

Policy: P015 – COVID-19 Vaccine - Events

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- I. **Purpose:** COVID-19 is a highly contagious communicable disease easily transmitted from person to person through aerosol droplets excreted when sneezing or coughing. Common symptoms include fever, cough, chills, headache, sore throat, nausea, vomiting, diarrhea, malaise, decrease in taste and smell, muscle aches and shortness of breath. Our goal is to provide COVID-19 vaccinations that has been FDA approved for Emergency Use Administration (EUA) in collective effort to decrease transmission of the SARS-CoV-2 virus and minimize morbidity and mortality rates
- II. **Policy:**
1. AP policy for COVID vaccine will be updated as needed. Staff will follow AP guidance when policy updates are in revision mode.
 2. Staff must be familiar with and fully understand all FDA United States approved and WHO listed COVID vaccine for Emergency Use Authorizations (EUAs) or otherwise. [refer to [AP Webpage](#)]
 3. All staff working events at Affiliated Physicians are required to receive the COVID vaccine primary series and strongly encouraged to receive a booster when eligible.
 4. Affiliated Physicians shall provide COVID vaccines to individuals identified by its contracted clients in a safe and efficient manner following all proper procedures set forth.
 5. Maintain records of documented vaccinations and report all vaccine administrations via local and/or state registry according to federal and state regulations.
 6. Store vaccine and maintain according to manufacturer and company protocols.
 7. Vaccines may be mix and matched for booster purposes ONLY. Not for administration of primary series. If patient inadvertently received a COVID vaccine not appropriate for their age group, mix and match may be necessary.

8. Once vaccine thawed, DO NOT refreeze. Once removed from fridge and warmed to room temperature, DO NOT place back in fridge.
9. Current COVID vaccines are specific for adults and adolescent age 5 and > for Pfizer and age 18 and > for Moderna and Janssen.
10. Administer vaccine via intramuscular route; deltoid muscle preferred. If patient requests another site for medical or personal reasons, okay to honor request using gluteal maximus or vastus lateralis muscles.
11. Sanitize work station periodically throughout vaccine programs.
12. Report serious adverse event(s) immediately to HOTLINE. Follow guidance from clinical leadership and follow proper incident reporting procedures [refer to Policy OP001].
13. Standing Physician Orders on file and active by state licensed physician/Medical Director; remains in effect for time period specified and is reviewed, revised and signed annually at minimum.
14. Staff working COVID vaccine programs required to utilize personal protective equipment (PPE) at all times during event operations except for when taking breaks.
15. When taking breaks, important to continue social distancing at all times and mask wearing if not eating or drinking.
16. Minimize waste of COVID-19 vaccine by taking proper precautions.
17. Review potential side effects with participants that can be seen with both D1, D2, and/or booster doses of COVID vaccines.
18. For IC patients, or those > 64 or < 12, Dose # 2 – Moderna – to be scheduled 28 days from 1st dose. 4-day grace period +/- from 28 day (as early as 24 days post first dose of COVID vaccine) not recommended, but allowed for extenuating circumstances ONLY.
19. For IC patients, or those > 64 or < 12, Dose #2 – Pfizer – to be scheduled 21 days from 1st dose. 4-day early grace period not recommended, but allowed for extenuating circumstances ONLY.
20. For patient who are age 12-64 it is recommended D2 be given at least 8 weeks past D1. Must educate all patients within this age group regarding the increased identified risks with receiving an mRNA vaccine sooner than the 8-week interval. Patient's within this age group may choose to receive the mRNA vaccine sooner than the 8-week interval once provided with this information.
21. If a patient requests to be dosed earlier than 21 [for Pfizer] or 28 [for Moderna] days respectively, each request is managed on a case-by-case basis and must be called into HL.
22. D3 of primary mRNA series for immunocompromised (IC) patients must be administered no sooner than 28 days from D2.
23. Booster dose for J/J must be at least two (2) months from D1.
24. If patient unable to receive 2nd vaccine dose on scheduled date, due to unforeseen circumstances, it is recommended they reschedule at their earliest convenience. No need to start vaccine series over if greater than the recommended 21 days for Pfizer, or 28 days for Moderna.
25. If a patient is age 5-17 and receives inadvertently the wrong formulation for their age group, administer follow up dose of Pfizer ONLY.
26. If a patient contracts COVID-19 after COVID vaccine dose #1 and before dose #2, patient must quarantine for at least 10 days prior to 2nd vaccine dose OR wait no more than 90

- days from known infection date to receive their 2nd dose. If greater than 90 days has lapsed between dose 1 and dose 2, patient should still receive dose 2 as soon as possible. This is considered a full vaccination series and series should not be started over.
27. Encourage patients to adhere to staying on track with dosing schedule when administering dose 1. Missed or skipped second doses can cause negative effects to oneself and/or to the surrounding community(s).
 28. Janssen COVID vaccine is a single dose administration and patient is considered fully vaccinated 2 weeks post receipt of the Janssen COVID vaccine.
 29. Staffing report [PM report] is generated and sent to site managers the day before all vaccine events.
 30. Event summary is provided to all staff members with special details outlining each scheduled event.
 31. Staff confirmation required at beginning of each vaccine event and is the responsibility of Site Management and/or Head Clinician to confirm all staff are accounted for.
 32. All COVID vaccine participants must be able to consent to treatment with sound mind and judgement.
 33. For a minor 16-17 years old: who has capacity, may obtain consent from parent or guardian via phone, in writing or in-person.
 - i. If via phone or in writing, there must be two (2) staff members who obtain such consent and document in patient medical record.
 34. For a minor 5-15 years old, capacity or not, requires a parent, guardian or designated adult caregiver to be present to consent for vaccination.
 35. If under age 18 or adult without capacity to make sound judgement there must a parent, guardian or designated adult caregiver present to consent.
 36. Okay to transport vaccine [punctured or non-punctured] from one community clinic to another – following best practices.
 37. Supply management maintained by logistics.
 38. Staff must be trained prior to working event and receive initial on-the-ground training.
 39. Should there be any noted deficiencies with skills on-the-ground determined by Site Management, Regional Directors, Head Clinicians, or Clinical Quality Compliance team member, additional observation(s) may be required.
 40. Clinical trial participants may receive COVID vaccine if the trial was for a non-approved EUA COVID vaccine and it is identified that the patient received ONLY a placebo.
 41. Persons 18+ outside of US who received a primary dose or series of a World Health Organization (WHO) listed vaccine is considered fully vaccinated and is eligible for a booster dose. If Pfizer or Moderna from outside of US, patient may choose Moderna, Pfizer or J/J for their booster. [not the case for Immunocompromised patients who are seeking D3 of their primary series. They must receive what they received prior – unless it is a non-US approved COVID vaccine. Then patient must receive Pfizer for their D3]
 42. Persons 18+ outside of US who received a full primary series of a WHO-listed vaccine is eligible to receive a booster dose of Pfizer ONLY. No Moderna or J/J. Unless Moderna or Pfizer were the vaccines they received outside of the US.
 43. Mix and Match dosing is allowed – **ONLY for Booster** vaccination doses for those who received Moderna or Pfizer. Patient who received J/J as a primary COVID vaccine dose is

eligible to receive Pfizer, Moderna or J/J as their booster – as long as it is 2 months from the original dose.

44. Mix-n-match is not allowed for IC patients who are receiving last dose of a primary series.
45. Moderate to Severely immunocompromised patients may receive D3 (final dose of primary series) at least 28 days from the second dose of their 2-part series and D4 five (5) months from receiving D3. **Mix and Match is now widely accepted for booster doses, regardless of IC or non-IC status.**
46. Those 18 years old or > (including moderately to severely immunocompromised) patients may receive D2 of J/J at least 2 months from date of their primary dose.
47. If patient severely allergic to specific vaccine type, mix and match for IC patient's primary series may be considered on a case-by-case basis and must be called into HL for further evaluation.

III. Procedure:

1. Staffing

Verify all staff members are present for COVID vaccine event.

- i. All staff must check-in with site manager (SM) upon arrival to event.
- ii. Program Management (PM) report is generated for SM prior to each event.
 - i. Report provides names, contact information and vaccination status for persons working the event.
- iii. SM must confirm all staff listed on PM report is present.
- iv. SM must confirm vaccination status.
 - i. All staff are required to be fully vaccinated to work AP events.
- v. All staff must sign in for each event worked.
 - i. Sign-in sheet will be available at each event.
- vi. If there is any missing staff or any extra staff, notify the Nursing HOTLINE.
- vii. Staffing will verify program staffing discrepancies and communicate with agencies, nurses and site operations accordingly.

2. Verify vaccine appointment

- i. Confirm participant has a scheduled appointment for vaccination.
- ii. Walk-ins accepted if client approves. **[refer to client specific event summary]**

3. Scheduling Dose 2 or subsequent COVID dosing appointments

- i. Scheduling is based on client specific needs and will be coordinated accordingly.
- ii. **Patients getting D1 of a mRNA vaccine:**
 - i. **Educate about the 8-week interval for D2 using the populated talking points.** [refer to
 - ii. **Screen for newly revised guidance regarding 12yo-64yo and no immunocompromised condition.**
 - iii. **If patient meets these criteria for 8-week interval, do not offer D2 appointments. Inform patients they should make an appointment at 8 weeks per new guidance.**
 - iv. **If patient meets criteria outside of this, e.g. immunocompromised, <12yo, and ≥65, then D2 appointments may be made 21 days for Pfizer and 28 days for Moderna.**

- iii. Patients coming in for D2 of a mRNA vaccine (<8 weeks), **the recommendation is to vaccinate.**
 - i. Inform patients who are **12yo-64yo** and **not with an immunocompromised condition** there is an increased identified risk.
 - ii. Should a patient inquire further and wants additional information, direct patient to **addendum 1.1.**
 - iii. Should a patient have additional questions after reviewing **addendum 1.1** defer them to speak with their PCP.
- 4. PPE
 - i. Don/Doff PPE according to policy when conducting COVID vaccine events to protect self and others from potentially spreading infectious material. PPE requirements subject to change. [N95/KN95, eye shield/goggle, gown] [refer to Policy P007]
 - ii. If providing direct patient care, gloves must be worn; change and hand sanitize in between each patient.
 - iii. If no direct patient care provided, no need for gloves. However, hand sanitizing must take place in between each patient interaction and masks must be worn.
 - iv. Surgical masks are acceptable for all Flu and COVID vaccine events, unless otherwise specified by client.
 - i. Both surgical masks and N95 masks will be provided and available by AP to all staff working vaccine events.
 - ii. If positivity rates begin to increase to undesirable numbers, staff may be directed to don N95 or KN95 masks.
 - iii. For fully COVID/Flu vaccinated staff members, it is the discretion of each individual staff member to choose which mask they don, N95 or surgical.
 - a. 'Fully vaccinated' refers to at least 2 weeks post receipt of the single dose J/J COVID vaccine or 2 weeks post receipt of the 2nd dose of a 2-part mRNA series for Moderna or Pfizer COVID vaccine. Likewise, with annual flu vaccine or COVID booster vaccine.
- 5. General Vaccine Information
 - i. Immunity is anticipated to last approximately 4-8 months from being deemed fully-vaccinated.
 - ii. Dosing Interval for 2-dose series
 - i. Pfizer – 21 days apart
 - ii. Moderna – 28 days apart
 - a. If second dose is missed – must be given as soon possible and DO NOT start series over.
 - b. If second dose is missed and not given at all, the following may occur:
 - i. No immunity to the virus
 - ii. A mutated virus
 - iii. Longer pandemic
 - iv. Resistance to the vaccine

- iii. Emergency Use Authorization (EUA) data sheets must be made available to all patients receiving the COVID vaccine.
 - i. Provide EUA information on-site.
 - a. QR code located on each EUA for patients to scan with a smartphone to view the EUA data sheets.
 - ii. Staff must familiarize self with the Affiliated Physicians Webpage for easy access and reference to Policies, Procedures, Forms, EUAs, Educational Documents, Standing Orders and more.
 - a. <https://affiliatedphysicians.com/nursing-protocols/>
6. Vaccine Risks
- i. Discuss with participants vaccine potential risks that have occurred outside of clinical trials during mass vaccinations - for each respective vaccine [Janssen, Pfizer, Moderna] at time of registration, as noted in provider and recipient manufacturer EUA sheets.
 - i. Janssen
 - a. Thrombosis with Thrombocytopenia
 - i. Rate has been highest in females age 18-49
 - ii. Some of these have been fatal
 - iii. Should symptoms occur, immediate follow up with medical professional is required
 - 1. Severe headache, severe abdominal pain, unusual leg pain, or shortness of breath.
 - b. Guillain-Barre Syndrome
 - i. Has been reported in some cases within 42 days following vaccine administration.
 - ii. Pfizer
 - a. Myocarditis – particularly after 2nd dose and within a few days of receiving the vaccine
 - b. Pericarditis – particularly after 2nd dose and within a few days of receiving the vaccine
 - c. Severe allergic reactions, including anaphylaxis + other hypersensitivity reactions (i.e. rash, pruritis, urticaria, angioedema, diarrhea, vomiting, and pain in extremity (arm)
 - iii. Moderna
 - a. Myocarditis - particularly after 2nd dose and within a few days of receiving the vaccine
 - b. Pericarditis - particularly after 2nd dose and within a few days of receiving the vaccine
 - c. Severe allergic reactions, including anaphylaxis
7. COVID Vaccination Patient Screening
- Can receive COVID vaccine dose if:
- i. Is not acutely ill.

- ii. Has not been told by an MD within the past 10 days must isolate due to possible exposure or having COVID-19 symptoms.
- iii. Receipt of monoclonal antibody treatment within the past 90 days for treatment of COVID-19 is no longer a disqualifier. [as of 02.18.22]
- iv. Is 18 years old or > for Moderna or Janssen, or 5+ for Pfizer.
- v. **Must not have had a severe life-threatening anaphylaxis reaction to a prior COVID vaccine.**
- vi. **Must not have any of the following symptoms within 15 minutes of receiving the 1st COVID vaccine dose:**
 - ✓ skin reaction (rash and/or hives)
 - ✓ angioedema (swelling beneath the skin)
 - ✓ stridor (harsh vibrating noise when breathing)
 - ✓ confusion
 - ✓ disorientation
 - ✓ difficulty breathing
 - ✓ abdominal pain
 - ✓ emesis

Can't receive if:

- i. Fever of 100.4 or greater or is feeling ill with COVID or Flu-like symptoms; runny nose, body aches, etc.
 - ii. Asked to quarantine due to COVID-19 infection or exposure within previous 10 days.
 - iii. Has received booster equivalent doses already.
 - iv. No Proof of Vaccine (POV)
 - v. Severe allergy to another COVID-19 mRNA vaccine
 - a. If patient reports serious adverse reaction with prior COVID vaccine dose(s), must report to HL.
 - i. If administered at an AP event
 - ii. Check Adverse Reaction flagged list and prior incident reports.
 - iii. If administered at a Non-AP event
 - 1. Will be handled on case-by-case basis with clinical leadership to review and provide direction.
- vii. Screen each patient for contraindication(s) and/or precautions
- i. **Pediatric population:** Vaccine is not available for the pediatric population < 18 years old at this time for Moderna or Janssen and < five (5) years old for Pfizer.
 - ii. **Immunocompromised individuals** can receive the COVID vaccine.
 - iii. Complete a **COVID-19 Vaccine Screening and Consent Form** on all vaccine participants or EMR screening form, whichever is applicable.
 - a. If 'Yes' or 'Unknown' to any disqualifying question, vaccine **CANNOT** be given. Defer patient to follow up with their PCP.
 - i. If disqualified for prior adverse reaction to the COVID vaccine, must be reported to the Hotline.
 - ii. If, inadvertent vaccine administration to a person with contraindications to receiving the vaccine: [i.e. < five (5)

years old for Pfizer or < 18 years old for Moderna or Janssen, or a previous severe allergy to any component of the COVID vaccine]

1. Must be reported to the Hotline
2. Complete incident report – include summary of findings.
 - a. Report to VAERS, ONLY
 - i. If patient with known severe allergy to any component of COVID-19 vaccine and still received a dose.
 - ii. Patient outside of the age requirement received a vaccine.
 - iii. Other medication error occurred

- b. If ‘No’ answered to all disqualifying questions, vaccine **CAN** be given.
- c. If ‘Yes’ answered to questions regarding low immunity or on drugs with immunity lowering effects, requires clinician education regarding likelihood immune response to the COVID-19 vaccine may be less than that of someone with a normal immune system.

8. D3 and D4 – Extra Doses and/or Boosters

i. For immunocompromised patients

- i. Moderna – Immunocompromised
 - a. D3 Adult 18+ [extra dose] = 0.5mL at least 28 days from D2
 - b. Booster [D4] Adult 18+ = 0.25mL at least three (3) months from D3
- ii. Pfizer - Immunocompromised
 - a. D3 Adult 12+ 0.3mL at least 28 days from D2
 - b. D3 Pediatric 5-11 0.2mL at least 28 days from D2
- iii. D4 [same manufacturer recommended] must be given at least 3 months post D3 instead of 5 months. [as of 02.18.22]
- iv. Patients who are IC and received D3 are able to mix-n-match for D4.
 - a. AP strongly encourages and recommends IC patients get the same, however, patients can choose the vaccine type they get for D4.
 - b. D4 is considered an IC patient’s BOOSTER. D3 is part of an IC patient’s primary series.

ii. General Population – non-immunocompromised patients

It is recommended that patients receive the same manufacturer for all doses within a primary series.

- i. Pfizer - General Public
 - a. Booster Adult 18+ 0.3mL at least 5 months from D2.
 - b. Booster 5-11 – not yet approved [as of 02.11.2022]
- ii. Moderna – General Public
 - a. Booster Adult 18+ booster 0.25mL at least 5 months from D2
- iii. J/J

- a. Booster Adult 18+ 0.5mL at least 2 months from D1 [for IC or non-IC patients]

9. Vaccine Documentation

- i. EMR [if applicable]
 - i. Must include prior vaccinations
 - ii. Must include responses to all qualifying questions
 - iii. Must include vaccine provided, clinician, route of administration, date, time, dose administered, injection site,
- ii. Hard Copy Consent [if applicable]
 - i. Must include prior vaccinations
 - ii. Must include responses to all qualifying questions
 - iii. Must include vaccine provided, clinician, route of administration, date, time, dose administered, injection site,
- iii. POV documentation
 - i. Place patient full name, DOB, Manuf., Expiration Date, Lot#, date of administration, location on POV card supplied by patient.
 - ii. If no POV card provided – but other supporting documentation has been provided to qualify patient for a booster vaccination [Dose #3 of a Pfizer or Moderna]
 - a. Provide new POV card
 - b. Cross off 1st and 2nd Dose COVID-19 with a pen.
 - c. Place 3rd Vaccine dose info on first ‘Other’ line and add ‘#3’ next to ‘Other.
 - d. For D4 – place ‘#4 CV’ and complete rest of line item.
 - e. For Janssen – place booster dose info on ‘2nd COVID dose’ line.
- iv. Errors
 - i. Documentation errors
 - a. Must communicate all documentation errors to HC immediately
 - b. HC must communicate with Hotline at time of incident
 - ii. Medication Errors
 - a. Must communicate all medication errors to HC immediately
 - b. HC must communicate with Hotline at time of incident
 - c. VAERS must be completed

10. Disqualifications (DQ)

- i. Complete DQ form on all patients who are disqualified.
 - i. Scan all DQ forms with end-of-day paperwork.
 - ii. Confirm all DQ patients are recorded in SharePoint document and inform onsite client contact, if applicable.

11. Proof of Vaccine (POV)

- i. The following are approved POV:
 - i. CDC POV card
 - ii. Photo of government issued CDC POV card
 - iii. State, County or City Vaccine registry lookup
 - iv. Physician documentation of prior 2 doses; with Manufacturer, Lot#, Date of Vaccine, Full Name, DOB

- v. Out-of-Country issued POV
 - ii. The following are steps to take regarding POV – unless otherwise specified by client. If client requires different process, Clinical Program Training (CPT) material and/or special notes within Access database will reflect client specific requests.
 - i. To complete a D2 of a 2-part COVID vaccine series, request POV or confirm if searchable to confirm manufacturer and date. In order to search, the following information is required:
 - a. Full Name – first and last
 - b. Telephone Number(s)
 - c. Full Address – including zip code
 - d. DOB
 - e. If unable to obtain manufacturer and/or date:
 - ii. If unable to produce a POV card and is not searchable or found via state or city vaccination databases, inform patient that once POV is obtained from originating location, can reschedule appointment. [again – refer to client specific information for instructions]
 - iii. D2 may be given to anyone who has received D1 elsewhere and provides POV, and if not otherwise disqualified based on consent questions, and unless otherwise specified by client.
 - a. If EMR or POV shows a different D1 manufacturer from what is being administered at the event, alert HOTLINE.
12. Walk-ins
- i. Walk-ins are okay, as long as there is enough vaccine, and approved by site operations manager and/or client.
13. Historical data –
- i. Must be included in patients’ medical record. i.e. dose #1, information must be documented in the patients EMR or hard copy consent and screening form.
 - i. Date of vaccination
 - ii. Lot #
 - iii. Location
 - iv. Manufacturer
 - v. If a patient has received a US approved COVID vaccine [Pfizer, Moderna or Janssen] in another country or state and is requesting to receive their second dose of a 2-part series or a booster vaccine dose at an AP event, adhere to the following:
 - a. **POV available – can be in the following form:**
 - i. Photo of POV card with ID
 - ii. CDC issued POV card
 - iii. Smartphone app that stores proof of vaccine
 - b. **POV not available**
 - i. Unable to proceed – unless otherwise specified by client.
14. Vaccine Lot # Lookup
- i. HC/ML/SM must confirm what the vaccine expiration date is by searching via www.vaxcheck.jnj for Janssen COVID vaccine or [Vial.Expiration.Date.Lookup | Moderna COVID-19 Vaccine \(EUA\) \(modernatx.com\)](http://Vial.Expiration.Date.Lookup.Moderna.COVID-19.Vaccine.(EUA).(modernatx.com)) for Moderna prior to event start time. Pfizer vials have the lot #s listed.
 - a) Input lot # that is on the vial
 - b) Click 'submit'

- c) Record lot # and expiration date and provide to each vaccination nurse
- d) If the expiration date and/or lot# is not correct on the logistics provided stickers
 - a. Discard the sticker sheets
 - b. Manually document correct lot# and expiration date on POV card and EMR or hard copy consent, whichever is applicable.
- e) If multiple lot #s exist at any single event, use one (1) lot # first before moving on to another
- f) Vaccine vial lot #s must be checked by the HC/ML/SM prior to passing to a vaccine station - to confirm same lot # is being used.
- g) Once a different lot # is initiated, HC/ML/SM must conduct another vaccine expiration check and report NEW lot # and expiration when passing NEW vial lot # to a station.

15. Beyond Use Date [BUD]

- i. This is the expiration date recorded when vaccine is taken out of the freezer and placed into the fridge.
 - i. Pfizer – 30 days from transfer to fridge
 - ii. Moderna – 30 days from transfer to fridge
 - iii. Janssen – Not Applicable. Janssen’s COVID vaccine expiration is the manufacturer listed expiration date and should not be used beyond that date.
- ii. Logistics will place the BUD on vaccine box or tray when moved from freezer to fridge. If manufacturer expiration date is before BUD, logistics will place the manufacturer expiration date on vials instead.
- iii. Field staff must monitor and confirm no vaccine beyond the BUD or manufacturer expiration dates is used.
- iv. If Expiration states a month with no specific date, the vaccine is good until 11:59p the last day of the month.
- v. If Manufacturer Expiration states a particular date, it is good until 11:59p of that date.
- vi. If a BUD is recorded by logistics with a time, the expiration is that exact date and time.
- vii. Should there be any discrepancy, compliance must be notified via Hotline.
- viii. Field Site Managers and Head Clinicians required to assess BUD for COVID vaccine prior to event start times and track via daily QC log.

16. Consent for Treatment

- i. All COVID vaccine participants must be able to consent to treatment.
 - a) If a patient is visibly under the influence of drugs or alcohol, AP staff reserves the right to turn individual away from receiving the COVID vaccine.
 - b) If a patient is a minor, patient must verbalize who his/her parent or guardian is or parent/guardian must provide proof of and must consent and sign on behalf of patient.
 - c) If minor patient [under 18 years old] or an adult patient who does not have capacity and is unable to verbalize who his/her parent or guardian is, parent or guardian must show proof of guardianship in order to consent to treatment for patient.

17. Minor Consents

i. 16-17-year-old

- i. For all minors, a parent or legal guardian must provide consent for vaccination.
- ii. For minors 16 or 17 years of age, such consent should be provided either in person or by phone, at the time of vaccine appointment.
- iii. Written statement of consent from a parent or guardian is accepted, where the parent or guardian is not available by phone to provide consent to vaccinate an unaccompanied minor age 16-17.
 - a. If consent is obtained via phone, there must be two (2) staff members who obtain consent and document in patient medical record. Documentation must include the following:
 - i. Parent/Guardian Full Name
 - ii. Parent/Guardian DOB
 - iii. Full Name of two (2) staff members

ii. 15-year-old or <

- i. For minors who are 15 years old or under 15 years of age, a parent or guardian must accompany the minor and consent to vaccination.

18. Out-of-Country Participants

- i. Patients from outside of the US can receive vaccine doses from AP events if they have POV of prior doses and have received a vaccine that is listed on the WHO list.
- ii. If patient received a single dose of a non-US FDA approved vaccine, but vaccine is on the WHO list, patient may continue series with the Pfizer or Moderna vaccine.
 - i. If received Moderna, Pfizer or J/J out-of-country, patient may receive same manufacturer for D2 or booster. Ex: D1 of Spikevax, patient may continue with D2 of Moderna.
- iii. If patient received a full series of a WHO list vaccine, may proceed with Moderna or Pfizer booster.
- iv. IC patients who receive a Janssen COVID-19 Vaccine primary series, may receive an additional dose and a booster dose, for a total of three (3) doses to be considered up-to-date.
 - i. An additional dose 28 days after D1, of either Moderna 0.5mL or Pfizer 0.3mL per the patient's request. Patient may choose to receive J/J as D2 as well.
 - ii. A Booster dose (D3) may be administered; either Moderna 0.5ml or Pfizer 0.3ml 2 months after D2.
- v. Boosters for Out-of-Country patients
 - i. Patients from out-of-country who received a COVID vaccine primary series that is on the WHO list are eligible to receive COVID boosters [Moderna or Pfizer].
- vi. If vaccine received outside of the US and is not on the WHO list, patient must start series over. May be Moderna, Pfizer or J/J.

19. Vaccine Storage and Use: [refer to CCM Policy for full Storage and Handling Procedures]

i. Pfizer's COVID vaccine storage:

- i. **12+ Purple Top** - Once thawed, 1.8mL NS RECONSTITUTION must be completed before use

Non-diluted vaccine - viable for

- One (1) month in refrigerator at 2-8 degrees Celsius, OR

- **2 hours** at room temperature
- Discard vaccine if not used within these time provisions.

Diluted Vaccine – viable for

- 6 hours at room temperature if diluted. Must discard after 6 hours. All vials need to be date and timed with dilution time.
- 12+ Gray Top** – Once thawed, NO DILUTION required
 - Can be at room temperature **up to 12 hours** before first puncture.
 - Once punctured, must be **used within 12 hours**.
 - Discard vaccine if not used within these time provisions.
 - 5-11 Orange Top** – Once thawed, 1.3mL NS RECONSTITUTION must be completed before use
 - Can be at room temperature **up to 12 hours** before dilution
 - Once diluted, must be **used within 12 hours**
 - Discard vaccine if not used within this time frame
 - Moderna COVID vaccine storage:**
 - Once thawed, NO DILUTION required
 - Can be stored at room temperature (46-77 degrees F.) **up to 24 hours**
 - Vials must be discarded at **12 hours** post first puncture if not used
 - Janssen (J&J) COVID vaccine storage**
 - Once thawed, NO DILUTION required
 - Can be stored at room temperature (46-77 degrees F.) up to 12 hours unpunctured
 - Can be at room temperature (46-77 degrees F.) **up to 2 hours** after first puncture OR
 - Can be stored at 36-46 degrees F. **up to 6 hours** after first puncture.
 - Vials must be discarded at

20. Mix & Match

- Mix & Match COVID vaccine is permitted for boosters ONLY.
 - If a participant has an adverse reaction to one type of COVID vaccine, they should be directed to discuss with their PCP. CDC does provide guidance, where participant may choose to try another type of COVID vaccine. [i.e. mRNA vs Viral Vector] – However, SEVERE Adverse Reaction patient would need to be managed in a controlled environment [i.e. MD office or hospital] and guidance must be provided by a physician.
 - If mild adverse reaction and patient consenting to receiving next dose, okay to proceed but encourage prior the importance of speaking with their PCP prior.
 - Monitor for 30 minutes in observation.
- If there is an inadvertent administration of cross-administration [i.e. 1st dose of Pfizer and 2nd dose of Moderna]
 - Patient is deemed fully vaccinated and no other vaccine to be administered, unless booster vaccine is necessary and patient meets time frame criteria.

- ii. Report to Hotline.
- iii. Complete VAERS report for medication error, if AP staff made the error.

21. COVID Vaccine Dosing

- i. Pfizer – age 12 years or > - Dose = 0.3mL IM [30mcg] – different formulation from 5-11 Pfizer vaccine
- ii. Pfizer – 5-11 years = 0.2mL [10mcg] – different formulation from 12+ Pfizer vaccine
- iii. Moderna – age 18 years or > - Dose = 0.5mL IM
 - i. IC D3 = 0.5mL
 - ii. IC D4 = 0.25mL
 - iii. Non-IC = 0.25mL
- iv. Janssen (J&J) – age 18 years or > - Dose = 0.5mL IM

22. Dosing Grace Period [+/- 4 day] D1 and D2 ONLY

- i. +/- 4-day grace period is generally not used for scheduling purposes. CDC guideline is to schedule 2nd dose vaccine with minimum interval of 21 days for Pfizer and 28 days for Moderna. Janssen is a single dose vaccine. AP, and according to CDC guidelines, recommends not dosing prior to the appropriate interval. However, patients may choose to dose early within the grace period timeframe for extenuating circumstances ONLY.
 - i. Contact Hotline for approval when extenuating circumstance is reported.
- ii. If patient miss getting dosed and is outside of this timeframe, patient should receive at their earliest convenience. No more than 2 weeks post vaccine scheduled date is most ideal.
- iii. If patient was infected with COVID in between D1 and D2 – ok to receive the 2nd dose when no longer infectious and purpl after having completed a 10-day quarantine/isolation period. It is important to encourage these individuals at their earliest convenience.

23. Pfizer COVID-19 Vaccine – mRNA 2-dose series

i. Overview

- i. Multi-Dose vial
- ii. Pfizer = 6 doses per vial (EUA information supersedes manufacturer data inserts)
 - a. FDA approved use of extra dose if equals full 0.3mL dose
- iii. Each dose = 0.3mL
 - a. Gently swirl vial after thawing.
 - b. Do not shake vial.
 - c. Inspect contents of vial; should appear white to off-white suspension. It may contain white or translucent product-related particulates.

24. Moderna COVID-19 Vaccine – mRNA 2-dose series

i. Overview

- i. Multi-Dose vial
- ii. 10-11 dose vial or 13-15 dose vial if available {as of 4/1/21}
 - a. Possible to get 11 full doses – if full 11th dose (0.5mL) is available, it is safe to use.
- iii. Each dose = 0.5mL

- a. Gently swirl vial after thawing.
- b. Do not shake vial.
- c. Inspect contents of vial; should appear white to off-white suspension. It may contain white or translucent product-related particulates.

25. Janssen (J&J) COVID-19 Vaccine – single dose vaccination

i. Overview

- i. Multi-Dose vial
- ii. **5 doses per vial**
- iii. **Each dose = 0.5mL**
 - a. Gently swirl in an upright position for 10 seconds before use.
 - b. Do not shake vial.
 - c. Inspect contents of vial; should appear slight yellow in color, clear to very opalescent suspension. If discolored or particulate matter observed, do not use and send back to Pelham office.

26. Pfizer Purple Cap COVID vaccine dilution process [1.8mL for 12+]

- i. Diluent has to be 0.9% sodium chloride injection (normal saline, preservative free)
 - i. **NEVER use Bacteriostatic normal saline or any other diluent.**
 - ii. Diluent will arrive separate from vaccine in an ancillary supply kit.
 - iii. Diluent should be a single-dose vial (SDV) for best practice.
 - a. Cannot use SDV for multiple vaccine vial reconstitutions.
 - b. Discard remaining Sodium Chloride after single use for reconstitution.
- ii. Dilute Pfizer vaccine **within 2 hours** once thawed.
- iii. Before dilution of Pfizer vaccine, invert vial gently 10 times.
 - i. HC/ML - clinical PM or CQC, where applicable, will be responsible for dilution process at Pfizer vaccine locations.
- iv. HC/ML needs to have completed a competency.
- v. If a nurse voices onsite that he/she is more comfortable with diluting their own vials, accommodate.
- vi. Diluting Pfizer COVID vaccine must be done using strict aseptic technique.
 - i. Do not shake vial.
 - ii. Inspect contents of vial; should appear white to off-white suspension and may contain white to off-white opaque amorphous particles.
 - iii. Do not use if discolored or if other particles are observed.
 - iv. Use sterile non-pre-filled syringe
 - v. Add and/or tighten sterile needle for IM injection to avoid vaccine leakage at hub connection.
 - vi. Pull plunger back to 1.8mL to pull in 1.8mL of air. [**1.3mL for 5-11 formulation**]
 - vii. Disinfect both diluent vial (provided separate from vaccine vial) and COVID vaccine vial using alcohol prep pads containing at least 70% isopropyl alcohol.

- viii. NOTE: all vial tops are dust covers and vial stoppers should not be considered sterile
- ix. Remove syringe needle cap, and insert needle into vial stopper of 0.9% NaCl diluent, inject air, and withdraw equal amount of diluent. [1.3mL for 5-11 and 1.8mL for 12+]
- x. Never add more diluent to Pfizer COVID-19 vaccine vial than what is needed.
- xi. Insert diluent needle into vaccine vial and dilute vial contents; equalize vial pressure before removing needle from the vaccine vial by withdrawing same amount of air into the empty diluent syringe.
- xii. Gently invert diluted vial contents 10 times to mix; do not shake.
- xiii. Record date and time of dilution on vial label.**
- xiv. Confirm all particles dissolved prior to withdraw of vaccine.
- xv. Unused diluted vaccine must be stored at temperature of 35-77 degrees F.
- xvi. Discard any unused vaccine after 6 hours from vaccine dilution.

27. Vaccine Preparation

- i. Use appropriate sterile non-pre-filled syringe with needle: typical 25g - 1” for most and 25g - 1 ½” for obese participants or those with greater adipose tissue at site of designated injection site.
- ii. Add and/or tighten sterile needle tip for IM injection to avoid vaccine leakage at hub connection.
- iii. Pull plunger back to desired volume of air. [not mandatory for such small volume]
 - i. Pfizer 12+ = 0.3mL
 - ii. Pfizer 5-11 = 0.2mL
 - iii. Moderna D1, D2, D3 = 0.5mL
 - iv. Moderna Booster and D4 = 0.25mL
 - v. Janssen = 0.5mL
- iv. Disinfect COVID vaccine vial using single-use alcohol prep pad containing at least 70% isopropyl alcohol.
 - i. NOTE: all vial tops are dust covers and vial stoppers should not be considered sterile
- v. Remove syringe needle cap, puncture vial top and add appropriate air volume.
- vi. With vial inverted, release plunger and allow for same amount of vaccine into syringe.
 - i. Expel air into vial and confirm proper volume of vaccine drawn up into syringe prior to removing needle from vial.

28. Administration

- i. Educate participant on potential side effects: body aches, low-grade fever, headache, etc.
- ii. With non-dominant gloved hand, identify injection site landmark [2-3 fingerbreadths below acromion process [for Deltoid Injection]]. Secure skin with pointer finger and thumb to make skin taut; avoid pinching skin. Opposite with younger patients with less flesh – pinch skin to avoid administering vaccine in wrong space.

- iii. Prepare deltoid muscle by disinfecting designated injection site with alcohol prep pad and let air dry. This should take 15-30 seconds.
- iv. Insert needle at 90 degrees into muscle with gloved dominant hand and inject vaccine.
- v. Remove needle and place directly into sharps container – **DO NOT** recap. If safety mechanism on needle, activate post vaccine administration and prior to placing into SHARPs container.
- vi. Apply gauze and/or Band-Aid as needed to injection site.
- vii. If D1, remind participant the need to receive D2 if receiving an mRNA vaccine and according to manufacturer EUA.
- viii. Document vaccine administration in EMR or Hard Copy Consent, whichever is applicable.
- ix. Provide proof of vaccine (POV) card or add to the POV card patient has provided. Important to include or confirm all information accurate:
 - i. First Name
 - ii. Last Name
 - iii. DOB
 - iv. Vaccine Information – ok to use sticker but must confirm LOT# is accurate.
 - v. Date – 2-digit date, 2-digit month, 2-digit year
 - vi. Location of Program – ex: DOH - Elmhurst

29. Multi-Vaccine Events

- i. Strict monitoring of vaccine stations by HC/ML required.
- ii. Limit one (1) vaccine type per station.
 - i. DO NOT have more than one (1) type of vaccine at any vaccine station.
- iii. Vaccine dispensing for all events – multi vaccine or single vaccine events – must be completed by the HC and/or ML.
- iv. HC/ML must track dispensing of vaccine vials.
- v. HC/ML responsible for reconstitution of all Pfizer COVID vaccine vials [if applicable for orange and purple top vaccine vials] prior to dispensing to vaccine stations.
- vi. HC/ML must communicate vaccine type and dosing for any clinician added to a vaccination station during the course of any event. This is frowned upon is to be conducted ONLY with the explicit approval of AP leadership team. No changing stations or positions/roles are allowed without this being approved.
- vii. Event doors cannot open unless HC/ML is present at the vaccination area and has completed education huddle with vaccination and observation stations.

30. Vaccine Key Points

- i. Confirm BUD is not past date prior to drawing up first dose of any vial.
 - i. Inform Hotline of expired vaccine if the beyond use date [BUD] is past.
- ii. Record date and time on vial for all first-time vial punctures.
- iii. Confirm lot# and expiration date and document accurately on POV card and consent form.
- iv. Unused vaccine must be stored at appropriate temperature according to manufacturer and Affiliated Physicians Cold Chain Management Policy & Procedure.

- v. Discard any unused vaccine according to manufacturer.
 - i. Do not attempt to get a full dose from multiple vials. If unable to get another full dose from a vial, discard the vial with remaining contents.
 - ii. No need to change needle between drawing up vaccine and administration, unless the needle has been damaged or contaminated.
- vi. Dispose of expired partial or empty COVID vaccine vials in Sharps Container

31. Potential Side Effects

- i. Can last 24-48 hours post vaccine administration
 - i. Chills
 - ii. Fever
 - iii. Headache
 - iv. Shortness of breath
 - v. Pain in arm
 - vi. Fatigue
 - vii. Redness and swelling at injection site

32. Post Vaccine Observation On-Site

- i. All COVID vaccine administrations require observation of patient after receiving vaccine dose.
 - i. 15 minutes if no known history of severe allergic reactions.
 - ii. If participant experiences adverse reaction during 15 minute observation, observe for additional 15 minutes or until symptoms resolve, whichever comes last.
 - iii. If there is a known allergy history to any component of the COVID vaccine, defer individual to follow up with their Primary Care Physician and **do not vaccinate**.
- ii. Be prepared to manage emergency situations. [refer to P014 – Emergency Medical Management <https://affiliatedphysicians.com/protocol/emergency-medical-management-of-adverse-reactions/>]
 - i. Appropriate medical equipment and medication must be available and used to manage immediate allergic reactions to the COVID vaccine.
 - a. Logistics responsible for delivering medical equipment and medication to all vaccination locations.
 - b. Site Management and Head Clinicians are responsible to confirm medical equipment and medications are readily available to all observation and vaccination team members prior to start of each event.

33. VAERS reporting

- i. For moderate to severe adverse events, refer to specific manufacturer guidelines located in each respective EUA and review with clinical management team. [Vaccine Adverse Event Reporting System \(VAERS\) \(hhs.gov\)](https://www.hhs.gov/vaers/)
 - i. Non-computer sites – require logistics scanning of incident reports into management system for review and reporting to VAERS online by clinical management team.

- ii. Sites with computer accessibility - complete VAERS report online on-site and provide confirmation email to compliance@affiliatedphysicians.com.

34. Documentation

- i. Obtain consent for treatment prior to administration of vaccine.
 - i. Do not take vital signs, vaccinate or treat a patient without expressed consent form.
- ii. Document each patient's vaccine administration on the consent form and POV card.
- iii. Record the following on Consent form:
 - i. Date of vaccination
 - ii. Vaccine Manufacturer – no stickers are located on the COVID vaccine vials, unlike with the influenza vaccine.
 - iii. Lot number
 - iv. Vaccine site [i.e. R or L deltoid]
 - v. Route of administration [i.e. IM]
 - vi. Name
 - vii. Address
 - viii. Title of person administering the vaccine [i.e. RN]
 - ix. Vaccine Dose #1 or Vaccine Dose #2
 - x. EUA and/or VIS with revised/publication date
 - xi. If vaccine not given – indicate reason on Consent form [i.e. Medical contraindication, patient refusal, etc.]

35. Disinfection

- i. Confirm all work stations are organized and disinfected at start of program.
 - i. Lysol spray for non-client facing surfaces.
 - ii. Sanitizing disinfectant wipes for all client-facing surfaces.
- ii. Disinfecting required periodically throughout events, not after each participant unless visibly soiled or contaminated.

36. Vaccine Waste

- i. Vaccine Tracker must be completed for each shift worked and submitted via email to projectmanagement@affiliatedphysicians.com prior to sending with end-of-event paperwork.
- ii. Goal of 'Zero Vaccine Waste'
 - i. If 4 or < doses remain at end of event, okay to discard and document on the wasted dose tracker. Report all waste to SM.
 - ii. If 5 or > doses remain at end of event, must attempt transfer to another active location.
 - iii. All partial doses remaining at completion of event can be discarded in a sharps container or transferred to another location dependent on the number of doses that are remaining.
 - iv. Doses wasted must be reported via CIR according to state and federal regulations.

- iii. If there is potential dose(s) that is/are going to be wasted, begin to look for anyone who may be interested in receiving the vaccine – if client is agreeable. If not – then document the doses wasted on your ‘Vaccine Tracker’ if applicable.

37. Vaccine Discrepancy

Important to avoid vaccine count discrepancies.

- i. Count Vaccine received and document on Vaccine Tracker at start of each shift.
- ii. Record usage on Medication/Vaccine Tracker
- iii. When vial empty must be shown to Team Lead in order to get replacement.
- iv. Empty vial is discarded by team member into designated SHARPs container.
- v. Mark the sign-in sheet with line under patient who received last dose of vial – indicating the start of new vial.
- vi. Site Manager manages vaccine throughout event and is responsible for all counts – including end-of-event.
- vii. Complete cross check with sign-in sheets received and vaccine out.
- viii. Any discrepancy must be reported immediately to the HOTLINE.

38. Supply Management

- i. Master packing and monitoring
 - i. Vaccine boxes and/or trays marked with date/time when moved from freezer to fridge by logistics.
 - ii. Vaccine box or tray marked with time when moved from fridge/cooler to room temperature. Moderna vaccine viable for 12 hours unpierced at room temperature.
 - iii. Vaccine vial is marked with date and time when first punctured for Moderna and Janssen, and for dilution with Pfizer.

Diagram 1.0 – COVID Vaccine Dosing

Type/Manufacturer of Vaccine	Age Group	Dose	Volume	Route	Instructions
Pfizer – Gray/Purple top	12 years old or >	30mcg	0.3mL	IM - intramuscular	Deltoid Muscle of Arm
Pfizer – Orange top	5-11	10mcg	0.2mL	IM - intramuscular	Deltoid Muscle of Arm
Moderna –	18 years old or >		0.5mL	IM - intramuscular	Deltoid Muscle of Arm
Moderna – IC	18 years old or >		0.5mL	IM - intramuscular	Deltoid Muscle of Arm
Moderna – Booster	18 years old or >		0.25mL	IM - intramuscular	Deltoid Muscle of Arm
Janssen (J&J) – COVID	18 years old or >		0.5mL	IM - intramuscular	Deltoid Muscle of Arm

Addendum 1.0

Guidance for administering Dose 3 and Boosters – effective date 09.24.21 and

D4 IC updated within AP Policy 02/11/2022

Proof of Vaccination (POV) must be available during the registration process in order to be eligible for Dose 3 or Booster of a COVID-19 vaccine. POV must have patients name, date of birth, vaccine type, and date of Dose prior doses.

For eligibility - staff must obtain attestation of eligibility for either Booster or D3 or D4. Staff should NOT need to ask reason or details of eligibility.

- D3: moderate to severe immunocompromised – considered the final dose of a primary series for IC patients.
- D4: is considered an IC patient’s booster dose.
- Boosters:
 - Age eligibility for boosters
 - 12+ for Pfizer
 - 18+ for Moderna and J/J

The following are accepted forms of POV:

1. CDC POV Card – Hard Copy
2. Photo of POV Card
3. State Vaccine Registration application, such as Excelsior Pass for NYS, or COVID safe pass for NYC
4. Physician document that states the 2 vaccines with lot#, Manuf., and dates. Must be signed by an MD with NPI or DEA #
5. If D1 and D2 were administered by AP, can look up patient status in portal or EMR. Data and/or IT Applications teams may be able to assist with this as needed.

Clearance at Registration – in order to clear registration with one of the before mentioned POV - the following must take place:

- ✓ Boosters are for all those who are fully vaccinated and who meet the dosing interval timeframe.
- ✓ Booster patients must have received Pfizer or Moderna D1 and D2 and a minimum of five (5) months from last date of their D2, unless IC.
- ✓ D3 for Pfizer or Moderna, or D2 for J/J is for immunocompromised patients ONLY
- ✓ D3 for Pfizer or Moderna, or D2 for J/J must be the same brand as D1 and D2; i.e. if D1 and D2 were Moderna, D3 must be Moderna
- ✓ D3 for Pfizer or Moderna, or D2 for J/J - must be a minimum of 28 days from the date of D2 for Pfizer or Moderna, or D1 for J/J.
- ✓ Booster (D4) for IC patients must be three (3) months from final dose of primary series (D3).
- ✓ Proof of age is required to meet age requirement
- ✓ Proof of identification is NOT required, but may be necessary if there is a vaccination discrepancy.
- ✓ In addition to attesting and meeting above eligibility, patients **MUST**
 - Meet appropriate age cut-off based on the type of vaccine being administered and current FDA approved age eligibility status.
 - Not be ill or sick with fever 100.4 or >
 - Not have experienced a severe adverse reaction to any component of a COVID vaccine shot

- Not have been asked to isolate or quarantine within the past 10 days due to COVID infection or exposure.

If patient got an mRNA vaccine (Pfizer or Moderna): effective 10/22/21

- Pfizer and Moderna booster doses are now available for 12+ for Pfizer and 18+ for Moderna received if vaccine primary series completed at least five (5) months ago. Those groups are:

If patient got Johnson & Johnson:

- People who received the J&J vaccine at least two months ago are eligible for a booster.
- Patient may choose which vaccine manufacturer [Pfizer, Moderna, or J/J] they want for their booster dose.
- All J/J booster vaccine must be administered at least 2 months following the initial vaccine dose, even if receiving the Moderna or Pfizer booster.

Mixing vaccine types:

- The science most strongly supports that Moderna and Pfizer recipients get a third dose of the same vaccine type. However, if someone prefers a different vaccine type, they are able to choose any of the three vaccines (at least 5 months after their second dose of Moderna or Pfizer for non-IC patients or at least 3 months after D3 for IC patients).
- For J&J recipients, all three vaccines are approved as a booster, but some scientific evidence indicates that a Moderna or Pfizer booster could be better.
- Direct patient to speak with their doctor or clinical staff at a vaccine site, if not sure which one they should get.

People who are immunocompromised

- Adults who received the Pfizer or Moderna vaccine at least 28 days ago, and are [moderately to severely immunocompromised](#), are eligible for a third dose of the vaccine, as part of their initial vaccination series. IC patients who complete their primary series by getting D3 are eligible to receive a booster three (3) months post D3. Patients need to attest to their eligibility.

Addendum 1.1 – Immunocompromised and Pregnant/Breastfeeding Talking Points

Should a patient who is **pregnant or breastfeeding** inquire about the safety of receiving a COVID vaccine:

- Clinical studies support safety and efficacy in pregnant and breastfeeding woman.
- COVID-19 vaccination is recommended for all peoples ages 5 years and older, including people who are pregnant, recently pregnant, breastfeeding or wanting to get pregnant. The benefits of receiving a COVID-19 vaccine during pregnancy outweigh any known or potential risks of vaccination.
- The vaccines do not contain the virus that causes COVID-19. They cannot give mom or baby COVID-19 or change their DNA.

Immune suppressed individuals

- Immunity to virus may not be as strong post receipt of vaccine.
- Body may not build immunity against the virus.


Addendum 1.2 – Change in Dosing Interval

TOPIC: mRNA dosing interval changes for high risk age group

Talking points:

- On February 22, the Centers for Disease Control and Prevention (CDC) updated its COVID-19 vaccination guidance to recommend extending the interval between the first and second mRNA COVID-19 vaccine doses to 8 weeks for many people ages 12 to 64 years.
- This is an update from the currently recommended interval of 3 or 4 weeks between the first and second doses of Pfizer or Moderna vaccine, respectively.
- This change was made based on new data indicating that an 8-week interval may help improve the immune response, increase vaccine effectiveness and lengthen the time of protection of vaccination against infection and hospitalization. It may also help lower the small risk of myocarditis and pericarditis, which has been associated—mostly among adolescent and young adult males—with mRNA COVID-19 vaccination.
- This update does not apply to everyone. People who are moderately or severely immunocompromised, adults ages 65 years and older, and others who may need early protection due to concern about an increased risk of severe illness from COVID-19 or high levels of community transmission should continue to receive their second mRNA vaccine at the 3-week or 4-week interval for Pfizer or Moderna, respectively. The interval for children 5 to 11 years of age is 3 weeks and has not changed.
- People ages 12 years and older who are moderately or severely immunocompromised should receive three doses in their mRNA primary vaccine series and should receive a booster dose with an mRNA vaccine at least 3 months after completing their third primary series dose.
- Non-IC patients who have already completed the 2-dose primary series do not need to repeat any of the doses but should receive a booster dose at 5 months after the second vaccination.
- Speak to your healthcare providers if you are unsure about when to receive your second COVID vaccination. **For more information about the COVID-19 vaccines:**
 - Visit nyc.gov/covidvaccine and cdc.gov/covidvaccine.
 - To find a vaccination site, go to nyc.gov/vaccinefinder or call 877-VAX-4-NYC (877-829-4692).
 - You can call 311 or 212-COVID-19 (212-268-4319) if you have questions or for help finding a NYC Health + Hospitals doctor.
 - Care is provided regardless of immigration status, insurance status or ability to pay.

IV. Resources:

1. <https://www.mayoclinic.org/diseases-conditions/coronavirus/symptoms-causes/syc-20479963>
2. <http://www.op.nysed.gov/prof/med/medmedicalassistants.htm#>
3. [What to know about COVID-19 vaccines and how they work - ABC News \(go.com\)](#)
4. [Why Moderna And Pfizer Vaccines Have Different Cold Storage Requirements : Shots - Health News : NPR](#)
5. [COVID-19 Vaccine U.S. Distribution Fact Sheet | Pfizer](#)
6. [What to Know About HIV and COVID-19 | CDC](#)
7. [PowerPoint Presentation \(cdc.gov\) \[work group discussion 9/22/20 - phase 1a and phase 1b of vaccine rollout\]](#)
8. [Phased Allocation of COVID-19 Vaccines \(cdc.gov\) \[updated 11/23/20 – phase 1a, 1b and 1c\]](#)
9. [Who Will Get The COVID-19 Vaccine First? Here's A Tentative Rollout Plan Considered By The CDC. | The Daily Wire](#)
10. [COVID-19: Who's at higher risk of serious symptoms? - Mayo Clinic](#)
11. [Certain Medical Conditions and Risk for Severe COVID-19 Illness | CDC](#)
12. [Side Effects of COVID-19 Vaccines By Moderna, Pfizer, AstraZeneca, J&J | Observer](#)
13. [BNT-162b2 \(Pfizer\) \(COVID-19 vaccine, mRNA-Pfizer\) dosing, indications, interactions, adverse effects, and more \(medscape.com\)](#)
14. [fact-sheet-for-hcp-administering-vaccine-vaccination-providers-full-eua-prescribing-information.pdf \(cvdvaccine-us.com\)](#)
15. <https://www.cvdvaccine-us.com/images/pdf/fact-sheet-for-recipients-and-caregivers.pdf>
16. [Some Vials Of COVID-19 Vaccine Contain Extra Doses, Expanding Supply, FDA Says : Coronavirus Updates : NPR](#)
17. [Pfizer-BioNTech COVID-19 Vaccine Questions | CDC](#)
18. [Phased Distribution of the Vaccine | COVID-19 Vaccine \(ny.gov\)](#)
19. [Pfizer-BioNTech COVID-19 Vaccine Questions | CDC](#)
20. [Single-Dose or Multi-Dose \(cdc.gov\)](#)
21. [Phased Distribution of the Vaccine | COVID-19 Vaccine \(ny.gov\)](#)
22. [Janssen COVID-19 Vaccine - EUA Fact Sheet for Healthcare Providers Administering Vaccine \(janssenlabels.com\)](#)
23. [Janssen COVID-19 Vaccine - EUA Fact Sheet for Recipients and Caregivers \(janssenlabels.com\)](#)
24. <https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/downloads/Moderna-Vaccine-Transport.pdf>
25. <https://www.cdc.gov/vaccines/covid-19/info-by-product/janssen/downloads/janssen-transportation-guidance.pdf>
26. 
State Provider
Guidance 051421_hi
27. <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#Appendix-A>

ⁱ Created Date – 11.30.20

ⁱⁱ Last reviewed/revised – 01.24.22, 02.11.22, 03.07.22

ⁱⁱⁱ Approved Date – 12.30.20, 1.23.20