





Immunization Program Provider Update:02/18/2022

Merideth Plumpton, RN - Nurse Program Coordinator

Meghan Knowles, MS - Provider Communication and Training Coordinator



Agenda - 02/18/2022

Slides and recording will be posted by end of the day at www.healthvermont.gov/COVID19-vaccine-healthpros#resources

6 months through 4 years pause and continued planning

ACIP meeting from 02/04 Updates

- Immunocompromised
- Janssen
- Antibody products
- Revaccination

General COVID-19 vaccine updates and reminders

- Mailings will go out next week
- New Pfizer temperature monitoring
- Single dose presentation

Vermont Vaccine Program Updates

- 2022 Vaccine Management Plan (Vaccine Storage and Handling SOP)
- Pneumococcal vaccine updates (PCV15, PCV20)
- 2022/2023 Flu season

Contact Information

- Ordering, vaccine storage and handling, vaccinespecific information:
 - AHS.VDHImmunizationProgram@vermont.gov
- Immunization registry and reporting questions:
 IMR@vermont.gov
- COVID-19 Vaccine Distribution Team: AHS.VDHCovidVaxDistribution@vermont.gov
- Program updates available on the Vaccine Information for Health Care Professionals Page: www.healthvermont.gov/disease-control/immunization-providers#vvpupdate

COVID-19 Vaccine for 6month through 4 years – PAUSE

COVID-19 vaccine for those 6 months through 4 years - Pause

"Pfizer-BioNTech asked for the delay after the companies discovered that the Omicron wave had led to a far higher rate of infection than they had previously recorded among young volunteers in their clinical trial. The new data underscored that the Omicron variant was better than the earlier Delta variant at evading the vaccine's protection, and it showed that two doses, which had already fallen short by another measure, were not effective enough.

As a result, the companies and the F.D.A. agreed to wait for the results from a third dose, which are expected in early April."

F.D.A. Delays Review of Pfizer's Covid Vaccine for Children Under 5 - The New York Times (nytimes.com)

See Pfizer's official 02/11 statement here:

www.businesswire.com/news/home/20220211005483/en/Pfizer-and-BioNTech-Provide-Update-on-Rolling-Submission-for-Emergency-Use-Authorization-of-Their-COVID-19-Vaccine-in-Children-6-Months-Through-4-Years-of-Age

COVID-19 Vaccine for those 6 months through 4 years-Ordering Guidance (Maroon cap)

- Orders placed last week for the new Pfizer COVID-19 vaccine product (maroon top) for ages 6 months – 4 years have been cancelled. Pfizer has postponed its FDA application for this age group pending further review.
 - Practices will be notified when this product becomes available to order again (prior orders will need to be re-submitted in VIMS)
 - Please communicate any planned changes to your intentions to vaccinate this
 age group to the Immunization Program/Distribution team (planning is ongoing to
 ensure regional coverage in vaccine availability and distribution of limited
 allocation)

COVID-19 vaccine for those 6 months through 4 years - Vermont implementation Plan

- ~26,000 total patients in this age group
- Medical homes will be the primary vaccinators
 - Pharmacies can only vaccinate age 3 and older, and few are participating for these ages
 - Community clinics are going to be very limited
 - Offices of Local Health will focus on vaccinating WIC participants and families and will conduct equity clinics. WIC families accounts for ~8,000 individuals in this age range.
 - See 02.08.2022 memo: still relevant with an extended implementation date <u>www.healthvermont.gov/sites/default/files/documents/pdf/HS-IZ-Memo-02.07.22-Provider-Preparation-6m-4y-COVID19-Vaccine.pdf</u>

Continuing to prepare...

We have been very impressed with the number of practices that ordered this vaccine and were preparing to serve this population.

- At least 39 facilities with clear interest in administering COVID-19 vaccine to 6 month to 4-year-olds. Of these, 30 are pediatric and 9 are family medicine facilities.
 - Approximately 21,000 kids age 6m-4 are associated with these 39 practices
 - We learned during conversations with office staff that most are ready to administer vaccine during
 in office appointments immediately, some are planning to do small clinics, and manyare
 anticipating a slow roll out.
- We are continuing to work through a geographic gap analysis and will continue to follow-up with practices.
- As you continue your own planning, please reach out to <u>AHS.VDHImmunizationProgram@vermont.gov</u> with any questions or concerns.

Continue to Normalize COVID-19 vaccination

- Demand for community clinics in Vermont continues to decline.
- There will be an increased reliance on the medical home moving forward, particularly for children.
- If your practice offers other pediatric vaccines, you should also offer COVID-19 vaccines.

The Immunization Program is continuing to work towards making the process as easy as possible

- We are developing a process which will allow COVID-19 orders to be placed at any point in the week with reduced COVID-19 reconciliation requirements (no longer weekly).
- Vaccine will continue to be available through depot transfers in whatever amount you need.

Information for Maroon Cap Product

Pfizer-BioNTech COVID-19 Vaccine Products

PRELIMINARY – SUBJECT TO CHANGE PENDING REGULATORY GUIDANCE AND AUTHORIZATION/APPROVAL; CDC DOCUMENT – SHARED FOR JURISDICTIONAL PLANNING PURPOSES ONLY

	Current P	roducts	Future Product
Age Indications ^a	12 years and older	5 through 11 years	6 months through 4 years ^d
Vial Cap Color and Label with Color Border	GRAY	ORANGE	MAROON
Preparation	Do Not Dilute	Dilute Before Use	Dilute Before Use
Amount of Diluent Needed per Vialb	Do Not Dilute	1.3 mL	2.2 mL
Dose Volume/Dose	0.3 mL/ 30 mcg	0.2 mL/ 10 mcg	0.2 mL/ 3 mcg
Doses per Vial	6 doses per vial	10 doses per vial (after dilution)	10 doses per vial (after dilution)
		Storage Conditions	
ULT Freezer (-90°C to -60°C)°	9 months	9 months	9 months
Freezer (-25°C to -15°C)	DO NOT STORE	DO NOT STORE	DO NOT STORE
Refrigerator (2°C to 8°C)	10 weeks	10 weeks	10 weeks
Room Temperature (8°C to 25°C)	12 hours prior to first puncture (including any thaw time)	12 hours prior to first puncture (including any thaw time)	12 hours prior to first puncture (including any thaw time)
After First Puncture (2°C to 25°C)	Discard after 12 hours	Discard after 12 hours	Discard after 12 hours

^a Use the appropriate product based on the age of the recipient.

b Diluent: Sterile 0.9% Sodium Chloride Injection, USP. Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent.

^c Regardless of storage condition, vaccines should not be used after 9 months from the date of manufacture printed on the vial and cartons.

d The vaccine is currently under emergency use authorization review by the Food and Drug Administration (FDA) for children 6 months through 4 years old.

Pfizer, 6mo – 4year, Maroon cap vaccine

- 100 dose minimum order from manufacturer
- Less than 100 doses will be available through the Depot
- Will ship on dry ice
 - Place in fridge upon receipt unless ultracold is available.
 - Can be stored for up to 10 weeks in refrigerated temperatures
- 2-3 dose series
 - 2 doses 21 days apart
 - Possible 3rd dose 2 months after 2nd dose
- Like other Pfizer products, the labeled information is unreliable. More will be presented on the future Immunization Program training. Pfizer manufacture training sessions will also have this information presented again as the approval nears.

Pfizer Training – will include Maroon cap information soon

Pfizer Vaccines US Medical Affairs hosts **frequent** Medical Updates & Immunization Site Training for All Healthcare Providers.

In addition to medical updates, sessions will focus on vaccine storage, handling, and administration of vaccines all vaccine formulations. These sessions will be updated to reflect new information and changes that evolve. Updates will be identified at the start of each session and explained during each presentation.

For a list of training sessions, including links and instructions for registration, visit the Pfizer training website

https://www.pfizermedicalinformation.com/en-us/medical-updates

ACIP Meeting 2/4/22 - Updates

Updated CDC guidance from 02/04 ACIP meeting

Summary of February 11, 2022 changes to the <u>Interim Clinical Considerations for Use of COVID-19 Vaccines | CDC</u>

- Updated guidance for moderately or severely immunocompromised people
 - Clarification of existing recommendation to receive a 3-dose mRNA vaccine primary series followed by a booster dose for a total of 4 doses
 - New guidance to shorten the interval between completion of the mRNA vaccine primary series and the booster dose to at least 3 months (instead of 5 months)
 - New guidance for those who received the Janssen COVID-19 Vaccine primary series to receive an additional
 dose and a booster dose, for a total of 3 doses to be up to date
- Updated guidance that it is no longer necessary to delay COVID-19 vaccination following receipt of monoclonal antibodies or convalescent plasma
- Updated guidance on receiving a booster dose if vaccinated outside the United States
- Updated contraindication and precaution section to include history of myocarditis or pericarditis after an mRNA COVID-19 vaccine as a precaution

COVID-19 Vaccination Schedule for People Who Are Moderately or Severely Immunocompromised

Vaccine	Dose a	nd I	nter	val									
Pfizer-	1st dose		2 nd			3rd						Boo	ster
BioNTech			dose	•		dos	se					dos	e*
(ages 5 years			(21 da	ays		(at l	east					(at le	ast 3
and older)			after			28 d	-					mont	
,			1st do	se)		afte						after	
						2nd	dose)					dose)
Moderna	1st dose			2 nd			3 rd						Booster
(ages 18 years				dose			dose						dose*
and older)				(28 days	6		(at lea	st					(at least 3
,				after			28 day	ys					months
				1 st dose)		after						after 3rd
							2nd do	ose)					dose)
Janssen	1st dose			Addition	nal					Booster			
(ages 18 years				dose†						dose*			
and older)				(at least						(at least 2			
and older				28 days after						months			
				1st dose)						after			
				1 0030)						additional			
										dose)			

^{*}Any COVID-19 vaccine can be used for the booster dose in people ages 18 years and older, though mRNA vaccines are preferred. For people ages 12–17 years, only Pfizer-BioNTech can be used. People ages 5–11 years should not receive a booster dose.

[†]Only Pfizer-BioNTech or Moderna COVID-19 Vaccine should be used

Janssen COVID-19 Vaccine

- A primary Janssen vaccine dose is recommended for people ages 18 years and older who are moderately or severely immunocompromised
- A second (additional) dose using an mRNA COVID-19 vaccine at least 4 weeks later.
- If Moderna COVID-19 vaccine is used for the second dose, administer a full dose, 100 mcg (0.5 ml).

www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19vaccines-us.html#appendix-b

Vermont Department of Health

Appendix B. Guidance for People who are Moderately or Severely Immunocompromised and Vaccinated with Janssen COVID-19 Vaccine

COVID-19 Vaccination History	And	Then	Next Dose Due
1 dose	The dose was Janssen COVID-19 Vaccine	Administer a second dose (an additional mRNA vaccine) at least 28 days after the 1st dose. • Pfizer: 0.3mL, or • Moderna 0.5mL	Administer a booster dose at least 2 months after the 2nd dose.* • Pfizer: 0.3mL, or • Moderna 0.25mL, or • Janssen: 0.5mL (mRNA is preferred over Janssen)
2 doses	Both doses are Janssen COVID-19 Vaccine	Administer a third dose (additional mRNA vaccine) at least 2 months after the 2nd dose. • Pfizer: 0.3mL, or • Moderna 0.5mL	Vaccination series complete; no additional vaccinations needed.
	1 dose of Janssen COVID-19 Vaccine and 1 dose of an mRNA COVID-19 Vaccine (given as booster dose, i.e., Pfizer 0.3mL or Moderna 0.25mL) ⁺	Administer a third dose (additional mRNA vaccine) at least 2 months after the 2nd dose. • Pfizer: 0.3mL, or • Moderna 0.5mL	Vaccination series complete; no additional vaccinations needed.
	1 dose of Janssen COVID-19 Vaccine and 1 dose of an mRNA COVID-19 Vaccine (given as additional dose, i.e., Pfizer 0.3mL or Moderna 0.5mL) ⁺	Administer a booster dose of any COVID-19 vaccine 2 months after the 2nd dose. • Pfizer: 0.3mL, or • Moderna 0.25mL, or • Janssen: 0.5mL (mRNA is preferred over Janssen)	Vaccination series complete; no additional vaccinations needed.

^{*}mRNA vaccines are preferred.

*When reviewing vaccination history, doses of the Moderna COVID-19 Vaccine received prior to February 7, 2022 should be considered to have been the booster dosage (0.25 mL; 50 mcg).

Description of moderate and severe immunocompromising conditions and treatment

Moderate and severe immunocompromising conditions and treatments include but are not limited to:

- Active treatment for solid tumor and hematologic malignancies
- Receipt of solid-organ transplant and taking immunosuppressive therapy
- Receipt of chimeric antigen receptor (CAR)-T-cell therapy or hematopoietic cell transplant (HCT) (within 2 years of transplantation or taking immunosuppression therapy)
- Moderate or severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Advanced or untreated HIV infection (people with HIV and CD4 cell counts <200/mm³, history of an AIDS-defining illness
 without immune reconstitution, or clinical manifestations of symptomatic HIV)
- Active treatment with high-dose corticosteroids (i.e., ≥20 mg prednisone or equivalent per day when administered for ≥2 weeks), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor necrosis factor (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory

Guidance for COVID-19 vaccination for people who are moderately or severely immunocompromised

Revaccination and administration outside general dosing guidance for immunocompromised

"On a case-by-case basis, providers of moderately or severely immunocompromised patients may administer mRNA COVID-19 vaccines outside of the FDA and CDC dosing intervals based on clinical judgement when the benefits of vaccination are deemed to outweigh the potential and unknown risks for the recipient. However, providers should not routinely administer additional doses of COVID-19 vaccine beyond those recommended in this guidance."

"A patient's clinical team is best positioned to determine the degree of immune compromise, need for revaccination, and appropriate timing of revaccination."

Interim Clinical Considerations Additional Considerations

General COVID Updates

Mailing from Immunization Program





Vermont Chapter

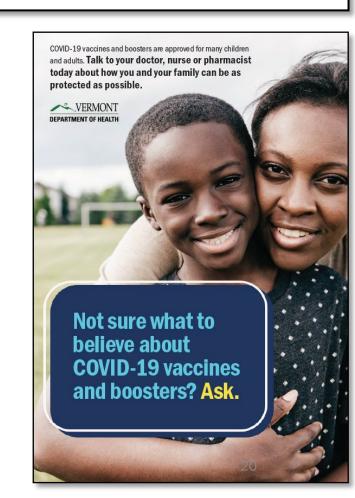
INCORPORATED IN VERMONT



What Families with Children Should Know About COVID-19 Vaccines

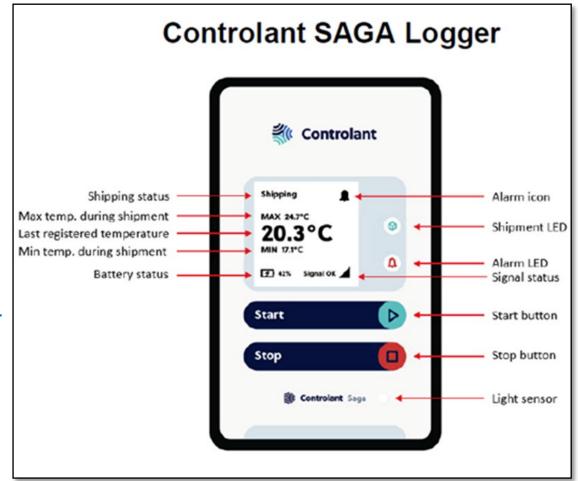
Every VAVP/VCVP enrolled office will receive a mailing NEXT week!

- One or two large posters for placement in your entrance or waiting room to every office. <u>COVID19-Ask</u> <u>Vaccine Poster 11x17 | VDH</u>
- A batch of handouts designed for parents and caregivers who may be hesitant for their child to receive the vaccine (VCVP enrolled only). <u>COVID19</u> <u>Vaccine in Children - Parent Handout | VDH</u>



New Data Logger on Pfizer direct shipments

Starting this week, Pfizer vaccine shippers will begin transitioning to an updated data logger from *Controlant*. This new device called "SAGA Logger" will provide improved performance for monitoring and reporting during shipment. For more information on this new device, please attend one of the many <u>training sessions offered by Pfizer</u>.



Single dose / prefilled

Pre-filled syringes/single dose vials will not be available for a long time.

- Logistically they are trying to make / package / distribute as much vaccine as possible
- Single dose vials would cut the manufacturing rate by more than half
- There are not enough materials to make what they need.

Single dose presentations are significantly more wasteful than multidose vials, in both vaccine waste, and material waste.

If you open a 10 dose vial and only use 3 doses (wasting 7 doses), the waste is similar to administering out of 10 single dose vials.

Please do not let concern over waste be a reason to not carry and administer COVID-19 vaccine to your patients.

AAP Grant Extension!



- Extension of monetary cap per practice up to \$10,000 (from \$5,000)
- Will apply to COVID-19 or Flu clinics held through the end of 2022
- http://www.aapvt.org/news/aapvt-chapter-still-accepting-grant-applications-flu-and-covid-19-vaccines
- If you would like to apply for the grant, please complete the application (either in word or pdf form) and email back to Birdie Pauley at BPauley@vtmd.org

V-Safe

www.cdc.gov/coro navirus/2019ncov/vaccines/saf ety/vsafe/printres ources.html



323388-AH

Add a Dependent in v-safe

You can add any dependent (family member, friend, or individual who relies on you for support) who is vaccinated in **v-safe.**

Children under age 16 years must be added to a parent or guardian's v-safe account. You can <u>add a dependent</u> to your existing account or <u>create a new account</u> if you don't have one yet. All **v-safe** communications will be sent to the parent's or guardian's smartphone.

Creating an account to add a dependent does not require that you enter your own vaccination information or complete health check-ins for yourself.

COVID-19 Vaccine VAERS Reminder



From VAERS:

The reporting requirements for COVID-19 vaccines are the same for those authorized under emergency use or fully approved. Healthcare providers who administer COVID-19 vaccines are **required by law** to report the following to VAERS:

- •Vaccine administration errors, whether or not associated with an adverse event (AE).
 - If the incorrect mRNA COVID-19 vaccine product was inadvertently administered for a second dose in a 2-dose series, VAERS reporting **is** required.
 - If a different product from the primary series is inadvertently administered for the additional or booster (third dose), VAERS reporting is required.
 - VAERS reporting is not required for the following situations:
 - If a mixed series is given intentionally (e.g., due to hypersensitivity to a vaccine ingredient)
 - Mixing and matching of booster doses (as of October 21, 2021, mixing and matching of booster doses is allowed)

To view reporting requirements and submit a report go to:

https://vaers.hhs.gov/reportevent.html

Importance of Beyond Use Date

The Immunization Program has received reports of vaccine administration past the vaccine BUD. This may result in the need to revaccinate patients and reduces public confidence in vaccination.

- When you transfer vaccine to another office, clearly document the BUD of that vaccine so that the receiving practice is aware.
- When you are receiving vaccine as a transfer, or as direct shipment, clearly label the correct BUD in your unit so it is apparent to all staff.
- Assign an individual and a back-up to take responsibility for reviewing the BUD of vaccines.
 Remove vaccine from unit promptly and document in VIMS.
- If you have vaccine with a BUD that is about to expire, please notify the Immunization Program for guidance on potential transfers to another location.

COVID-19 Vaccine Expiration Date and BUD Guidance (healthvermont.gov)

Vermont Vaccine Program Updates

Updated 2022 Vaccine Management Plan

The updated **2022 Vaccine Management Plan** is posted in Section I of the <u>Vermont</u>

<u>Department of Health Vaccine Storage and</u>

<u>Handling</u> website and went out to all offices by e-mail on 02/11/2022.

Practices are required to review, print and complete the updated 2022 Vermont Vaccine Management Plan and have it available for review during the VCVP/VAVP compliance, COVID-19 compliance and S&H unannounced site visits.

If you have any questions, please contact the Immunization Program by e-mail:

<u>AHS.VDHImmunizationProgram@vermont.gov</u> or call 1-800-640-4374.



Vaccine Storage and Handling Standard Operating Procedures (SOP) (Revised February 2022)

Vermont Immunization Providers

This Vaccine Storage and Handling SOP is based on the CDC Vaccine Storage and Handling Toolkit and "You Call the Shots" webinars. It provides information for proper management of publicly-funded vaccine. Use of this template assures that vaccine is managed according to VCVP/VAVP and Vermont Immunization Program requirements. Post these guidelines near your storage unit where they can be easily accessed. All office staff should be aware of this plan.

Date Reviewed	Name & Credentials	Webinars Viewed

Pneumococcal Vaccine - Adult

<u>Use of 15-Valent Pneumococcal Conjugate Vaccine and 20-Valent Pneumococcal Conjugate Vaccine</u>

<u>Among U.S. Adults: Updated Recommendations of the Advisory Committee on Immunization Practices—</u>

<u>United States, 2022 | MMWR (cdc.gov)</u>

- Adults ages 19 through 64 years with certain underlying medical conditions or other risk factors who
 have not previously received a pneumococcal conjugate vaccine or whose previous vaccination history
 is unknown should receive either PCV20 or PCV15. If PCV15 is used, this should be followed by a dose
 of PPSV23.
- The new recommendations are summarized in Table 1 of the MMWR article.
- This vaccine will be available in your VIMS catalogue starting April 1st. The <u>Vaccine Availability Sheet</u> will be updated to reflect this change.
- A new <u>Pneumococcal Conjugate Vaccine Information Statement</u> (VIS) is available now.

2022/2023 Flu vaccine

- Practices will place flu orders on their own in the beginning of September, similar to last season.
- Flu vaccine has been available to all, regardless of age, the last couple of years. This
 was due to special funding through the CDC and concern over co-infection with
 COVID-19.
- In the 2022/2023 season the flu vaccine will once again be available only to those
 64 years and under.

Questions?

Immunization Communication

Vaccine Information for Health Care Professionals website: www.healthvermont.gov/covid-19/health-care-professionals/vaccine-information-health-care-professionals

- Now links all recent e-mail communications and ordering guidance for the week are available on the website.
- <u>Updates: <5 Vaccine Approval and Guidance for Immunocompromised 2.15.2022</u>
- <u>Current COVID-19 Ordering Guidance</u> E-mail sent early in the week from <u>AHS.VDHCovidVaxDistribution@vermont.gov</u> with Wednesday's ordering guidance.

Pfizer Training

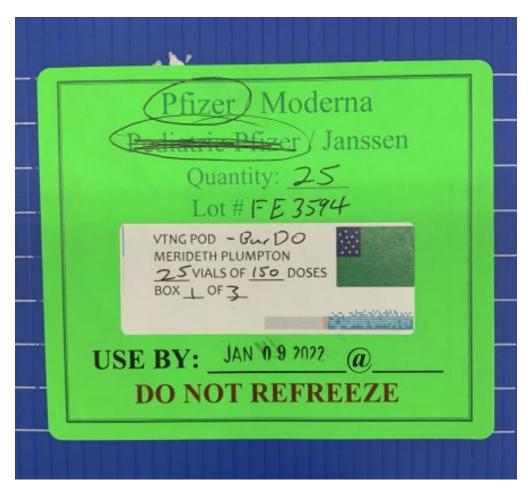
Pfizer Vaccines US Medical Affairs hosts **daily** Medical Updates & Immunization Site Training for All Healthcare Providers.

In addition to medical updates, sessions will focus on vaccine storage, handling, and administration of vaccines all three vaccine formulations: Adult Pfizer (purple cap, dilute), Adult Pfizer (gray cap, do not dilute), Pediatric Pfizer (orange cap, dilute)

These sessions will be updated to reflect new information and changes that evolve. Updates will be identified at the start of each session and explained during each presentation.

For a list of training sessions, including links and instructions for registration, visit the Pfizer training website - https://www.pfizermedicalinformation.com/en-us/medical-updates

Documentation with Depot Deliveries



Monitor at the following times Time vaccine was placed inside the vaccine carrier	TIME	Circle one	TEMPERATURE	INITIALS	ALARM DISPLAYED		
	0845	AM / PM	°C		Y / N		
At delivery location 1	to total	AM / PM	°C	-	Y / N		
At delivery location 2	17/19	AM / PM	°C		Y / N		
At delivery location 3		AM / PM	°C	and in column 2	Y / N		
At delivery location 4		AM / PM	°C		Y/N		
Must use vaccine b	Date	Time					
31 days (744 hours or 1 mo storage and transferred to	JAN 0 9 2022	0845					

Assessing patient need and clinic planning

- As your patients continue to get vaccinated at community clinics, utilize the IMR reporting tools to help inform outreach and vaccine need.
 - Patients who have NOT received any COVID-19 doses | VDH IMR:
 - Patients who have missed/are late for a second COVID-19 dose | VDH IMR:
 - Patients who HAVE received a COVID-19 dose | VDH IMR: