Administration of COVID-19 Vaccinations in Primary Care: An Implementation Toolkit

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Chapter 1. What is in this toolkit and how is it organized?

This toolkit focuses primarily on implementation of COVID-19 vaccination in a health center or clinic with minimal disruption to the clinic's routine workflow. The guide includes prompts for questions you may need to ask, examples of many types of documents that you may need (and information about where to find more documentation), and lessons-learned from our experience at Gabriel Park Primary Care Clinic at OHSU.

How this toolkit is organized

We start by providing links to the most up-to-date information about the COVID-19 vaccines and how to communicate about them, for clinicians and patients. Next, we discuss federal, state and county resources to support in-clinic vaccination. Then, we provide ste-by-step information about developing and implementing a COVID-19 vaccination workflow. This includes information about administering, documenting, and coding/billing for the COVID-19 vaccines. The toolkit is organized into chapters, and most chapters contain active links to external websites for additional information as well as handouts, checklists and other material that can be found at the end of this document.

Pass on the learning

This guide is intended to be a "living document." We hope to update it, as needed. If you implement a workflow for administering COVID-19 vaccines as part of routine clinical care, we would love to learn from and integrate your experiences into this guide. Please send us an email to share your experiences.

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Chapter 2. Knowledge and evidence related to COVID vaccines

In this section, we share links to detailed information about the vaccines for COVID-19 that have been approved for use. The vaccine information and use authorizations are rapidly changing, so we provide links to get the most up-to-date information. Through these links, you can get information about these vaccines and evidence to-date of their efficacy, plus additional information and communication resources.

2.1. Information for Clinicans

- Interim clinical considerations for COVID-19 vaccines (updated frequently)
- Booster shots and additional doses of the COVID-19 vaccines
- Pediatric vaccine information
- How COVID-19 vaccines work
- <u>Understanding mRNA COVID-19 vaccines</u>
- Understanding viral vector COVID-19 vaccines
- Vaccine cold-chain information
- COVID-19 vaccines and allergic reactions
- What to expect after getting vaccinated
- How the CDC is making COVID-19 vaccine recommendations
- Vaccine safety monitoring after a vaccine is authorized or approved for use
- **COVID-19** Vaccination Training

Pfizer BioNTech (COMIRNATY)

- Information about the Pfizer-BioNTech COVID-19 Vaccine
- Full list of ingredients Pfizer
- CDC training Pfizer
- How to thaw, prepare, and administer Pfizer
- Pfizer Vaccine preparation infographic
- Evidence from the Pfizer-BioNTech clinical trials for adults
- Evidence from the Pfizer-BioNTech clinical trials for children (starts on slide 17)
- Demographic information of adult trial participants
- **Pfizer Standing Orders**

Moderna

- Information about the Moderna COVID-19 Vaccine
- Full list of ingredients Moderna
- CDC training Moderna
- How to thaw, prepare, and administer Moderna
- Clinical trials Moderna
- Demographic information for trial participants
- **Moderna Standing Orders**

J&J Janssen

- Information about the J&J Janssen COVID-19 Vaccine
- How to prepare and administer J&J Janssen
- Full list of ingredients J&J Janssen
- CDC training J&J Janssen
- <u>J&J Janssen Standing Orders</u>

2.2. Vaccine resources for patients and community members

- Fact Sheet for Recipients and Caregivers
 - o Pfizer-BioNTech
 - o Moderna
 - o J&J Janssen
- What to Expect after Getting a COVID-19 Vaccine (1 page)
 - o English
 - o **Spanish**
- Myths and facts about COVID-19 vaccines and how to find credible information
- What to expect when getting your COVID-19 vaccine
- Video: What to expect at your COVID-19 vaccine appointment (Source: CDC, 48 seconds long)
- Video: How mRNA vaccines work (for kids) (Source: AAP, 2:53 minutes long)

Chapter 3. Federal, state and county resources for in-clinic vaccination efforts

Several federal initiatives have provided funding to states and counties to support vaccination efforts. This chapter provides an overview of the types of support available and how to access it. Although we primarily focus on Oregon, we try to provide resources and links for clinics in other states to locate similar resources.

3.1 How to register as a vaccination site

One of the most important changes to vaccines in the Fall of 2021 is that there may not be mass vaccination sites for COVID-19 and clinics will need to get more involved in vaccinating people. Check with your state leaders to learn how to get identified as a vaccination site and get access to vaccines.

For information about signing up to be a COVID-19 vaccine provider, see your state's COVID-19 **Provider Registration website**

In Oregon, you can put your clinic on the Get Vaccinated Oregon Site here:

https://admin.getvaccinated.oregon.gov/#/provider

Oregon is utilizing a hub and spoke distribution model for vaccine distribution. The Oregon Health Authority (OHA) has identified thirteen Vaccine Redistribution Hubs for COVID-19 vaccine across the state, to widen vaccine access and prevent waste. All provide the Pfizer vaccine, with most of the Hubs providing other COVID-19 vaccines as well. More information about ordering vaccines in Oregon is in Section 6.1.

3.2. Supplemental funding for vaccine storage and handling equipment

The OHA/Oregon Immunization Program is announcing the availability of funding for vaccine storage and handling equipment. This funding is available to all existing Vaccines for Children (VFC), Vaccine Access Project (VAP), and CARES providers of influenza vaccines. The funding is also available for facilities that are offering COVID-19 vaccine, and this includes for clinicians that are not yet enrolled. To become eligible as an enrolled facility, complete the ALERT IIS part of the enrollment (you do not have to have completed the entire enrollment process). Allowable purchases will be reimbursed up to \$1,000 per vaccination facility.

Allowable purchases include:

- Vaccine storage units (i.e., refrigerators and freezers approved for vaccine storage). Note: NO dorm-style combined refrigerator/freezer units allowed under any circumstances.
- Temperature monitoring equipment
- Vaccine transport coolers that are purpose built for maintaining appropriate refrigerator or freezer temperatures for vaccines
- Supplies required as part of a clinic's immunization activities (e.g., first aid kit, EpiPen, etc.)

https://app.smartsheet.com/b/publish?EQBCT=1e38f1448f5f424fb0d478adeb7a144b

3.3. COVID-19 vaccination administration supplemental funding (Oregon specific)

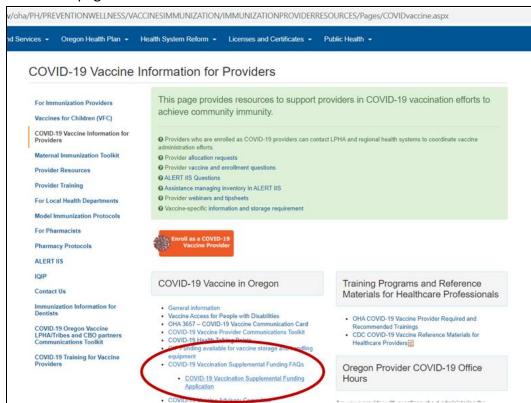
This funding is to pay for uncovered costs related to COVID-19 vaccination incurred by Patient Centered Primary Care Home (PCPCH), Certified Community Behavioral Health Centers (CCBHC) and OHA-recognized Public Access Clinics. See more information <u>here</u>.

This program contains two tracks:

- Comprehensive Services: Pays up to \$75 per COVID-19 vaccination administered by PCPCH clinics and CCBHCs providing comprehensive services such as costs involved in conducting outreach, education, scheduling, follow up, tracking, reporting, management and ordering of vaccines. Vaccination services provided on or after January 1, 2021 will be funded through the Comprehensive Services program even if registration occurs at a later date.
- Direct Cost Reimbursement: Provides direct cost reimbursement for clinics not participating in the Comprehensive Services Track, and covers expenses related to vaccination activities, supplies and equipment. PCPCH, CCBHC and Public Access Clinics may choose to participate in the Direct Cost Reimbursement Track if they do not choose the Comprehensive Services Track. Expenses incurred on or after January 1, 2021 are eligible for reimbursement through the Direct Cost Reimbursement

The only clinics that may not qualify will be those who have received significant financial support or grants from other programs (specifically LPHAs). Oregon Health Authority launched the program in June 2021 and has 40 clinics participating, and have distributed \$1M in supplemental funding.

Information about OHAs clinic funding program, including an application and FAQs can be found on the Information for Providers page of the OHA website:



Chapter 4. Roles and functions for in-clinic vaccination

Vaccination is a routine part of primary care. This chapter describes how the roles and functions for COVID-19 vaccination might be a little bit different for your clinic. We try to describe the tasks in detail so that you can apply this to your clinic among the staff (and potentially volunteers) that you have, as each clinic will describe tasks differently.

4.1. Roles for vaccination in-clinic

See next page.

4.2. National resources about staffing and roles

- Vaccine clinic time and budget worksheet (Harvard Primary Care Center) This tool is intended to assist site managers at outpatient clinics or offsite locations with preparation, workforce planning and budgeting for COVID vaccination in compliance with NASEM, ACIP, state, and county guidelines and regulations, principally focused on Moderna, Pfizer, or J&J vaccine distribution. Input parameters can be customized and adjusted in the yellow highlighted columns at the right, and will automatically update the Results sheet (next sheet). The current version assumes costs of purchasing the vaccines are subsumed and federally funded under current CARES Act provisions. Hence, the calculator focuses on prep and administration costs including workforce, PPE and auxiliary supplies. Calculations are meant to be estimates only, with usual disclaimers. Prior to use, we recommend this readiness quick-start guide. See also the SINGLE DOSE VERSION for Johnson and Johnson (Janssen) administration protocols.
- <u>Vaccine clinic readiness checklist</u> (state of California) A lot goes into preparing your clinic to vaccinate your patients and community with the growing list of authorized COVID-19 vaccines. Before vaccines arrive, review this checklist of key tasks and available videos and job aids to make sure your clinic is ready.

Daily Tasks				
Function	Tasks	Materials Needed	Training Needed	
Vaccine ordering, transportation, and handling	Order vaccines at least 5 days prior to dosing, for first and second doses Document receipt of vaccine in state registry system	Special cooler for vaccine transport		
Offer the vaccine, document response	If yes: Add a note to the appointment notes or place the patient and/or visitor on the appropriate resource schedule using the COVID Vaccine visit type If no: Document in appointment notes	Script, workflow	Training on script and workflow	
Screening and consent for vaccine	give handouts (VIS and vaccine questionnaire)	Vaccine information sheet and vaccine questionnaire	Brief training in what questions to ask. Questions on laminated cards.	
Screening for 15 vs 30- minute monitoring	Asks about factors that might differential people with different monitoring needs	Questions to differential monitoring length	Review of vaccine questionnaire and monitoring requirements	
Answering patient questions	Answer patient questions that require a bit more detail; Assisting patients with yes responses on COVID questionnaire. Initial judgement on length of observation. Document questions in the EHR	FAQs to help with answer question	Clinical personnel address to answer COVID question and engage LIP, as needed	
Register a visitor who does not have a chart	Follow the standard registration process for a new patient	Computer with EHR access or paper forms		
Identify whether patient has already received a COVID-19 vaccination (ALERT-IIS)	Search for the person in the vaccine registry system Confirm when and what brand of vaccine was administered, if any. Submit error corrections when relevant	Computer with internet access		
Prepare syringes	This person punctures one vial at a time when the first patient consents to be vaccinated, draws up all vaccines, and places them in refrigerator Communicate via team secure chat to all clinical teams: how many doses are available until what time	Syringes vaccine	Proper handling and preparation of vaccine for administration	
Prepare vaccine cards	Write out the vaccine cards or apply stickers with the vial information	Cards		
Vaccinate people	Administers vaccines Disposes of vaccine waste (sharps, trash	Filled syringes Alcohol swabs Cotton balls Band aids	Proper technique for IM administration of vaccine. Judgement on appropriate needle length.	
Document vaccine given	This person documents the vaccination delivery in EHR and the state immunization registry system, if both needed	Computer with EHR access or paper forms	Training on brief documentation	

Create an appointment for second dose the appropriate number of days from first vaccine	Search by name, DOB Make appointment for the correct dose (28-day booster) at the correct vaccination site location give patient appointment card or send appointment message via email or MyChart	Computer with EHR access Secure internet connection	EHR scheduling access
Medical oversight of monitoring	Be immediately available to provide first aid assistance during the monitoring period if needed. Be alerted by the monitor if there is a problem	LIP information sheets: ACLS, BLS, and How to use EpiPen auto injector	Basic first aid
Monitor patients following vaccination	Observe or check-in on patients for 15 or 30 minutes, as indicated following vaccination; Offer juice, water or crackers, if needed Alert Medical Lead for monitoring if there is a problem	Clear instructions on who to contact if there's a problem	Basic first aid
Monitor vaccine supply throughout the day	Open new vial when requested, ensuring that all prepared doses have been used Ensure all unused doses are discarded at the end of the day	Guidance from clinic leadership about vaccine best practices	
Document waste	Log into the state registry system and report unused doses	Computer with internet access	Immunization system knowledge

Chapter 5. Sample workflow for first and second doses

We want to acknowledge that you and your clinic are already experts at administering vaccines in your clinic; you do this as a routine part of care every day. A good place to start is the workflow your clinic uses for administering other vaccines (e.g., flu, TDAP, MMR). If you have a written workflow, it can be used as a starting point.

Many of the systems you use for routine vaccination will be applicable to COVID-19 vaccines:

- Recording in the EHR if someone declines the vaccine
- Documenting vaccination into the state immunization registry system
- Creating and using dot phrases and standing orders to save time
- Scrubbing charts and identifying scheduled patients who need the vaccine
- Team-based effort involving multiple providers (e.g., MAs, physicians, PAs, NPs)
- Providing vaccine handouts, such as after-care information about the vaccine, potential side effects, and how to report adverse events
- Handling vaccine hesitancy by having discussions and countering misinformation
- Finding and bringing supplies into the exam room: bandaid, cotton swab, alcohol pad, etc.
- Disposal of sharps and other materials

However, COVID-19 vaccines are different from other routine vaccinations in several key ways:

- COVID-19 vaccines have special storage requirements
- COVID-19 vaccines need to be drawn rather than using pre-filled syringes, with an eye toward trying to minimize waste
- Monitoring period post-vaccine means that patients are in the clinic for a minimum of 15 extra minutes, which has the potential to impact patient visit flow
- A second dose is needed within a very specific timeframe
- Patient need to receive an immunization card
- COVID-19 vaccines are more emotionally charged than most other vaccines; there may be more reluctance among clinic staff to bring up COVID-19 vaccination, unique hesitancy among patients and more heated feelings on the part of patients who decline it, as well as community opposition to vaccination. It can, therefore, take more time to manage this vaccine at several steps in the process.

In this section, we walk you through the workflow at our clinic, offer some key questions to consider during the planning process for your clinic, and provide you with sample scripts that you can use to get your team started.

5.1. OHSU case study: What we put in place before starting in-clinic vaccination

We made sure that our clinic was enrolled with the Oregon Health Authority as a COVID-Vaccine provider. COVID-19 vaccine ordering, transportation and handling is handled by the Back Office Supervisor. The MA who is responsible for the operations of the clinic med room orders all other vaccines, but we wanted the Back Office Supervisor to manage COVID-19 vaccines. The BOS submits a vaccine order to the OHSU Pharmacy, specifying the quantity and type of vaccine (inclusive of first and second doses). The order is submitted via email at least 5 days prior to dosing. [Note: this method of ordering vaccines is atypical.

Section 6.1 provides more information on how clinics can order vaccines through the Oregon hub and spoke distribution model.]

Vaccines come in a "kit", which is a pack of 100 doses, along with all accompanying supplies: syringes, needles, alcohol wipes, bandaids, gauze. When the vaccines arrive at the clinic, the Back Office Supervisor documents the receipt in ALERT, Oregon's immunization registry. In ALERT, the vaccines display in the clinic's inventory.

Delegation protocol / Standing orders to administer vaccine. The Delegation Protocol within the Epic EHR provides complete information including documentation instructions and copies of the federal fact sheets to provide to patients. Licensed Registered Nurses (RN), Licensed Practical Nurses (LPN), Medical Assistants (MA), or Pharmacists will enter orders using "Per Delegation Protocol" order mode and sign the order.

We developed a protocol to keep patients safe/observed during monitoring. Since patients would be doing monitoring in the exam room, we needed to be sure that a licensed provider was located in the hallway and could be available immediately if there was a problem.

We prepared and distributed scripts for all clinical team members who may have direct patient contact, including schedulers, front desk, MAs, care coordinators, and licensed providers.

We identified a Vaccine Lead to oversee each day's vaccination process. The Lead is responsible for drawing up the vaccine, preparing accompanying vaccine cards and labels, monitoring time to ensure vaccine is viable, discarding of old vaccine, and reporting any unused doses in ALERT at the end of each day.

We made several changes to our Epic EHR. First, we wanted to make every patient's vaccination status visible to every clinic staff member. We modified the DAR (the list of daily scheduled appointments) so that vaccination status was visible. This helped the front desk to offer vaccine when checking patients in for an appointment. We also edited the provider view in Epic so the patient's vaccination status is aligned with the schedule view. We discussed with staff how to correct information in the ALERT state immunization registry if the information conflicted with a patient's self-reported vaccination status.

- Where is a patient's COVID-19 vaccination status displayed in your EHR? Which clinic staff can view this?
- Are you able to make changes to your EHR to support in-clinic vaccination?
- Are clinic staff comfortable with asking patients about vaccination status?
- Who in your clinic is trained to access the state immunization registry system? Who is trained to troubleshoot and address errors in the immunization registry?
- How will you record when a patient declines the vaccine?
- Is there an efficient way to combine COVID-19 vaccines with flu, childhood immunizations, or other routine vaccines (or special vaccine clinic hours for flu)?
- Can you set aside appointment blocks for administering COVID-19 vaccines?

5.2. OHSU case study: Team-based approach to offering the vaccine

We tried to remove as many patient barriers as possible. For example, COVID-19 vaccine was available in all clinics, on all days, not on special days or only during certain appointment blocks.

We offer vaccine from a team-based perspective. If someone calls us for any reason (dental, behavioral health, primary care) they are offered a vaccine if we don't have evidence that they've received it. We configured our EHR so that every person in the clinic has info about vaccination status. If unknown or not vaccinated, or need a second dose, they offer it. Scheduling, front desk, care managers, MAs are trained to ask "Would you like to get a COVID-19 vaccine while you're here for your doctor's visit." Sample phone scripts are available in section 5.11 at the end of this chapter. Staff will need support for this approach, especially in areas where there is a lot of community resistance to vaccination. We used all-staff morning huddles to review the workflow, look ahead at the schedule, and talk about any issues or concerns.

Our three main pathways are for (1) staff to offer when scheduling a visit; (2) front desk to offer during check-in; and (3) MA to offer during rooming. Note that both patients and visitors are offered the vaccine during check-in and rooming. If patients accept the vaccine, in accordance with clinic protocol, front desk will add a note to the appointment notes or place the patient and/or visitor on the appropriate resource schedule using the COVID Vaccine visit type.

If the patient declines the vaccine during any of these touches, it could be that they received a COVID-19 vaccination at another location. In these cases, the MA checks records; if possible updating the chart to reconcile outside records. If the patient has not been vaccinated, the MA or front desk alerts the PCP of opportunity to discuss vaccine hesitancy with the patient.it's noted in the appointment notes which will prompt the licensed provider to bring up vaccination during the visit.

We initially scrubbed the schedule intensely to identify patients ahead of time and ran reports throughout the day to try to identify unvaccinated patients, but now we rely on the team-based approach. We are not proactively reaching out to patients who are unvaccinated. During Spring 2021 we utilized intensive resources to reach out to patients to connect them with mass vaccination sites, and we got poor results with very few patients getting vaccinated.

Clinical team members were trained in motivational interviewing techniques to have a conversation with patients who are reluctant or concerned about getting the vaccine. This type of counseling can be documented (see section 7.9). This approach has resulted in some people changing their minds, or at least being willing to have a conversation again at their next appointment. Motivational interviewing techniques for 1-5 minute conversations about vaccination: https://www.cdc.gov/vaccines/covid-19/hcp/engagingpatients.html

Some patients will be put off by the team-based approach, where every clinic contact includes a question about getting vaccinated. One example workflow for this is to set a 60 day declination process in health maintenance. If the patient declines, the health maintenance alert will disappear, and in 60-90 days it will reappear to prompt clinic staff to ask the patient about it again. At that point, the patient may have changed their mind or be open to a conversation with a trusted provider.

- How will your clinic handle scheduling? Will phone staff, front desk, and rooming MAs be trained to offer and schedule the vaccine?
- Will your clinic administer the vaccine to accompanying family members if they want it? If so, how will you document those vaccines and bill for them?
- Who will conduct the screening and consent for the vaccine, and determine the 15- or 30-minute monitoring period?

Additional communication resources:

- Key Things to Know about COVID-19 Vaccines
- Frequently Asked Questions about COVID-19 Vaccines
- Answering Patients' Questions About COVID-19 Vaccine and Vaccination
- How to Tailor COVID-19 Information for Your Specific Audience
- How to Address COVID-19 Misinformation

5.3. OHSU case study: Vaccine on arrival

When the patient checks in for their appointment, the front desk gives them a pre-vaccination checklist to fill out with the COVID-19 vaccine screening questions (see link at the end of this chapter). This checklist, modified from the CDC version, is laminated so it can be cleaned and reused for multiple patients. Then the MA goes to the waiting room to get the patient, who hands the sheet to the MA to review. If the MA has any question about what is on the screening form, they raise it with the Vaccine Lead. Upon rooming the patient, the MA signs the order for the vaccine and makes a decision about a 15-minute or 30-minute monitoring time.

The MA indicates to the Vaccine Lead that they need a vaccine and the dose and accompanying supplies (gauze, alcohol pad, bandaid) are brought to the exam room. The MA administers vaccine early in the visit to starting the monitoring clock. In most cases, vaccination happens before taking vitals and before agenda setting for the appointment. The MA also schedules the second dose appointment. The visit then proceeds as usual.

The monitoring time is usually up by the time the provider has completed the appointment and left the room. When the MA returns to the room to give the patient the after-visit summary, the MA can check the time and make sure everything is OK. If the monitoring time is not yet up, the MA will put a flag on the door and the door stays open to continue monitoring by clinical team members in that hallway.

We vaccinate parents, caregivers, friends or family who comes in with the patient. If that person is not already a patient, the front desk will complete a registration in the EHR and create the appointment.

Our state's immunization registry automatically pulls vaccination data from our EHR once a month; no staff time is needed for that.

- What rooms will you use to vaccinate people?
- Are there days or clinic sessions that might be better for giving COVID-19 vaccines (lighter schedule?)

- How will your clinic staff communicate with each other when a vaccine vial is opened to minimize wastage?
- Are your MAs and clinicians comfortable with using standing orders? If not, how will the vaccines be ordered in an efficient way?
- How will the team know when a room is open, but not yet clean? When it's clean and available? When a room is occupied?
- Where will you monitor patients after their vaccination?
 - Will this be inside an exam room with the door open, inside a larger space within the clinic (e.g., waiting room), or is it possible to do this outside under a structure (e.g., a tent) or in personal cars?
 - If monitoring inside the building, how can you keep people moving so exam rooms for vaccinations open quickly?
 - o How will you keep people physically distanced?
 - o How will you identify and monitor people who need 15- and 30-minute monitoring?
 - Who will oversee the monitoring, checking in on patients periodically and available to rapidly respond if a serious reaction occurs?
- How will patients know when they can leave?
- Documentation (see section 7.9 for documenting)

5.4. OHSU case study: Second doses

We blocked slots on the MA schedule to deliver second doses of the COVID-19 vaccines. Second dose appointments are put on the MA visit schedule by the MA.

When the patient arrives at our clinic for the second dose, they are given a Second Dose pre-vaccine checklist to complete (see link at the end of this chapter). Then there are two potential workflows: 1. The patient waits in the lobby, the MA comes and administers the vaccine in the lobby, and the monitoring time happens there with the patient setting a timer on their phone. 2. The MA walks the patient back to an exam room that is set aside for second doses, located near the triage nurse desk. The triage nurse is responsible for monitoring.

For second doses that are no-shows, we developed a "Well App" text that goes to their phone and reminds them that they've missed the dose, and patients can reschedule directly from that text. We found from sending these reminders, that a number of people received a second shot elsewhere.

- How will you remind patients about their second dose appointment? Do you already have appointment reminder systems (e.g., phone, text message) or clinic workflows that could be utilized?
- What steps will you take if patients are a no-show for their second appointment?
- Second doses take much less time. The patient's reaction to the vaccine is unlikely to change and there is less screening and fewer questions. However, the patient must return to the clinic for a special visit, not linked to an existing doctor's appointment.
 - Who in your clinic would be best to administer second doses? Knowing that there is some flexibility in the window for second doses (see section 6.7), could you schedule one week's worth of second doses onto a single day?

- What days or times would you have an MA or other staff available to do second doses, noting that you will still need a qualified provider to oversee the monitoring?
- Are you able to block appointments, or schedule appointments directly with the MA?
- Where will people wait for their second dose of the vaccine and do their monitoring time?

5.5. Monitoring protocols

Post-vaccine monitoring is the biggest limiting factor in how a vaccine clinic will function. You must provide space for every person to safely sit for 15 minutes after being vaccinated, distanced from others. A small number will need 30 minute monitoring. Effective planning of monitoring space is essential. Some ideas are:

- Bring 15-minute people to the lobby. They can self-time the 15 minutes using their phone or watch.
- Move 30-minute people to a conference room.
- Have people return to their cars if the parking lot is large enough to accommodate this. People can write the time on their windshield or be handed a piece of paper for their dashboard.
- If you have ample exam rooms, have them sit in an exam room with the door open.

Regardless of where you choose to monitor people, you will need a few team members to keep an eye on people. You will need one licensed provider at all times to be immediately available in case of a reaction.

You will need to have some supplies on hand for (extremely rare) vaccine reactions. In general, the critical piece is benadryl and epinephrine. Anaphylactic reactions are EXTREMELY rare. In our experience the vast majority of reactions were vasovagal reactions from people with either needle phobias or anxiety around vaccine administration itself. For this reason, it was important to have someone available that can offer this latter group juice/water/crackers and have the ability to take basic vitals, etc. We extended monitoring of anyone with vasovagal reactions to 30 minutes (minimum) of monitoring with the requirement that they must feel back to baseline before leaving the facility.

5.6. Billing

The COVID-19 vaccine was purchased by the U.S. government and is therefore available to every person at no cost. People receive the vaccine regardless of ability to pay and regardless of their insurance status. Providers are able to bill insurance for the administration of the COVID-19 vaccine. CMS has several toolkits on this centralized resource page to assist with billing: https://www.cms.gov/COVIDvax In addition, we cover coding information in Section 6.10.

Oregon and other states may have funding through FEMA to supplement insurance reimbursement. Please see Chapter 3 for more information about support for vaccination.

Even if you are not currently billing or planning to bill, it is prudent to collect insurance information from people along with a clear message that they will not pay anything out of pocket for the vaccine.

5.7. Vaccine "waste" or unused doses

In early 2021, vaccine supply was scarce and a lot of attention was given to maximizing every drop of vaccine in a vial. Since May 2021, there has been a major shift in recommendations about waste:

Vaccine vials may be opened without every dose being used. As access to COVID-19 vaccine increases, it is important for providers to not miss any opportunity to vaccinate every eligible person who presents at your primary care clinic for a COVID-19 vaccine. As there are opportunities to vaccinate more people, it may increase the likelihood of leaving unused doses in a vial. Your clinic may want to consider that despite following best practices to use every dose possible, that should not be at the expense of missing an opportunity to vaccinate every eligible person when they are ready to get vaccinated. https://www.cdc.gov/vaccines/covid-19/downloads/wastage-operational-summary.pdf

5.8. Special considerations for pediatric/adolescents

5.8.a. Is the COVID-19 vaccine recommended for children and adolescents?

The American Academy of Pediatrics (AAP) recommends COVID-19 vaccination for all children and adolescents 5 years of age and older who do not have contraindications using a COVID-19 vaccine authorized through an Emergency Use Authorization (EUA) or Biologics License Application (BLA), recommended by CDC, and appropriate for their age and health status. Read the AAP statement.

5.8.b. Do adolescents need special consent or assent to receive the COVID-19 vaccine?

This information comes from the American Academy of Pediatrics.

State and/or local laws determine who is able to consent or assent for COVID-19 vaccines; the same as other vaccines. In most places and instances, a parent's consent is required for a child or adolescent to receive a vaccine. While this may not always require a signature, you may consider obtaining one for COVID-19 vaccines. Health care providers administering the vaccine should inform vaccine recipients of the following: (1) FDA has authorized emergency use of the vaccine (2) known and potential risks and benefits related to emergency use (3) that they have the option to accept or refuse the product and (4) be informed of any available alternatives to the product and their known risks and benefits. Each recipient should receive a fact sheet that includes essential information about the vaccine. The fact sheets for health care professionals administering the vaccine as well as recipients were approved as part of the authorization and are available from the FDA website:

- **Fact Sheets for Health Care Providers**
- EUA Fact Sheet for Recipients and Caregivers (12 years of age and older)
- EUA Fact Sheet for Recipients and Caregivers in Spanish (12 years of age and older)
- **EUA Fact Sheet for Recipients and Caregivers (5-11 years of age)**
- **EUA Fact Sheet for Recipients and Caregivers in Spanish (5-11 years of age)**

5.8.c. Special considerations for vaccinating patients under age 12

Information from Pfizer for the 5-11 years of age formulation:

Standing Orders for Administering Vaccine **Preparation and Administration** Storage and Handling Summary

- Administer catch-up vaccinations to patients who are behind. Most parts of the country have experienced decreased rates of routine childhood and adolescent immunizations during the pandemic. The time is now to call patients and families and encourage them to return and get caught up. As some patients and families may be hesitant to return to the office, the AAP has reinvigorated its #CallYourPediatrician campaign, which includes resources that practices can use to amplify this message. Information on reminder/recall strategies is available here.
- Promote COVID-19 vaccine confidence. Misinformation about COVID-19 vaccine abounds. Vaccine hesitancy threatens the promise of herd immunity against COVID-19. Practices can utilize <u>resources</u> in the AAP Immunizations CampaignToolkit to promote vaccine confidence. In addition, practices can utilize the CDC's COVID-19 vaccine confidence resources. Consider ways that patients and families in your practice like to receive information and use these mechanisms to debunk common myths and answer frequently asked questions.
- Know the COVID-19 vaccination sites in your community: If your practice chooses not to administer COVID-19 vaccine, you should identify and compile information about nearby COVID-19 vaccination sites to share with your patients and families. A good resource is https://www.vaccines.gov/search/ which allows you to search by product and zip code. Parents can also text their ZIP code to 438829 (GETVAX); or call 1-800-232-0233. Encourage everyone to be vaccinated and ask families to notify you if your patient receives COVID-19 vaccine elsewhere. This will help ensure a comprehensive immunization record.

5.8.d. Drive-through clinics for administering COVID-19 vaccines:

Much like flu shots, pediatric clinics may want to develop and offer drive-through COVID-19 vaccination clinics. The CPCRI mass-vaccination site toolkit is a good source of information and guidance on special considerations for COVID-19 vaccine drive-through clinics. Other resources include this blog post from a pediatric EHR vendor that offers good advice for planning, setting up, and operating a drive-through flu shot clinic. It includes a patient/family-facing video from a Portland pediatric clinic that describes what to expect.

5.8.f. Communication resources specific to pediatric populations:

- How to talk with parents about COVID-19 vaccination for pediatric patients
- COVID-19 vaccination of minors
- <u>Coadministration of COVID-19 vacci</u>nes with other vaccines
- AAP COVID-19 vaccine campaign toolkit

5.9. Recommendations for welcoming BIPOC and other groups that are disproportionately impacted by COVID-19:

The COVID-19 pandemic has highlighted health inequity rooted in the unjust living realities in many of our communities both urban and rural- especially for Black, Latinx, Indigenous, and Native Hawaiian/ Pacific Islander Americans. Members of these communities are at a disproportionately high risk of mortality and have low vaccination rates.

When developing an equitable vaccination strategy, consider the following:

- 1. Be aware of implicit bias within your clinic. Taking steps to recognize and correct unconscious assumptions toward groups can promote health equity¹.
- 2. Take the time to listen. Vaccine hesitancy has myriad reasons, and many patients are looking for answers to their questions from a trusted source (you!). Building trust and taking time to answer questions with today's evidence takes time and humility. But it is worth it.
- 3. Connect with community partners and resources. Provide information about outreach events, hours and same day accessibility to local churches, food banks, after-school centers and labor partners. Organize a listen and plan session with community leaders to tailor content messaging that resonates with community members and encourages vaccination. Community based organizations can help tailor communication content for varying health literacy and education levels, with an emphasis on ease of accessibility.
- 4. Recognize the barriers to equitable, quality health care in your community, and know where the resources are. Safety net clinics such as Federally Qualified Health Centers and the Local Public Health Authorities and in Oregon, the local CCOs will often have connections to social service resources that can assist with transportation to the clinic for vaccination, as well as resources for other needs preventing vaccination such as food and housing insecurity.
- 5. Provide language and culturally specific communication services. Include American Sign Language and braille in both outreach, registration, education and follow up information. Community based organizations can help to tailor content that is culturally specific and relevant to the community you serve.
- 6. Support populations with limited digital literacy by providing non-digital registration, educational materials, and resource options. Simplify the registration process and make it convenient and try to offer digital and non-digital options.
- 7. Offer vaccination during non-traditional hours or days of the week to provide access to individuals who cannot leave work, lack childcare or eldercare.

5.10. Addressing requests for medical or religious vaccine exceptions

Individuals seeking an exception from a COVID-19 vaccination requirement will likely be required to fill out and submit to their employer a request for an exception using an exception request form. When there is additional guidance for providers in responding to these requests from patients, we will add it to this toolkit.

(A) A medical exception must be corroborated by a document signed by a medical provider, who is not the individual seeking the exception, certifying that the individual has a physical or mental impairment that limits the individual's ability to receive a COVID-19 vaccination based on a specified medical diagnosis, and that specifies whether the impairment is temporary in nature or permanent.

¹ Fam Pract Manag. 2019 Jul-Aug; 26(4):29-33. Edgoose, J.; Quioque, M.; Sidhar K. How to Identify, Understand, and Unlearn Implicit Bias in Patient Care.

5.11. Materials you might find useful

- CDC's Prevaccination Checklist for COVID-19 Vaccines
- Our modified prevaccination checklist for first and second doses (in our clinic, these are laminated and can be cleaned and reused)
- Sample scripts for front desk
- "Job Breakdown Sheet" for each role and workflow for COVID-19 vaccination
- EpiPen instructions
- ACLS instructions
- BLS instructions
- Vaccine cold-chain information
- COVID-19 vaccine FAQs from OHSU
- Symptoms of Coronavirus
- Vaccine clinic time and budget worksheet (Harvard Primary Care Center)
- Vaccine clinic readiness checklist (state of California)
- Billing resources
- How to handle unused doses

Additional communication resources:

- Key Things to Know about COVID-19 Vaccines
- Frequently Asked Questions about COVID-19 Vaccines
- Answering Patients' Questions About COVID-19 Vaccine and Vaccination
- How to Tailor COVID-19 Information for Your Specific Audience
- How to Address COVID-19 Misinformation
- Motivational Interviewing Techniques for 1-5 Minute conversations
- Vaccine hesitancy resources from <u>Boost Oregon</u> and <u>CDC</u>

Pediatric Populations

- How to talk with parents about COVID-19 vaccination for pediatric patients
- COVID-19 vaccination of minors
- Coadministration of COVID-19 vaccines with other vaccines
- AAP statement on COVID-19 vaccine recommendations

Chapter 6. Vaccination procedures

This chapter provides training resources for your vaccinators, as well as vaccination instructions for each of the vaccines. For example, how to thaw the vaccine vials, how to reconstitute the Pfizer vaccine, how to fill syringes, administer the vaccine, monitor people after receiving the vaccination, and how to complete the vaccination record card. It also covers coding and billing for services.

6.1. Ordering vaccines

Oregon is utilizing a hub and spoke distribution model for vaccine distribution. The Oregon Health Authority (OHA) has identified thirteen Vaccine Redistribution Hubs for COVID-19 vaccine across the state, to widen vaccine access and prevent waste. All provide the Pfizer vaccine, with most of the Hubs providing other COVID-19 vaccines as well.

Each Hub serves as a central site to receive vaccines, store them for brief periods of time, repackage them into smaller batches, and redistribute them to clinics and other administering sites. Hubs will allow vaccinators such as clinics, pharmacies, and public health sites to have smaller quantities of the Pfizer vaccine available in their conventional vaccine freezers and refrigerators, where they may be safely stored for up to 6 weeks. In addition, many Hubs are distributing Moderna and J&J vaccine, allowing providers to access small or large quantities of these vaccines that are already on hand in the state.

Hubs provide COVID-19 vaccine to each region's enrolled pandemic vaccine providers, the "Spokes." OHA is covering the operating costs of any Hubs that request reimbursement, so there is no cost to the Spokes for this service, and OHA has produced a Fact Sheet for each Hub that provides detail about its ordering and delivery process. You may request the Fact Sheet for your region's Hub by emailing COVID19.VaccineRequest@dhsoha.state.or.us.

Note for sites deciding how much of the Pfizer vaccine to order: As of May 19, 2021, the FDA has authorized Pfizer vaccine to be stored for up to 2 weeks in a conventional vaccine freezer (-25 to -15C) plus up to one month in a vaccine refrigerator (2 to 8C). This means that facilities without an ultra-cold freezer can safely store the Pfizer vaccine on site for up to 45 days.

Note about Johnson & Johnson vaccine supply: While J&J is not available from the manufacturer as of July 2021, sites can obtain it by responding to the OHA's statewide vaccine request survey. Sites that are served by a Hub that handles J&J will receive the vaccine via delivery from the Hub. For other jurisdictions, the OHA will ship J&J directly to the enrolled vaccinator.

For information on your Vaccine Redistribution Hubs:

To connect with your region's Redistribution Hub and/or questions related to Redistribution Hubs, email: COVID19.VaccineRequest@dhsoha.state.or.us.

6.2. Training vaccinators

CDC training (CM available):

WB4460: COVID-19 Vaccine Training: General Overview of Immunization Best Practices for **Healthcare Providers**

https://www2.cdc.gov/vaccines/ed/covid19/SHVA/index.asp

PROGRAM DESCRIPTION: CDC has created a new, web-on-demand, self-paced module for healthcare providers who will be administering Pfizer-BioNTech COVID-19 Vaccine. This module will provide information to healthcare professionals about COVID-19 vaccine manufactured by Pfizer Pharmaceuticals, based on the recommendations of the Advisory Committee on Immunization Practices and guidance from the manufacturer.

OBJECTIVES: At the conclusion of the session, the participant will be able to:

Describe the Vaccine Safety, Development, and Emergency Use Authorization (EUA) mechanism to provide approval for COVID-19 vaccines.

Describe the general storage and handling requirements for COVID-19 vaccines.

Describe the general vaccine administration procedures for COVID-19 vaccines.

Describe documentation and reporting procedures for adverse events associated with COVID-19 Vaccines.

Locate current immunization resources to increase knowledge of team's role in program implementation for improved team performance.

Implement disease detection and prevention health care services (e.g., smoking cessation, weight reduction, diabetes screening, blood pressure screening, immunization services) to prevent health problems and maintain health.

WB4464: Moderna COVID-19 Vaccine: What Healthcare Professionals Need to Know https://www2.cdc.gov/vaccines/ed/covid19/moderna/index.asp

PROGRAM DESCRIPTION: CDC has created a new, web-on-demand, self-paced module for healthcare providers who will be administering Moderna COVID-19 Vaccine. This module will provide information to healthcare professionals about COVID-19 vaccine manufactured by Moderna, Inc., based on the recommendations of the Advisory Committee on Immunization Practices and guidance from the manufacturer.

OBJECTIVES: At the conclusion of the session, the participant will be able to:

Describe characteristics of the Moderna COVID-19 vaccine used to prevent COVID-19 infection.

Describe storage and handling requirements for Moderna COVID-19 vaccine.

Describe vaccine preparation procedures for Moderna COVID-19 vaccine.

Describe vaccine administration procedures for Moderna COVID-19 vaccine.

Locate current immunization resources to increase knowledge of team's role in program implementation for improved team performance.

Implement disease detection and prevention health care services (e.g., smoking cessation, weight reduction, diabetes screening, blood pressure screening, immunization services) to prevent health problems and maintain health.

WB4461: Pfizer-BioNTech COVID-19 Vaccine: What Healthcare Professionals Need to Know https://www2.cdc.gov/vaccines/ed/covid19/pfizer/index.asp

PROGRAM DESCRIPTION: CDC has created a new, web-on-demand, self-paced module for healthcare providers who will be administering Pfizer-BioNTech COVID-19 Vaccine. This module will provide information to healthcare professionals about COVID-19 vaccine manufactured by Pfizer Pharmaceuticals, based on the recommendations of the Advisory Committee on Immunization Practices and guidance from the manufacturer.

OBJECTIVES: At the conclusion of the session, the participant will be able to:

Describe characteristics of the Pfizer-BioNTech COVID-19 vaccine used to prevent COVID-19 infection.

Describe storage and handling requirements for Pfizer-BioNTech COVID-19 vaccine.

Describe vaccine preparation procedures for Pfizer-BioNTech COVID-19 vaccine.

Describe vaccine administration procedures for Pfizer-BioNTech COVID-19 vaccine.

Locate current immunization resources to increase knowledge of team's role in program implementation for improved team performance.

Implement disease detection and prevention health care services (e.g., smoking cessation, weight reduction, diabetes screening, blood pressure screening, immunization services) to prevent health problems and maintain health.

WB4470: Janssen COVID-19 Vaccine (Johnson & Johnson): What Healthcare Professionals Need to Know

https://www2.cdc.gov/vaccines/ed/covid19/janssen/index.asp

PROGRAM DESCRIPTION: CDC has created a new, web-on-demand, self-paced module for healthcare providers who will be administering Janssen COVID-19 Vaccine. This module will provide information to healthcare professionals about COVID-19 vaccine manufactured by Johnson & Johnson, based on the recommendations of the Advisory Committee on Immunization Practices and guidance from the manufacturer.

OBJECTIVES: At the conclusion of the session, the participant will be able to:

Describe characteristics of the Janssen COVID-19 vaccine used to prevent COVID-19 disease.

Describe storage and handling requirements for Janssen COVID-19 vaccine.

Describe vaccine preparation procedures for Janssen COVID-19 vaccine.

Describe vaccine administration procedures for Janssen COVID-19 vaccine.

Locate current immunization resources to increase knowledge of team's role in program implementation for improved team performance.

Implement disease detection and prevention health care services (e.g., smoking cessation, weight reduction, diabetes screening, blood pressure screening, immunization services) to prevent health problems and maintain health.

6.3. Procedures for filling syringes

How to Thaw and Prepare the Moderna Vaccine

https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/index.html

How to Thaw the Vaccine

- Vaccine may be thawed in the refrigerator or at room temperature.
- Refrigerator: Between 2°C and 8°C (36°F and 46°F) for 2 hours and 30 minutes

- Room temperature: Between 15°C and 25°C (59°F and 77°F) for 1 hour
- Vials that have not been punctured may be kept at room temperature (between 8°C and 25°C (46°F and 77°F)) for up to 12 hours. Do **NOT** refreeze thawed vaccine.

How to Prepare the Vaccine

- 1. Ensure you have an adequate number of people ready to receive the vaccine before preparing it.
- 2. Follow aseptic technique. Perform hand hygiene before vaccine preparation, between recipients, when changing gloves (if worn), and any time hands become soiled.*
- 3. Unpunctured vials: Check the expiration date. Never use expired vaccine. Note the date and time the vial is punctured. Keep the vaccine between 2°C and 25°C (36°F and 77°F) for up to 6 hours. Discard any unused vaccine after 6 hours. (If your vial is already punctured, check the beyond-use time. Never use vaccine after the beyond-use time.)
- 4. With the vial upright, gently swirl the vaccine. Do NOT shake. If the vial is shaken, contact the manufacturer.
 - Note: Gently swirl the vaccine before withdrawing subsequent doses.
- 5. Examine the vaccine. It should be white to off-white in color and may contain white particles. Do not use if liquid contains other particulate matter or is discolored.
- 6. Using a new, sterile alcohol prep pad, cleanse the stopper of the multidose vaccine vial.
- 7. Choose the correct equipment, including the correct needle size.
- 8. Withdraw 0.5 mL of vaccine into the syringe. + Ensure the prepared syringe is not cold to the touch.
- 9. Bring the dose of vaccine from the designated preparation area immediately to the treatment area for administration.

How to Thaw and Prepare the Pfizer Vaccine

https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/index.html

How to Thaw the Vaccine

- Vaccine may be thawed in the refrigerator or at room temperature.
- Refrigerator: Between 2°C and 8°C (36°F and 46°F)
 - o 25 to 195 vials may take 2 to 3 hours to thaw in the refrigerator.
 - o Fewer number of vials will take less time.
- Room temperature: Up to 25°C (77°F) between 30 minutes and 2 hours
 - Vials at room temperature must be mixed within 2 hours or returned to the refrigerator.
- Do NOT refreeze thawed vaccine.

How to Prepare the Vaccine

- 1. Ensure you have an adequate number of people ready to receive the vaccine before preparing it.
- 2. Follow aseptic technique. Perform hand hygiene before vaccine preparation, between recipients, when changing gloves (if worn), and any time hands become soiled.*

^{*}Gloves are not required unless the person administering the vaccine is likely to come in contact with potentially infectious body fluids or has open lesions on the hands. If worn, perform hand hygiene and change gloves between recipients.

[†]Changing needles between drawing vaccine from a vial and injecting it into a recipient is not necessary unless the needle has been damaged or contaminated.

- 3. Remove vaccine from the freezer or refrigerator. Allow vaccine to come to room temperature. Vials can be held at room temperature for up to 2 hours before mixing. After 2 hours, return unmixed vials to the refrigerator.
- 4. Before mixing, check the expiration dates of the vaccine and diluent. NEVER use expired vaccine or
- 5. With the vaccine at room temperature, gently invert the vial 10 times. Do not shake the vial. If the vial is shaken, discard the vaccine. The vaccine is white to off-white in color and may contain opaque particles. Do not use if liquid is discolored.
- 6. Using a new, sterile alcohol prep pad for each vial, wipe off the stoppers of the diluent and vaccine vials.
- 7. Using a 21-gauge (or narrower) needle, withdraw 1.8 mL of 0.9% sodium chloride (normal saline, preservative-free) into a mixing syringe. After use, discard diluent vial and any remaining diluent.
 - o Do NOT use or save the remaining vaccine diluent to mix additional vaccine or for other uses.
 - Do NOT use bacteriostatic normal saline or other diluents to mix the vaccine.
- 8. Inject 1.8 mL 0.9% sodium chloride (normal saline, preservative-free) diluent into the vaccine vial.
- 9. Using the mixing syringe, remove 1.8 mL of air from the vaccine vial to equalize the pressure in the vaccine vial.
- 10. Gently invert the vial containing vaccine and diluent 10 times. The vaccine will be off-white in color. Do not use if discolored or contains particulate matter. Do not shake. If the vial is shaken, discard the vaccine.
- 11. Note the date and time the vaccine was mixed on the vial.
- 12. Keep mixed vaccine between 2°C and 25°C (36°F and 77°F) and administer within 6 hours. Discard any unused vaccine after 6 hours. Do not return to freezer storage.
- 13. Choose the correct equipment, including the correct syringe and needle size.
- 14. Cleanse the stopper on the vial of mixed vaccine with a new, sterile alcohol prep pad. Withdraw 0.3 mL of mixed vaccine into the syringe. Ensure the prepared syringe is not cold to the touch.
- 15. Remove any air bubbles with the needle still in the vial to avoid loss of vaccine. Use the same needle⁺ to withdraw and administer the vaccine, unless contaminated or damaged.
- 16. Bring the dose of vaccine from the designated preparation area immediately to the treatment area for administration.

*Gloves are not required unless the person administering the vaccine is likely to come in contact with potentially infectious body fluids or has open lesions on the hands. If worn, perform hand hygiene and change gloves between recipients.

[†]Changing needles between drawing vaccine from a vial and injecting it into a recipient is not necessary unless the needle has been damaged or contaminated.

How To Prepare the J&J Janssen Vaccine

https://www.cdc.gov/vaccines/covid-19/info-by-product/janssen/downloads/Janssen-Prep-and-Admin-Summary.pdf

- 1. Follow aseptic technique. Perform hand hygiene before vaccine preparation, between patients, when changing gloves (if worn), and any time hands become soiled.*
- 2. Unpunctured vials: Check the expiration date by:
 - Scan the QR code on the outer carton, or

- o Call the manufacturer (1-800-565-4008,) or
- Go to https://vaxcheck.jnj/
- Use CDC's expiration date tracker to document expiration date changes.
- o Do not discard vaccine until ensuring the expiration date has passed.

As the expiration date approaches, check the expiration date again using the same process. Never use expired vaccine.

Punctured vials: Check the beyond-use time. Never use vaccine after the beyond-use time.

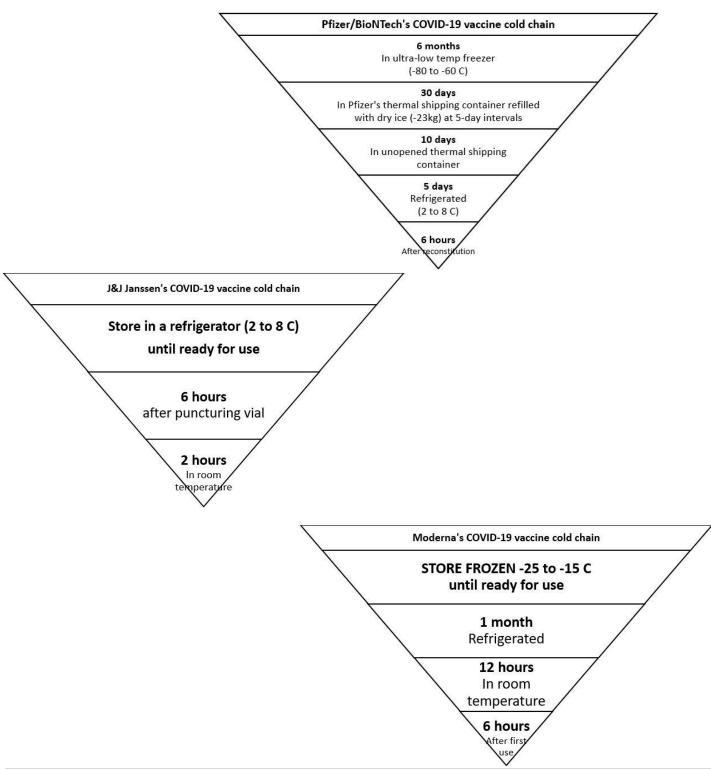
- 3. With the vial upright, gently swirl the vaccine for 10 seconds. Do NOT shake. If the vial is shaken, contact the manufacturer. Note: Gently swirl the vaccine before withdrawing subsequent doses.
- 4. Examine the vaccine. It should be colorless to slightly yellow, clear to very opalescent suspension. Do not use if liquid contains particulate matter or is discolored.
- 5. Using a new, sterile alcohol prep pad, cleanse the stopper of the multidose vaccine vial.
- 6. Choose the correct equipment, including the correct needle size. Use a new, sterile needle and syringe for each injection.
- 7. Ensure the needle and syringe are secured tightly together. Withdraw 0.5 mL of vaccine into the syringe.†
 - Regardless of the type of syringe used, ensure the amount of vaccine in the syringe equals
 - o If the amount of vaccine remaining in the vial cannot provide a full 0.5 mL dose, discard the vial and contents.
 - o Do not combine vaccine from multiple vials to obtain a dose.
- 8. Note the date and time the vial was first punctured. Keep the vaccine between 2°C and 8°C (36°F and 46°F) for up to 6 hours or at room temperature (up to 25°C or 77°F) for 2 hours. Discard any unused vaccine if not used within these timeframes.

†Changing needles between drawing vaccine from a vial and injecting it into a recipient is not necessary unless the needle has been damaged or contaminated.

^{*}Gloves are not required unless the person administering the vaccine is likely to come in contact with potentially infectious body fluids or has open lesions on the hands. If worn, perform hand hygiene and change gloves between patients.

5.6. Vaccine freezing and thawing guidelines

The following infographics show the amount of time each vial can be held at each stage.



6.4. Procedures for administering vaccinations



- Perform Hand hygiene for 15-20 sec. Gloves are not required for IM injections per CDC/ACIP/OSHA
- Position patient and self ergonomically. Have patient relax arm on their lap. Position yourself parallel to the patients arm to align your back
- Have patient roll up sleeve all the way to the shoulder to expose injection site
- Palpate the acromion process (bony tip of shoulder). Mark it with your pinky or ring finger depending on whether you are using a 2 or 3 fingerbreadth measurement
- Measure 2-3 fingerbreadths directly below the acromion process
- Form a V shape with your thumb and index finger as shown above
- Mark injection site by measuring from your web of thumb and middle of your index finger
- Avoid the top 2/3 of the deltoid which is where the bursa and joint space is to prevent shoulder injury

Administering Pfizer, Moderna, and J&J Janssen Vaccine

All three vaccines have the same instructions for administration.

https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/index.html https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/index.html https://www.cdc.gov/vaccines/covid-19/info-by-product/janssen/index.html

- 1. Assess recipient status:
 - Screen for contraindications and precautions.
 - Review vaccination history.
 - Review medical considerations.
- 2. Bring the dose of vaccine from the designated preparation area immediately to the patient treatment area for administration.
- 3. Ensure staff has the correct PPE before administering vaccines and implement policies for the use of face coverings for vaccine recipients older than 2 years of age (if tolerated). Note: gloves are not required for administering vaccines but some staff prefer to use them.
- 4. Ensure that your pre-filled syringe has an appropriately sized needle for the designated recipient⁺, then administer the vaccine immediately by intramuscular (IM) injection in the deltoid muscle.
- 5. Observe recipients after vaccination for an immediate adverse reaction:
 - **30 minutes**: Persons with a history of an immediate allergic reaction of any severity to a vaccine or injectable therapy and persons with a history of anaphylaxis due to any cause
 - **15 minutes**: All other persons

⁺Changing needles between drawing vaccine from a vial and injecting it into a recipient is not necessary unless the needle has been damaged or contaminated. Larger individuals will require a longer needle, as seen below.

Needle Size Recommendations				
MALE	FEMALE	NEEDLE SIZE		
А	dults≥age 18 yrs.			
Less than 130 Lbs	Less than 130 Lbs	5/8- 1 inch		
130- 150 Lbs	130-150 Lbs	1 inch		
153-260 Lbs	153- 200 Lbs	1- 1.5 inches		
260 + Lbs	200 + Lbs	1.5 inches		

6.5. Procedures for monitoring people following the vaccination

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html

Observation period following COVID-19 vaccination

CDC currently recommends that persons without contraindications to vaccination who receive an mRNA COVID-19 vaccine be observed after vaccination for the following time periods:

- 30 minutes: Persons with a history of an immediate allergic reaction of any severity to a vaccine or injectable therapy and persons with a history of anaphylaxis due to any cause.
- 15 minutes: All other persons

6.6. Procedures for filling out vaccine cards



People will receive a vaccination record card, shown below. Vaccination site staff should fill out the vaccine manufacturer, lot number, date of first dose, and date the second dose is due. Encourage people to enroll in VaxText, a free text messaging to receive COVID-19 vaccine second dose reminders: VaxTextSM COVID-19 Vaccination Second-Dose Reminder. If you do not have ample supply of vaccination record cards, you may need to make additional photocopies.

6.7. Considerations when setting a date for dose 2 for Pfizer and Moderna

6.7.a. Setting a date for dose 2 - Pfizer

https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/index.html

Persons age 12 years and older should receive 2 doses at least 21 days apart. Range: 17-42 days

- Second doses administered up to 4 days before the recommended date (17 or more days after first dose) are considered valid. However, doses administered earlier do not need to be repeated.
- Second doses should be administered as close to the recommended interval as possible.
 - Do not use the grace period to schedule appointments for the second dose.
- There is no maximum interval between the first and second dose.

6.7.b. Setting a date for dose 2 - Moderna

https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/index.html

Persons age 18 years and older should receive 2 doses at least 28 days apart. Range: 24-42 days

- Second doses administered up to 4 days before the recommended date (24 or more days after first dose) are considered valid. However, doses administered earlier do not need to be repeated.
- Second doses should be administered as close to the recommended interval as possible.

- o Do not use the grace period to schedule appointments for the second dose.
- There is no maximum interval between the first and second dose.

6.8. For more information about vaccination procedures

- OHSU training
- CDC training Moderna
- <u>CDC training Pfizer</u>
- CDC training J&J Janssen
- How to thaw, prepare, and administer Moderna
- How to thaw, prepare and administer J&J Janssen
- How to thaw, prepare, and administer Pfizer
- Pfizer Vaccine preparation infographic
- Managing anaphylaxis
- Clinical considerations

6.9. Materials you might find useful about vaccination procedures

- Pfizer Standing Orders
- Moderna Standing Orders
- J&J Janssen Standing Orders
- Transport temperature log

6.10. Coding for services related to COVID-19 vaccines and immunization administration and counseling

This information comes from the American Academy of Pediatrics

The CPT Editorial Panel has developed several new SARS-CoV-2 vaccine product and immunization administration codes. The new CPT codes

- clinically distinguish each coronavirus vaccine product and the specific dose for better tracking, reporting, and analysis
- allow for unique CPT vaccine administration codes for each vaccine product
 - o This includes unique codes for a 1st dose of a single product and a 2nd dose

This level of specificity is a first for vaccine administration codes, and offers the ability to track each vaccine dose, even when the vaccine product is not reported (eg, when the vaccine may be given to the patient for free). The CPT codes for the administration include:

- clinic expense costs of storage and ordering
- counseling provided to patients or caregivers on the date the vaccine is administered
- administering the vaccine
- updating the electronic health record and the vaccine registry

Note you will not report the immunization administration codes (90460-90461, 90471-90474) when administering a Coronavirus vaccine.

		CPT Codes				
Vaccine Product Information	Vaccine	Product	1st Dose	2 nd Dose	3 rd Dose	Patient Age
	Manufacturer		Admin	Admin	Admin	
Severe acute respiratory syndrome	Pfizer-BioNTech	91300	0001A	0002A	0003A	≥12 years
coronavirus 2 (SARS-CoV-2) (Coronavirus						
disease [COVID-19]) vaccine, mRNA-LNP,						
spike protein, PF, 30 mcg/ 0.3mL dosage,						
diluent reconstituted, for IM use						
SARS-CoV-2 (Coronavirus disease	Moderna	91301	0011A	0012A	0013A	≥18 years
[COVID-19]) vaccine, mRNA-LNP, spike						
protein, PF , 100 mcg/0.5mL dosage, for						
IM use						
SARS-CoV-2 (coronavirus disease [COVID-	Janssen	91303	0031A	N/A	N/A	≥18 years
19]) vaccine, DNA, spike protein,						
adenovirus type 26 (Ad26) vector,						
preservative free, 5x1010viral						
particles/0.5mL dosage, for IM use						

Vaccine Counseling Coding

Vaccine Counseling with No Administration

There may be occasions when a patient or parent presents to their medical home for vaccine counseling, particularly for the COVID-19 vaccine. Increasing vaccine hesitancy surrounding this vaccine may be greater and some older adolescents may seek out information on their own. There are many mechanisms by which you can get information out to your patients, however, for those who opt for in-person (ie, in office or telehealth) individual counseling there are coding options. You should check with your payers for guidance on the most appropriate way to code as some have limitations on the use of Z codes with office-based E/M services (eg, 99212). Note, if you provide vaccine counseling on the day you also administer the vaccine to the patient you may not report counseling separately. Coding options include:

ICD-10-CM codes

Z71.89 Other specified counseling

Z28.21 Immunization not carried out because of patient refusal

Z28.82 Immunization not carried out because of caregiver refusal

CPT Options:

99201-99215 Office-based E/M service: based on time spent with the patient/caregiver.

99401-99404 Preventive Medicine Counseling: based on time spent counseling (Note this code is not listed as an approved telehealth service). May not be used for group counseling.

99411-99412 Preventive Medicine Group Counseling: Used for group visits when discussing vaccine safety

Coding Tips:

- You will not report a 90460, 90461, 90471—90474 with any COVID-19 vaccine administration code.
- Report only one vaccine administration code per COVID-19 injection
- If you see the patient for a significant and separately identifiable E/M service in addition to the COVID-19 vaccine, append modifier 25 to the E/M service. For example, you see a patient for a routine preventive medicine service (eg, 99394) and they decide to get the COVID-19 vaccine, report the 99394 and the appropriate product (as required) and the administration code only. Counseling is captured in the COVID-19 vaccine administration code.

Your ICD-10-CM code for COVID-19 vaccine administration is Z23

Patients with Private Insurance Coverage

Bill insurance using the appropriate CPT code as outlined in the coding guidance above. Some private payers appear to reject or deny claims if the product code (9130x) is listed on the claim. For these payers, send only the administration code (00xxA).

Patients without Coverage

Uninsured people receive COVID-19 vaccine through the CDC's COVID-19 Vaccination Program. Payment for vaccine administration is available directly from HRSA via the COVID-19 Uninsured Program Portal. You will be paid the current Medicare rate for COVID vaccine claims.

Participation in the CDC COVID-19 Vaccination Program requires the following steps:

- 1. Enrolling as a provider participant (through UnitedHealth Group and Optum ID), 2.
- 2. Checking patient eligibility
 - To do so, you must first upload a spreadsheet of patients for whom you would like to submit claims to the HRSA COVID-19 Uninsured website. Download a template for the spreadsheet Once you have uploaded this spreadsheet to the HRSA COVID website, it takes about 24 hours for the patients to be verified as self-pay and a temporary COVID-19 Uninsured ID will be provided.
- 3. Submitting patient information
 - You may use this "Uninsured ID" just like you would a child's insurance ID
- 4. Submitting claims
 - o Submit claims electronically to the COVID Fund using your typical claims submission process.
- 5. Receiving payment via direct deposit.

Providers who participate in the COVID-19 Vaccination Program must confirm that the patient is uninsured and agree not to balance bill recipients. Providers should refer to their local public health jurisdiction for information on enrolling in the program.

