observation period)
 - c. If recipient refuses to wait for observation period, document refusal on the Vaccine Clinic Emergency Response Form (Appendix A)
7. Clocks will be in the observation area to note time of day to support timing of observations
8. Patients may be allowed to leave upon completing 15 or 30 minutes of observation (as directed) without symptoms or signs of hypersensitivity reaction (flushing, fever, generalized rash, urticaria, lightheadedness, shortness of breath, etc.)
9. If no APP or MD is on-site, the Standing Order for the Medical Management of Vaccine Reactions in COVID-19 Vaccination Clinics should be followed.

10. If an APP or MD is on-site, the Standing Order for the Medical Management of Vaccine Reactions in COVID-19 Vaccination Clinics should be followed until the time of provider arrival.
11. Emergency Response Plan for Vaccine Clinic with APP or MD on site
- a. If there are any complaints of feeling unwell/possible reaction:
 - i. Check vital signs (BP, HR, Temp, SpO2) and notify the APP or MD on site
 - ii. Document the vital signs on a provided Vaccine Clinic Emergency Response form (Appendix A)
 - iii. Monitor patient and VS as directed below based on type/severity of potential reaction
 - iv. Complaint of Localized Reaction (i.e., soreness, redness, itching, or swelling at the injection site):
 1. Apply a cold compress to the injection site.
 2. If itching and swelling are confined to the injection site where the vaccination was given, observe closely for the development of generalized symptoms.
 - v. Mild Hypersensitivity Reaction (local Rash, Transient flushing):
 1. Consider diphenhydramine 25-50mg PO or Loratadine 5-10mg PO.
 2. Monitor vital signs every 15 minutes until symptoms stabilize or resolve.
 3. If progression of symptoms, call 911
 - vi. **Moderate – Severe Hypersensitivity Reaction (generalized rash, flushing, urticaria, shortness of breath, bronchospasm, wheezing, hypotension):**
 1. **Call 911**
 2. **Epinephrine (EpiPen) is the first-line treatment for anaphylaxis, and there is no known equivalent substitute.** Administer a 0.3 mg dose IM EpiPen autoinjector in the mid-outer thigh. Epinephrine dose may be repeated 2 additional times every 5–15 minutes (or sooner as needed) while waiting for EMS to arrive.
 3. Consider administering Benadryl 50mg PO or IM and Albuterol inhaler while awaiting EMS
 4. Monitor vital signs every 3 minutes until EMS arrives
 - vii. Slight bleeding:
 1. Apply a gauze compress over the injection site
 - viii. Continuous bleeding:
 1. Place thick layer of gauze pads over site and maintain direct and firm pressure
 2. Raise the bleeding injection site (e.g., arm) above the level of the patient’s heart until bleeding subsides
12. After any reaction event:
- a. The Vaccine Clinic Reaction Response Form should be entered into the patient’s medical record.

Emergency Procedures

5. If patients report feeling unwell during their observation period:
 - a. Check vital signs (BP, HR, Temp, SpO2) and notify APP
 - b. Document the vital signs on a provided Vaccine Clinic Response form (Appendix A)
6. If patients are not recovering after treatment, call 911 for transfer to the ED:
 - a. Call 911
 - b. Stay with the patient, checking VS, noting if there is any reported change in how they are feeling
 - c. If patient becomes unresponsive or becomes acutely unwell; proceed with emergency response
 - d. Clear area of others in vaccination area (towards reception desk)

7. If patients become unresponsive, labored breathing, appear anaphylactic (i.e., sudden, or gradual onset of generalized itching, erythema (redness), urticaria (hives), angioedema (swelling of the lips, face, or throat), severe bronchospasm (wheezing), shortness of breath, shock, abdominal cramping, or cardiovascular collapse):
 - a. Administer an EpiPen
 - b. Call 911
 - c. Stay with the patient
8. If Patient is unresponsive:
 - a. Activate an emergency response – Call 911
 - b. Check the carotid for no longer than 10 seconds
 - c. Simultaneously look for chest rise/listen for breaths
 - d. *If no pulse:*
 - i. Call for help, and start compressions (on the lower half of the breastbone)
 - ii. Ensure manual compressions are at a rate of 100-120/minute
 - e. Ask someone to bring the Emergency Equipment to the patient
 - f. Defibrillate (if indicated) as soon as the AED is available
 - i. Turn on AED
 - ii. Apply combi-pads immediately
 - iii. Follow the AED prompts
 1. Shock (as indicated) followed by IMMEDIATE CPR
 2. Remember to reassess the patient, pulse and rhythm every 2 minutes/5 cycles and rotate compressors (following prompts)
 - g. Document/Record findings
 - i. Document the event on a Vaccine Clinic Reaction Response Form
 1. Forms should be delivered to the medical director of the vaccine clinic

Daily – Unit Close

1. Wipe down all chairs with provided germicidal wipes

Appendix A: Vaccine Clinic Response Form Template

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VACCINE CLINIC – REACTION RESPONSE

Complete for each medical emergency response
except cardiac arrest

(Employee only) Primary Unit _____

Date: ____/____/____	Time (24 hour): _____	Clinic Location: _____
Patient Type: <input type="checkbox"/> Employee <input type="checkbox"/> Out Patient		Gender: <input type="checkbox"/> Male <input type="checkbox"/> Female Transgender: <input type="checkbox"/> M-T-F <input type="checkbox"/> F-T-M
Allergies: <input type="checkbox"/> NKA		
Medical Emergency: <input type="checkbox"/> Allergic Reaction <input type="checkbox"/> Syncopal <input type="checkbox"/> Cardiac Symptoms <input type="checkbox"/> GI <input type="checkbox"/> Seizure <input type="checkbox"/> SOB <input type="checkbox"/> Hypoglycemia <input type="checkbox"/> Intoxication <input type="checkbox"/> Stroke like / Weakness <input type="checkbox"/> Other: _____		
LIP: _____		Observer: _____
Witness: _____		
Physical Exam / Present Illness:		
PMHx: _____		
Vital Signs: Time (24 hour): _____ HR: _____ BP: _____ RR: _____ Time (24 hour): _____ HR: _____ BP: _____ RR: _____ Time (24 hour): _____ HR: _____ BP: _____ RR: _____ Time (24 hour): _____ HR: _____ BP: _____ RR: _____		
Other Findings:		
Communications: <input type="checkbox"/> ED <input type="checkbox"/> Other: _____		
Treatment / Medications: <input type="checkbox"/> O ₂ applied: _____ <input type="checkbox"/> Diphenhydramine hydrochloride 25 mg PO <input type="checkbox"/> Diphenhydramine hydrochloride 50 mg IM <input type="checkbox"/> Other: _____		<input type="checkbox"/> Epinephrine 0.3 mg IM via EpiPen® <input type="checkbox"/> Oral Glucose gel 15 grams <input type="checkbox"/> Albuterol 17 grams (2 puffs meter dosed Inhaler) <input type="checkbox"/> Bandage
Disposition: <input type="checkbox"/> ED <input type="checkbox"/> Other: _____		Comments: _____
Mode of Transport: _____		Time (24 hour): _____

X _____ Recorder Signature & Credentials _____ Print Name _____ Date: ____/____/____ Time (24 hour): _____

X _____ Provider Signature & Credentials _____ Print Name _____ Date: ____/____/____ Time (24 hour): _____

Patient Refusal of Care or Transport (Provide complete demographic information in patient ID box):

_____ has offered me further evaluation and care including transportation to the Emergency Department. They have explained the possible risks if I refuse such treatment. I understand that my refusal may result in making my condition worse. I understand the risks as explained to me, and I refuse any further evaluation, care, or transportation.

X _____ Patient's Signature _____ Print Name _____ OR

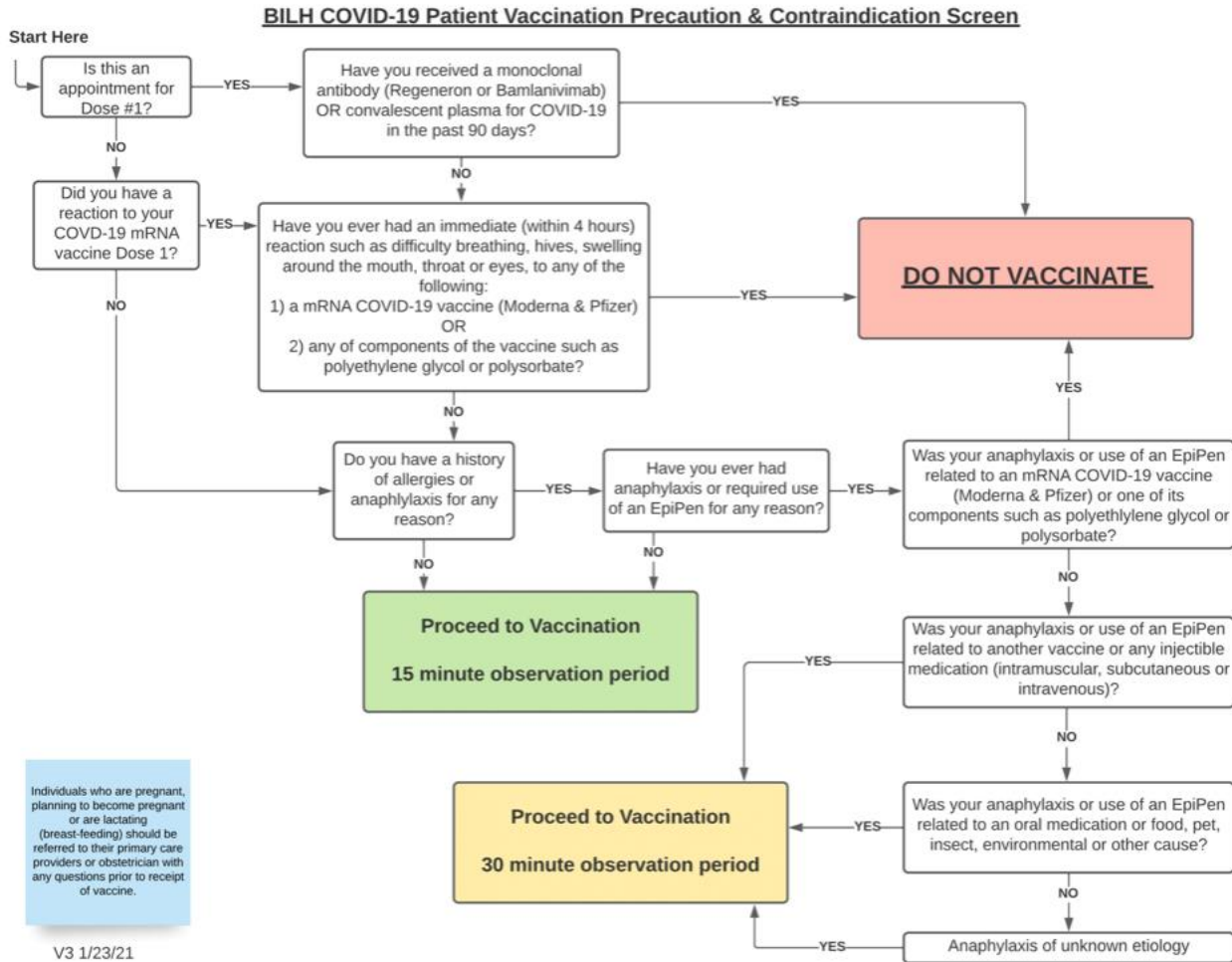
X _____ Signature of Person authorized to sign for patient _____ Print Name _____ and _____ Relationship to patient

Date: ____/____/____ Time: ____:____:____ a.m. o.p.m.

X _____ Witness Signature _____ Print Name _____ Date: ____/____/____ Time (24 hour): _____

Distribution: White = Medical Records ■ Canary = EOHHS (employee) gr PCP (outpatient) ■ Pink = Patient / EMT

Appendix B: [BILH COVID-19 Patient Vaccination Precaution & Contraindication Screen](#) (Please utilize hyperlink to ensure most accurate version is used).



Characteristics of Reactions and Vaccine Side Effects Following mRNA COVID-19 Vaccination

Characteristics of Reactions and Vaccine Side Effects following mRNA COVID-19 Vaccination			
Characteristic	Immediate allergic reactions (including anaphylaxis)	Vasovagal reaction	Vaccine side effects (local and systemic)
Timing after vaccination	Most occur within 15-30 minutes	Most occur within 15 minutes	Most occur within 1-3 days
Signs and Symptoms			
Constitutional	Feeling of impending doom	Feeling warm or cold	Fever, chills, fatigue
Cutaneous	Skin symptoms in ~90% including pruritus, urticarial, flushing, angioedema	Pallor, sweating, clammy skin, sensation of warmth	Pain, redness, swelling at injection site; lymphadenopathy in same arm as vaccination
Neurologic	Confusion, dizziness, lightheadedness, loss of consciousness	Dizziness, lightheadedness, syncope, weakness, changes in vision (e.g. tunnel vision), changes in hearing	Headache
Respiratory	Shortness of breath, wheezing, bronchospasm, stridor, hypoxia	Variable; may be accompanied by anxiety and elevated heart rate	N/A
Cardiovascular	Low blood pressure, elevated heart rate	Variable; may have low blood pressure or low heart rate during syncopal event	N/A
Gastrointestinal	Nausea, vomiting, diarrhea, abdominal cramps	Nausea, vomiting	Vomiting or diarrhea may occur
Musculoskeletal	N/A	N/A	Muscle and joint aches
Vaccine Recommendation			
Recommended to Receive 2 nd dose of mRNA COVID-19 vaccine?	NO Refer to Allergy to discuss whether they can safely receive the vaccine in a setting with advanced medical care available or Refer for non-mRNA COVID-19 vaccine, once available	YES	YES

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

COVID-19 mRNA Vaccine (Moderna & Pfizer Bio-NTech) Management of Potential Post-Vaccination Side Effects

Following COVID-19 mRNA vaccination 80-92% of patients will develop at least one local symptom and 55-83% will develop at least one systemic symptom. For most patients, post-vaccination side effects related to a COVID-19 mRNA vaccination occur within the first 3 days of vaccination, will last no longer than 1-3 days and may be managed with supportive care. These side effects will differ by age group and dose in vaccine series. Typically, these symptoms are more frequent and severe following the second dose and among younger persons compared to older persons.

The most common post-vaccination side effects, their relative frequency and general guidance for management are detailed below. This guideline does not cover immediate side effects occurring during observation period. The patient's underlying comorbidities must be considered when determining if symptoms should prompt clinical evaluation.

Routine prophylactic administration of analgesics/antipyretics for the purpose of preventing post-vaccination symptoms is not currently recommended by the CDC, as information on the impact of such use on mRNA COVID-19 vaccine-induced antibody responses is not available at this time.

This guidance is based on available clinical trials and emergency use authorization and will continue to change as additional data is acquired.

Local Site Reactions			
Symptom	Severity	Frequency	Management
Pain, Redness or Swelling at Injection Site	Mild - Does not interact with daily activities AND/OR >2cm, <5cm	Pain: 75-85% Redness: 3-8% Swelling: 4-11%	Apply a clean, cool, wet cloth to site. Exercise arm to reduce stiffness
	Moderate - Limits daily activities AND/OR 5-10 cm	Pain: 30% Redness: 1-8% Swelling: 2-11%	Apply a clean, cool, wet cloth to site. Exercise arm to reduce stiffness Consider OTC analgesic (Tylenol or NSAID-per usual recs by their MD)
	Severe - Prevents daily activities AND/OR >10 cm	Pain: 1-3% Redness: 0.5-2% Swelling: 0.5-2%	Apply a clean, cool, wet cloth to site/icing. Exercise arm to reduce stiffness; OTC analgesic (Tylenol or NSAID-per usual recs by their MD); If persists beyond 3 days, Call MD
Lymphadenopathy (Typically unilateral on side of vaccination)	Any	<1% in Pfizer but up to 9% in Moderna after 2nd vaccine	Reassurance that this is a sign the vaccine is working; Consider OTC analgesic (Tylenol or NSAID-per usual recs by their MD); If lasts > 2 weeks, contact MD

Systemic Reactions			
Symptom	Severity	Frequency	Management
Fever (Temperature (T) of 100.4 degrees or higher)	Overall - any new fever >100.4	10-16%	Rest; Increase fluid intake; Wear light/loose fitting clothing
	Mild - Does not interact with daily activities - T 100.4 - 101	10%	
	Moderate - Limits daily activities - T 101.1 - 102	5%	Rest; Increase fluid intake; Wear light/loose fitting clothing; OTC analgesic (Tylenol or NSAID-per usual recs by their MD); Call MD if persists beyond 48 hours and consider testing for COVID through BILH testing site
	Severe - Prevents daily activities - T > 102	1%	Rest; Increase fluid intake; Wear light/loose fitting clothing; OTC analgesic (Tylenol or NSAID-per usual recs by their MD); Call MD if lasts >24 hours.
Headache	Mild - Does not interact with daily activities	Very common, typically worse with 2 nd dose	Rest; Consider OTC analgesic (Tylenol or NSAID-per usual recs by their MD)
	Moderate - Limits daily activities	Mild: 25-50%	

	Severe - Prevents daily activities	Moderate: 13-25%	Rest; hydration; Consider OTC analgesic (Tylenol or NSAID-per usual recs by their MD)
		Severe: 1-3%	Rest; Hydration; Consider OTC analgesic (Tylenol or NSAID-per usual recs by their MD); Call MD
Chills		Mild: 5-30% Moderate: 4-20% Severe: <1%	Rest; hydration; Consider OTC analgesic (Tylenol or NSAID – per usual recs by their MD); Call MD if persists beyond 48 hours and consider testing for COVID through BILH testing site
Fatigue		Mild: 30-60% Moderate: 20-35% Severe: 10%	Rest, hydration. Call MD if persists beyond 7 days.
Myalgias & Joint Pain		Mild: 5-50% Moderate: 5-20% Severe: 0.5-6%	Rest; hydration; Consider OTC analgesic (Tylenol or NSAID – per usual recs by their MD); Call MD if persists beyond 7 days.
Diarrhea	Overall - any new diarrhea	11%	Rest; oral hydration
	Mild – 2-3 loose stools/day	9%	
	Moderate – 4-6 loose stools/day	2%	Rest; oral hydration/ broth; Call MD if persists >48 hours
	Severe - >6 times with signs of dehydration	<1%	Unlikely vaccine related; Consider urgent evaluation
Nausea/Vomiting	Overall - more common with Moderna after second dose	1-12%	Rest; oral hydration
	Mild – vomiting 1-2 times/day	2-11%	
	Moderate – vomiting >2 times/day	<1%	Rest; oral hydration/broth
	Severe- vomiting >2 times/day & signs of dehydration- dizziness, decreased urinary output	<0.5%	Unlikely vaccine related; Consider urgent evaluation

Non-Vaccine Related			
Symptom	Severity		Management
New or Worsening: Cough Shortness of breath Sore throat Loss of taste or smell	Any	*NOT a side effect of the vaccine	Contact PCP to be evaluated Arrange for COVID testing through BILH testing site

References:

[Vaccines and Related Biological Products Advisory Committee Meeting 12/17/20 – FDA Briefing Document Moderna Vaccine](#)
[Vaccines and Related Biological Products Advisory Committee Meeting 12/10/20 - FDA Briefing Document Pfizer-BioNTech Vaccine](#)
[FDA EUA Fact Sheet for Providers - Moderna](#)
[FDA EUA Fact Sheet for Providers – Pfizer-BioNTech](#)

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