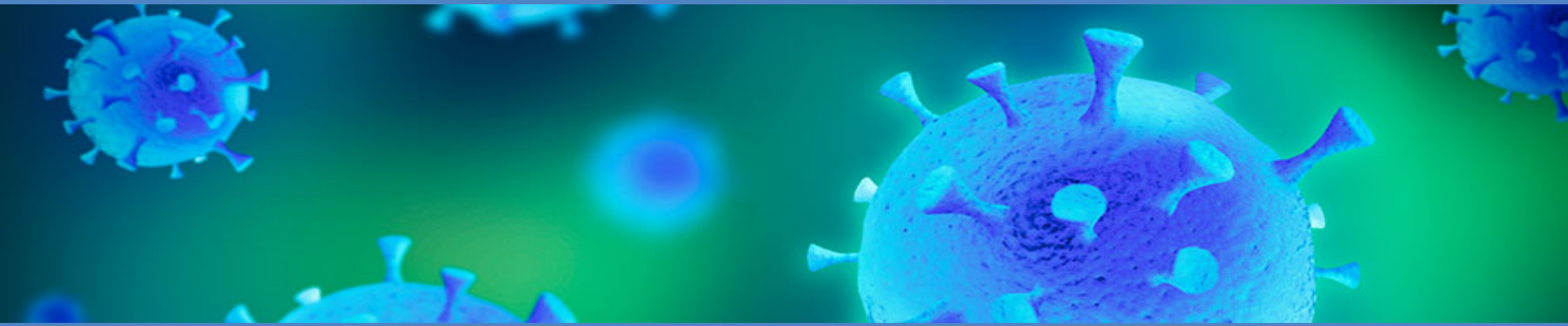
VCHIP / CHAMP / VDH COVID-19 UPDATES



Wendy Davis, MD FAAP - Senior Faculty, Vermont Child Health Improvement Program, UVM

Breena Holmes, MD FAAP – VCHIP Senior Faculty & Physician Advisor, MCH Division, VDH

March 3, 2021

Technology Notes

1) **All participants will be muted upon joining the call.**

2) **If you dialed in or out, unmute by pressing #6 to ask a question (and press *6 to mute).**

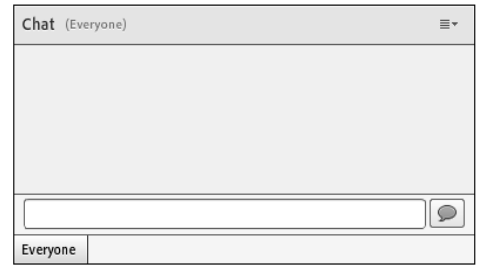
If you are having audio difficulties and are using your computer speakers, you may wish to dial in:

Call in number – 1-866-814-9555

Participant Code – 6266787790

Presenters: Please avoid the use of speakerphone and make sure your computer speaker is muted if you dialed in via phone.

3) To ask or respond to a question using the ***Chat*** box, type your question and click the  icon or press Enter to send.



Overview

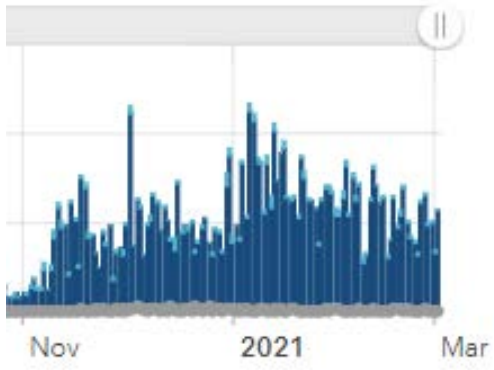
https://www.nytimes.com/2021/03/02/world/dolly-parton-moderna-vaccine-covid.html

- Celebrating Dolly Parton's generosity in funding vaccine development!
  - See the video @DollyParton: "Dolly gets a dose of her own medicine"
  - Sung to Jolene: *"Cuz once yer dead then that's a bit too late!"…* "don't be such a chicken-squat!"
- Reminder – weekly event schedule:
  - **VCHIP/CHAMP/VDH calls: M/W/F;** Gov. Media Briefings Tues/Fri; VMS call with VDH Commissioner Levine Thursday
- Situation, VDH, federal updates; Tuesday media briefing
- Practice Issues: ***Pregnant and Lactating Women*** *(Kelley McLean, MD – MFM, UVM MC)*
- Q & A/Discussion

[Please note: the COVID-19 situation continues to evolve very rapidly – so the information we're providing today may change quickly]

Situation update

New Cases	115
15,487 Total	
Currently Hospitalized	23
Hospitalized In ICU	5
Hospitalized Under Investigation	1
Percent Positive 7-day Avg.	1.4%
People Tested	332,411
Total Tests	1,083,198
Recovered	12,842
82.9% of Cases	
Deaths	207
1.3% of Cases	
Last Updated: 3/3/2021, 10:52:15 AM	

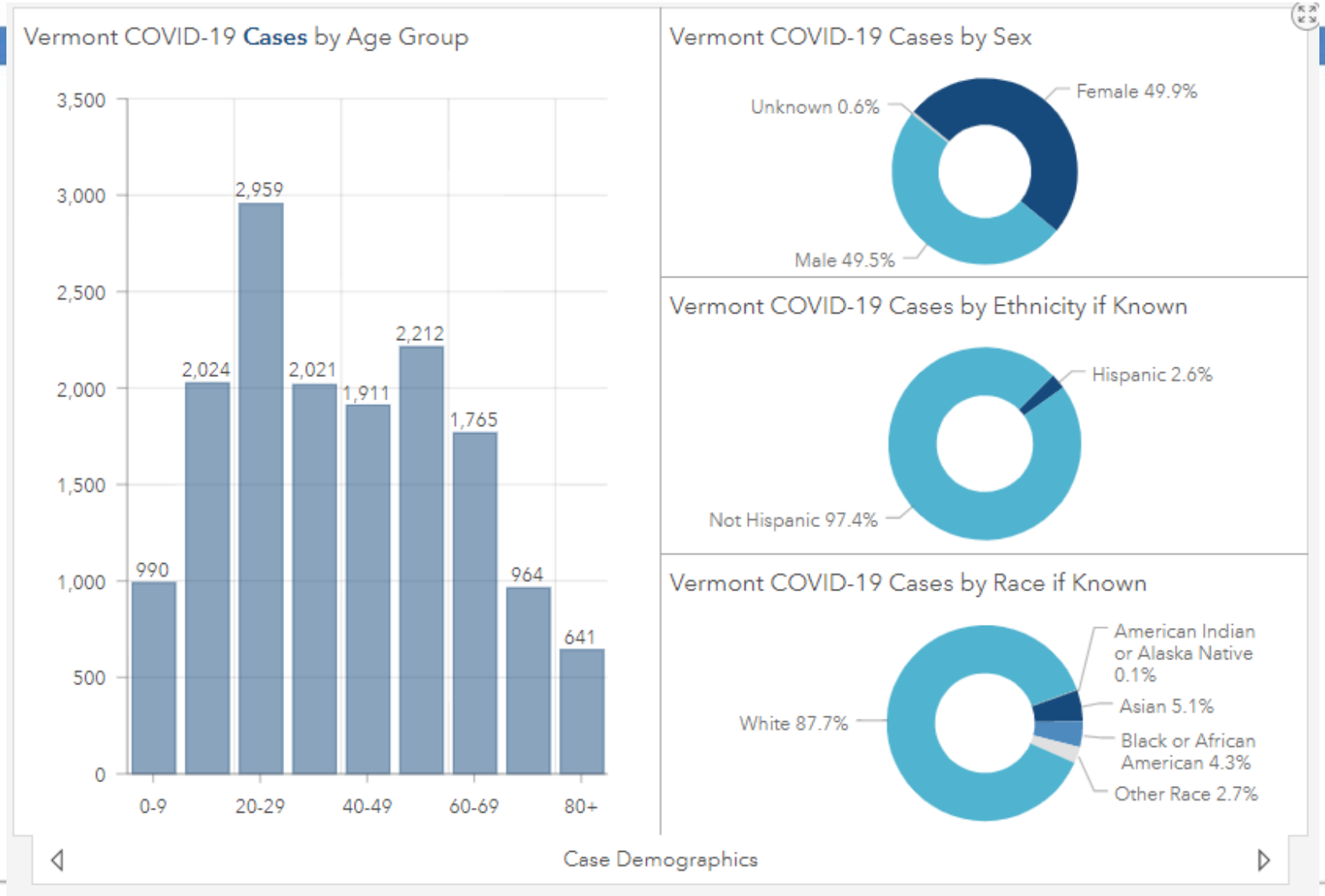


VT New Cases, Probables, Deaths

https://www.healthvermont.gov/covid-19/current-activity/vermont-dashboard

- U.S. **28.7 million+** cases; **515,710 deaths**
  - https://www.nytimes.com/interactive/2020/us/coronavirus-us-cases.html (updated 3/3/21)
  - 3/2/21**: 57,780 new cases; 1,306 d.; 46,388 hosp.**
  - Past week: average 65,468 cases/day (decrease of 19% from average 2 weeks earlier)
  - **2.5 million+ deaths worldwide; 114.7 million+ cases**)
- **COVID Tracking Project** – cease data coll. 3/7/21
- VDH **Weekly Data Summary**(2/26/21)
  - **Weekly Spotlight Topic – *Cases among Black, Indigenous and People of Color (BIPOC)***
    - Disproportionate # BIPOC w/COVID-19 in VT. Focus on 1,742 VT resident cases who are Asian, African American or Black, American Indian or Alaskan Native, Hispanic or race other than white.
  - Find previous summaries at: https://www.healthvermont.gov/covid-19/current-activity/weekly-data-summary

Situation update



https://www.healthvermont.gov/covid-19/current-activity/vermont-dashboard

COVID-19 Cases in VT K-12 Learning Communities (While Infectious)

- COVID-19 Cases in Vermont K-12 Learning Communities While Infectious
  - https://www.healthvermont.gov/sites/default/files/documents/pdf/COVID19-Transmission-Schools.pdf
  - Table updated **Tuesday & Friday** w/data through previous Sunday & Wednesday.

February 28, 2021

Cases in Vermont K-12 Learning Communities While Infectious

Learning Community Schools with less than 25 students are reported in the "Total for all Suppressed Schools" row at the end of the table.	Cases Reported In the Past 7 Days	Total Cases
TOTAL FOR ALL SCHOOLS	20	657

February 24, 2021

Cases in Vermont K-12 Learning Communities While Infectious

Learning Community Schools with less than 25 students are reported in the "Total for all Suppressed Schools" row at the end of the table.	Cases Reported In the Past 7 Days	Total Cases
TOTAL FOR ALL SCHOOLS	33	649

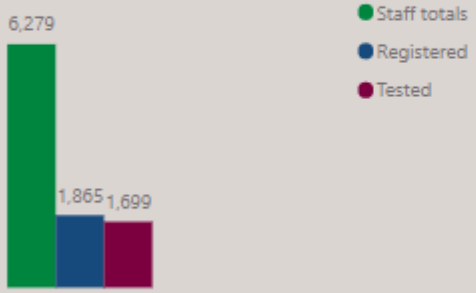
- VT College & University dashboards:
  - **UVM update: effective March 1, all students to be tested 2X/week** (3d. In between; reeval 3/13)
  - Violations of Green and Gold Promise, except for 1st missed test, to be reviewed for suspension in accordance with UVM policy (on-campus res. students will have 48 hours from a final conduct decision of suspension to vacate their residential hall and leave campus); thru 3/31 for now.

AOE School Staff Testing Dashboard

School Staff Testing: Weekly Summary

VERMONT

Summary



Week	Staff totals	Registered	Tested
Jan 31	6,279	1,865	1,699

Test Results

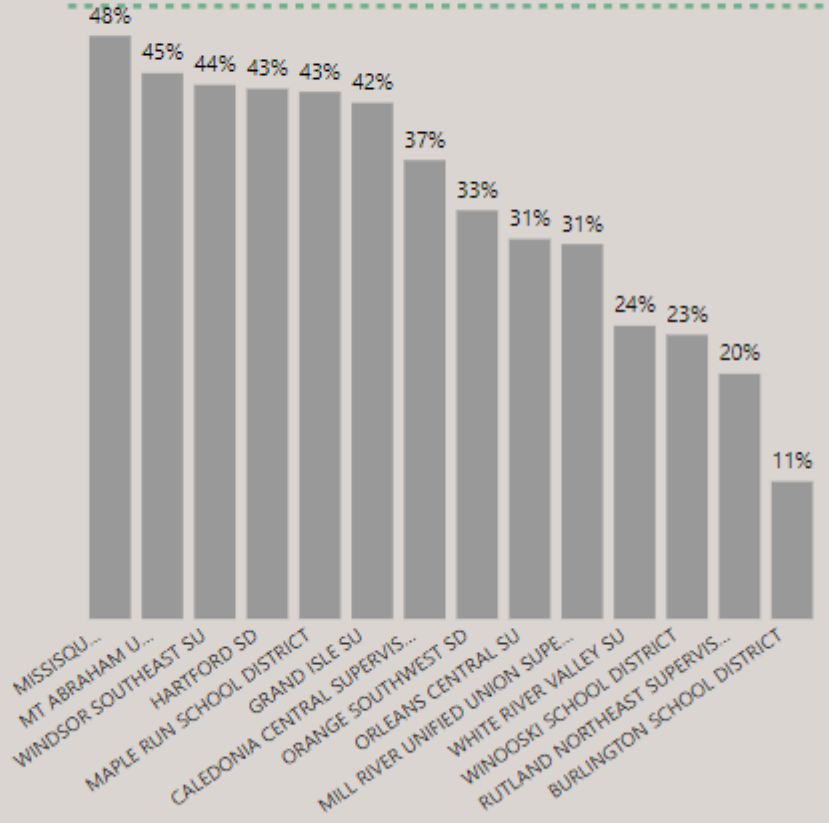
Negative	1,656
Inconclusive	16
Not Tested	9
Positive	2

% Positive
0.12%

Week	Inconclusive	Negative	Not Tested	Positive	Total
Jan 31	16	1,656	9	2	**1,683**

Select Testing Week: January 31, 2021

% Registered by SD/SU



SD/SU	% Registered
MISSISQUOI VALLEY SCHOOL DISTRICT	48%
MT ABRAHAM UNIFIED SCHOOL DISTRICT	45%
WINDSOR SOUTHEAST SU	44%
HARTFORD SD	43%
MAPLE RUN SCHOOL DISTRICT	43%
GRAND ISLE SU	42%
CALEDONIA CENTRAL SUPERVISORY UNION	37%
ORANGE SOUTHWEST SD	33%
ORLEANS CENTRAL SU	31%
MILL RIVER UNIFIED UNION SUPERVISORY UNION	31%
WHITE RIVER VALLEY SU	24%
WINOOSKI SCHOOL DISTRICT	23%
RUTLAND NORTHEAST SUPERVISORY UNION	20%
BURLINGTON SCHOOL DISTRICT	11%
Total	**30%**

Data source: Vermont Testing/Vaccine Registration System.
Updated 2/10/2021 8:23:10 AM

Week of Jan. 31; updated 2/10/21

https://education.vermont.gov/news/covid-19-guidance-vermont-schools/school-staff-covid19-surveillance-testing/school-staff-covid-19-surveillance-testing-weekly-summary

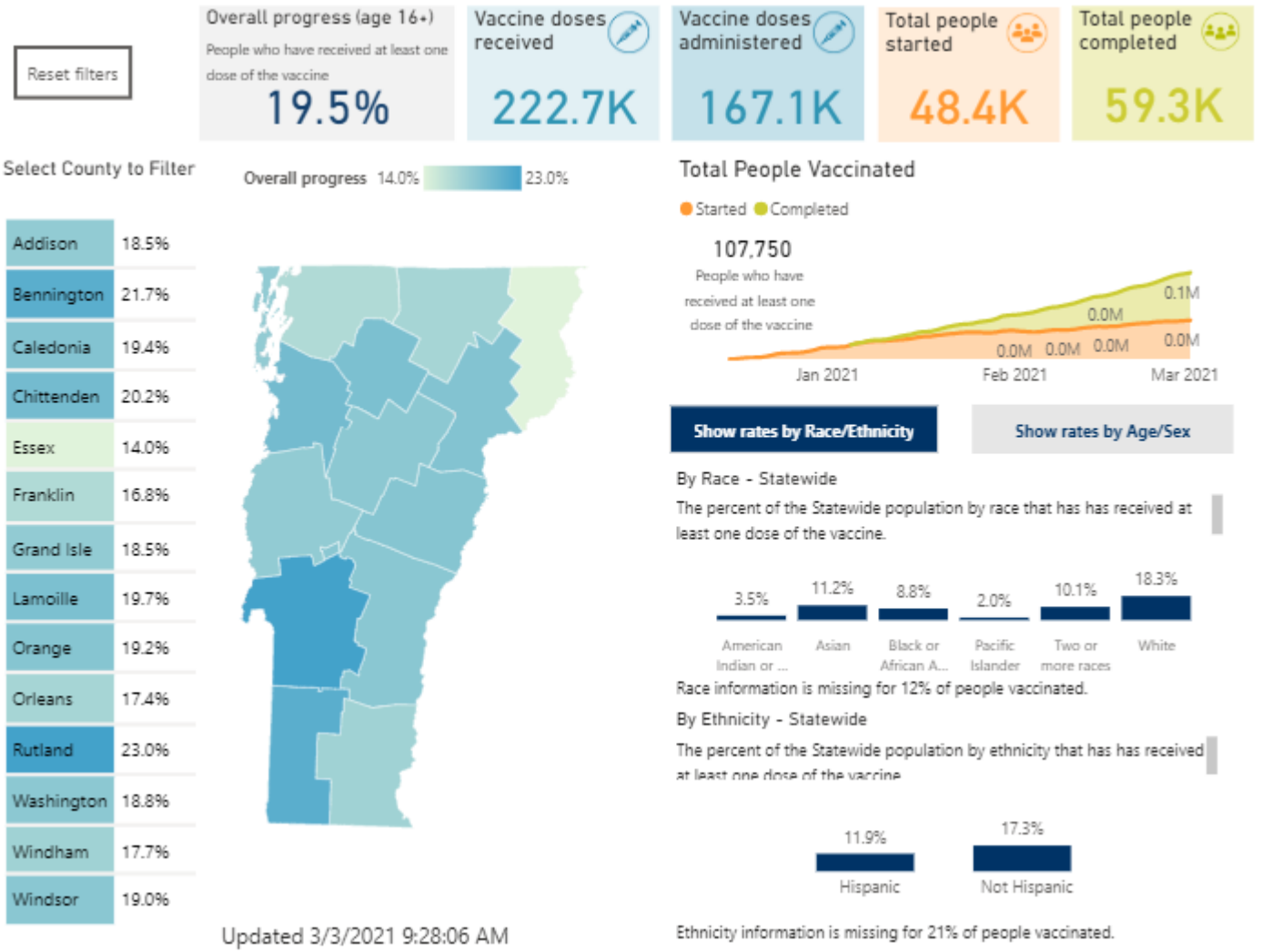
VERMONT DEPARTMENT OF HEALTH

VCHIP Vermont Child Health Improvement Program, University of Vermont Larner College of Medicine

VDH COVID-19 Vaccine Dashboard

- Daily updates Tuesday thru Saturday
- Data = counts reported by end previous day; subject to change.
- https://www.healthvermont.gov/covid-19/ vaccine/ covid-19-vaccine-dashboard

***NOTE* (2/17/21):** to align w/CDC reporting, # of doses rec'd. for VA & VNG were removed from # doses rec'd.; accounted for ~8,300 doses.



VDH COVID-19 Vaccine Registration & Sites

https://www.healthvermont.gov/covid-19/vaccine/getting-covid-19-vaccine

GETTING THE COVID-19 VACCINE

HEALTH DEPARTMENT APPOINTMENTS

KINNEY DRUGS APPOINTMENTS

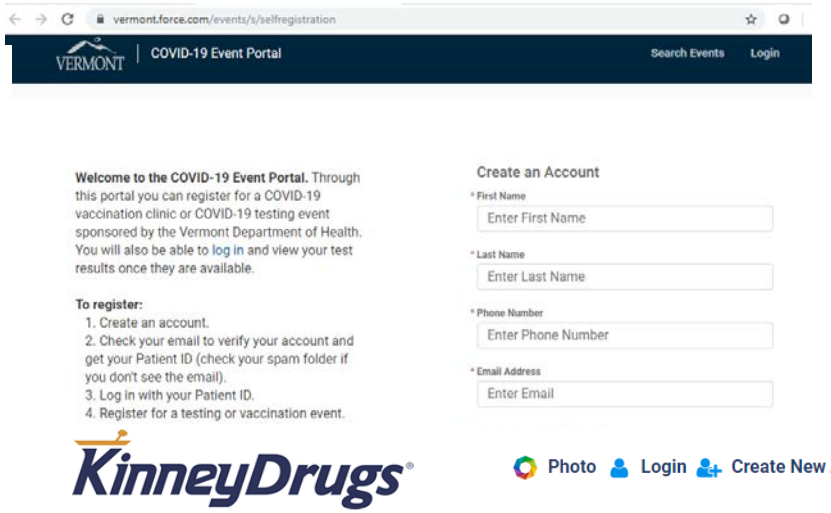
WALGREENS APPOINTMENTS

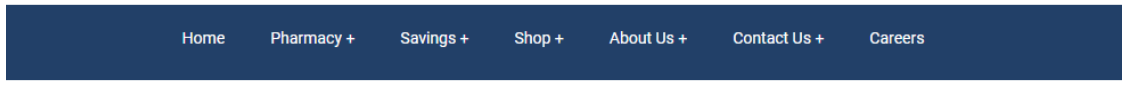
People age 65 years and older can make appointments now.
There are enough appointments for everyone who is eligible. Appointments are required. Clinics cannot accept walk-ins.

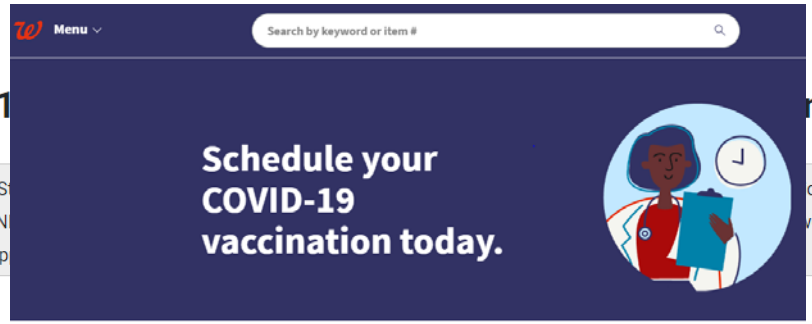
To make an appointment online with the Health Department:

1. Create an account (anyone can do this anytime!)
You may already have an account if you were tested for COVID-19 at a Health Department site.
2. Make an appointment when your age group is eligible to get the vaccine.

Can't make an appointment online or need help with an online appointment? Contact our call center at 855-722-7878.







VERMONT
DEPARTMENT OF HEALTH

March 3, 2021

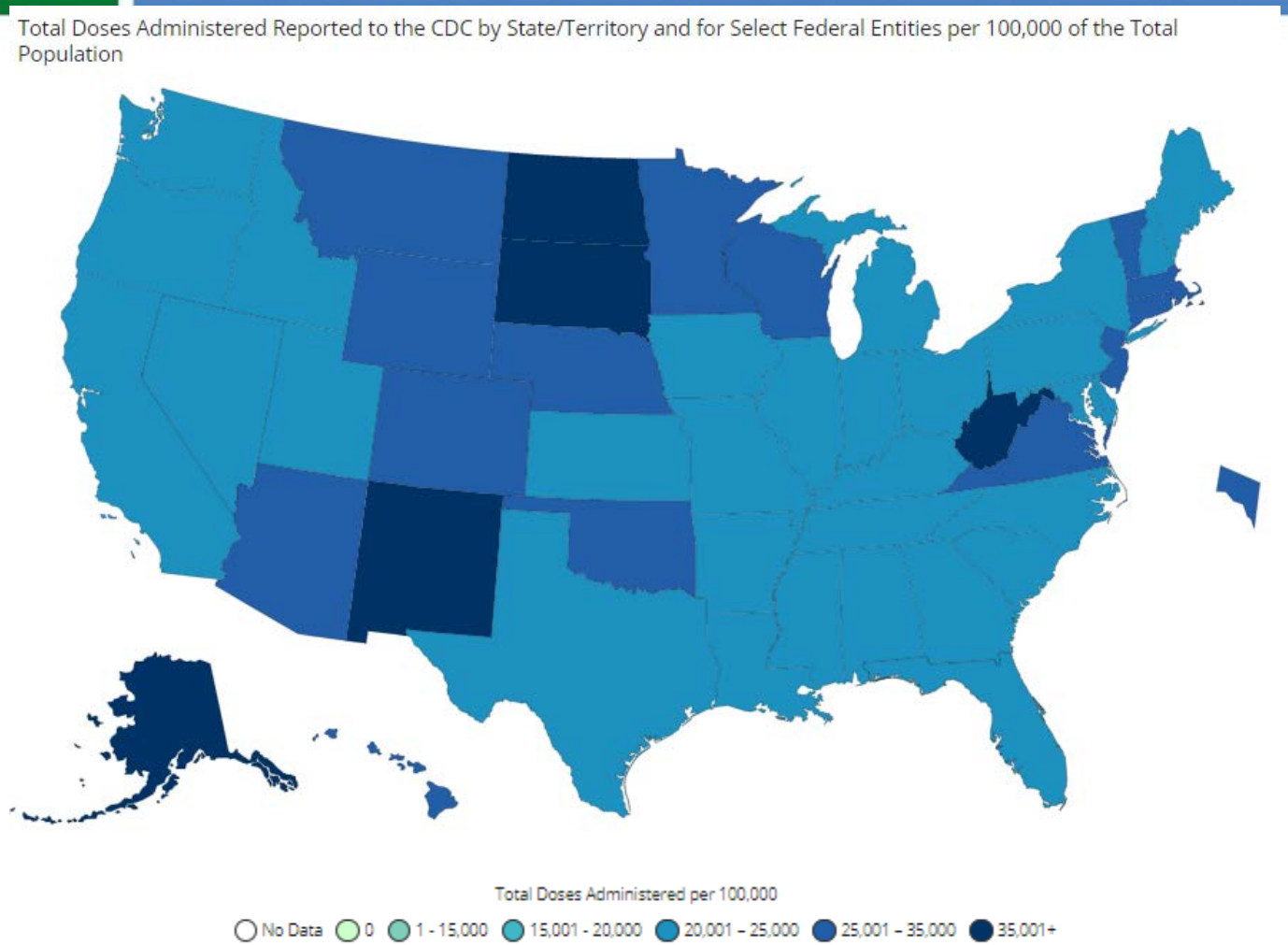
VDH COVID-19 Vaccine Registration & Sites (cont'd.)

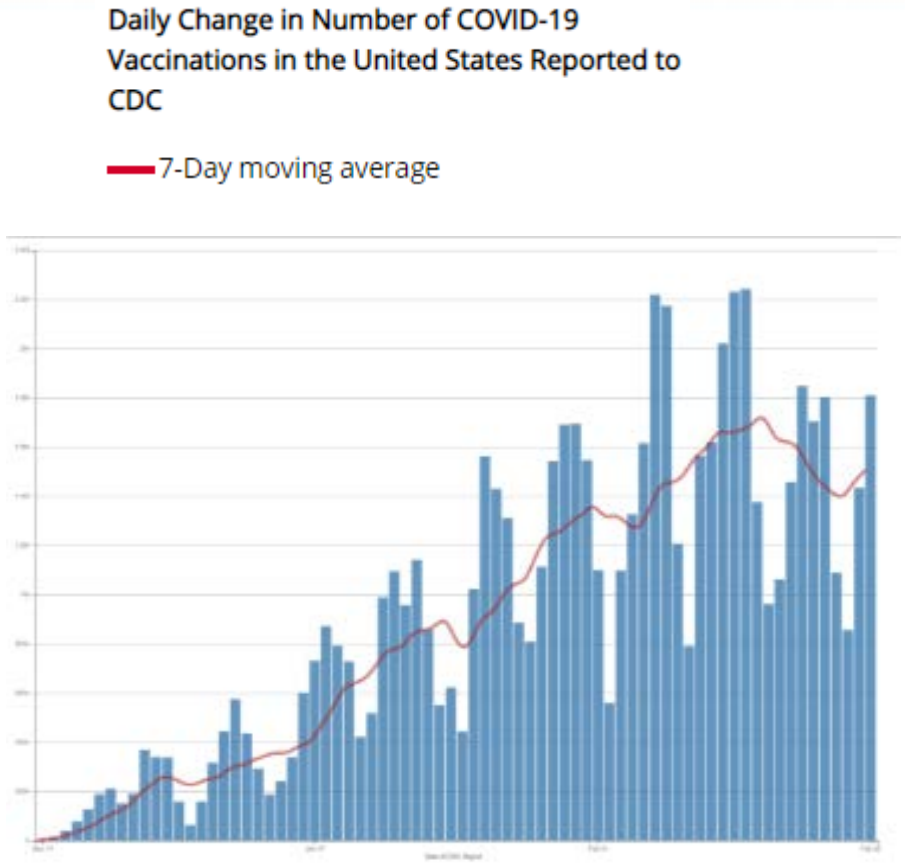
- Appointments from 3/3/21 – 5/22/21
  - **1,345 clinics** (health care, VDH POD – does not include pharmacies); **205,814** total appointments
  - VDH Local (District) Health Office sites; health care sites
- **Online (preferred)** and **phone** appointment scheduling:
  - 1-855-722-7878
  - *If you need to speak with someone in a language other than English, call this number, and then press 1.*
- **Call Center Hours:**
  - Monday-Friday, 8:15 a.m. – 5:30 p.m.
  - Saturday and Sunday, 10:00 a.m. – 3:00 p.m.

VDH Updated Vaccine Toolkit

- **Updated**: Eligibility-specific, “alert” messaging (currently 65+)
  - Social media posts; blog/newsletter; email; letter
- General, “evergreen” messaging about vaccines – includes new posts about preparing for vaccine eligibility, safety and efficacy of vaccines, and importance of getting vaccinated.
  - Social media posts
  - Blog/Newsletter
  - Posters (8.5”x11” and 11”x17”). Files for full-bleed posters for commercial printing are available upon request (available in multiple languages).
  - Vaccine fact sheet: “Things You Should Know About COVID-19 Vaccines.” (available in multiple languages).

From the CDC Vaccine Tracker



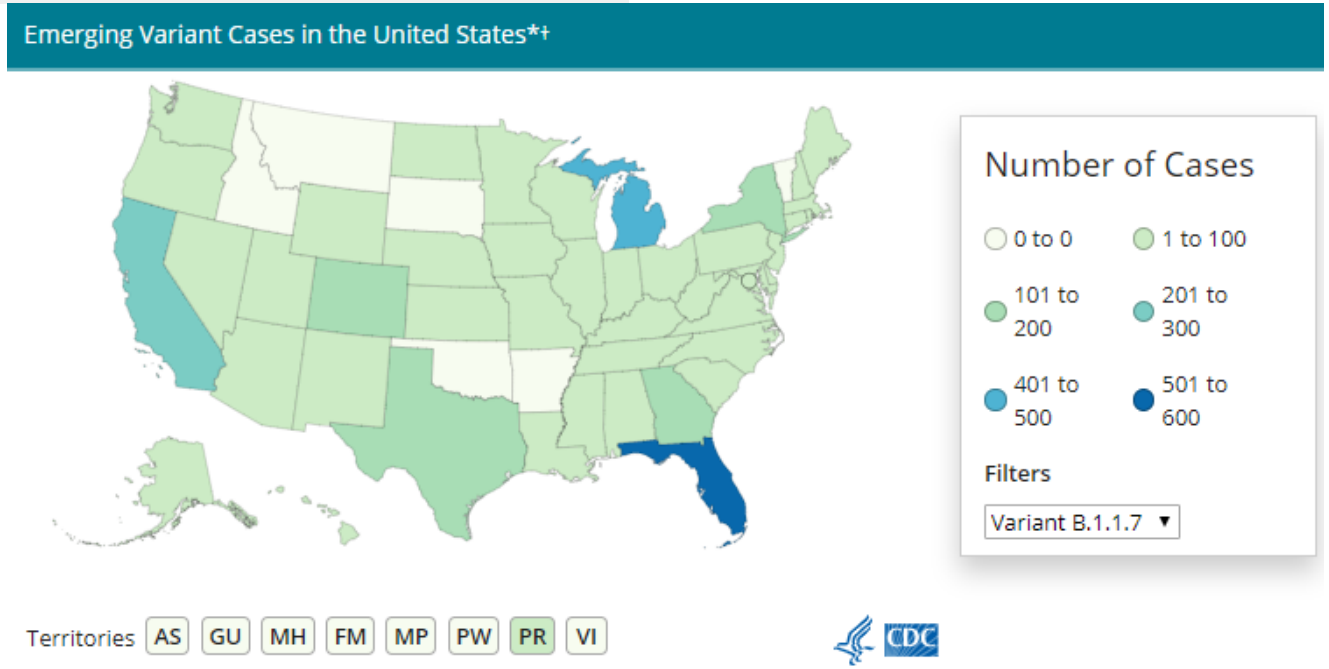


https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/index.html

https://covid.cdc.gov/covid-data-tracker/#vaccinations

From the CDC: U.S. COVID-19 Cases Caused by Variants

Variant	Reported Cases in US	Number of Jurisdictions Reporting
B.1.1.7	2506	46
B.1.351	65	17
P.1	10	5



https://www.cdc.gov/coronavirus/2019-ncov/transmission/variant-cases.html

VDH Update: Vaccine Implementation Advisory Committee

Met Friday, 2/26/21 – Agenda:

- Overview; Vermonters with developmental disabilities as a high risk health condition; current landscape; equity efforts; J & J vaccine; vaccine hesitancy & outreach; public comment
  - https://www.healthvermont.gov/covid-19/vaccine/about-covid-19-vaccines-vermont#conditions
- **High-risk health conditions in Phase 5:** current cancer; chronic kidney disease; COPD (incl. emphysema & chronic bronchitis; heart disease, incl. heart attack, heart failure, CHF, CAD, (angina, acute and chronic ischemic heart disease), cardiomyopathies, and pulmonary hypertension. Does NOT include high blood pressure.

(list cont'd. next slide)

VDH Update: Vaccine Implementation Advisory Committee

- **High-risk health conditions in Phase 5** (cont'd.): Immunocompromised due to solid organ transplant, blood, or bone marrow transplant, immune deficiencies, or other causes; or HIV with a low CD4 cell count or not on HIV treatment; prolonged use of corticosteroids or other immune suppressing drugs; severe obesity (BMI of 40 or above); pregnancy; Type 1 and Type 2 diabetes; **disabilities** incl. **chromosomal disorders** (Down syndrome); **intellectual disabilities** (IQ of 70 or below); disabilities that compromise lung fcn. (neurologic/muscular conditions such as muscular dystrophy, spina bifida, and multiple sclerosis); sickle cell disease
- VMS/AAPVT/VAFP have actively working with AHS to make this a streamlined process!

Tuesday Media Briefing (3/2/21)

Governor Phil Scott

- Vaccine registration 65+ as of 3/1: 18,600 by COB.
- Next, certain high-risk conditions – strategy from start: protect at most risk & preserve life. Already seeing outcome in elderly population.
- With J & J vaccine EUA + increased supply from, Moderna & Pfizer, VT can scale up more quickly
- This Monday, March 8, open phase 5 to VTers w/**certain high-risk conditions**. Split into 2 groups (even among this group, age is still a factor).
  - Monday, 3/8: **Phase 5a** – 55+ yo.
  - Monday, 3/15: **Phase 5b** – 16+ w/same conditions

Tuesday Media Briefing (cont'd.)

Governor Phil Scott

- March 13 last year declared SOE. Now almost 1 year later, all at greatest risk will be elig. for vax – "remarkable achievement"
- With increased supply of J & J & federal pharmacy program supply, also able to expand for **2 other systems**
  - As we discussed 2/26, our kids are not doing well; set goal of IP school 5d/wk.
  - Beginning next week, adding **teachers/school staff, child care/early education provs**. (incl. giving option of J & J or 2-dose w/Walgreen's).
  - Also **expansion phase 1a**: eligibility in public safety system.
  - On pace to be in v. good place by late spring or early summer.
  - [Governor then stepped away for White House/governors' call]

Tuesday Media Briefing (cont'd.)

AHS Secretary Mike Smith

- Total pop 65+ - 69 yo ~42K. Expect completion relatively quickly.
- If homebound & not contacted, call 855-722-7878 Friday, 3/5/21.
- Expect >21K 1st doses this week – by 3/15, will increase capacity to administer to 25K 1st doses/wk. By end March, 35K 1st doses/wk.
- Beginning 3/3, VNG will assist w/vaccine administration.
- S. Burl at Doubletree Inn; next wk. Barre & Springfield. (same registration on web site/call ctr.) 3/15: more VNG sites as supply increases.
- Walmart to begin this wk. at 6 stores in VT – must register thru state web site (don't call stores directly).
- Kinney large vax event: Spaulding HS, Sunday March 7 (~1,100 1st doses). Walgreens continues to participate.

Tuesday Media Briefing (cont'd.)

AHS Secretary Mike Smith

- Week of 3/8/21, open Phase 5 16-64 w/high-risk conditions. (~75K)
  - Phase 5a: 55+ w/high-risk conditions.
  - Phase 5b 16+ (reg. opens 8:15 a.m.)
- Find list of conditions at VDH web site
- Make appointment same way; do NOT need to contact HCP. Will be asked questions: have one of health cond. = self-certification. Provide info for HCP that you see for your condition; if w/o HCP, will still receive vaccine. VDH may use info to confirm elig. either thru med records or by contacting your provider. We may also reach out to those w/o provider to make connections to health care professional.
- Starting 3/8/21, appts. for child care, teachers, school staff (just >35K).

Tuesday Media Briefing (cont'd.)

AHS Secretary Mike Smith

- Week of 3/8/21, leverage new supply & federal pharmacy program.
- Teachers/school staff will have 0ption to receive single-dose J & J at clinics: J & J is ideal candidate for on-site vax approach.
- More details to follow Friday, 3/5/21.
- Vaccine will also be avail. at Walgreen's – list of eligible employees will be given to Walgreen's. Info will be given directly to educators/child care providers as appts. become available.
- Program will look & operate differently than current efforts.
- Age groupings will be expanded as supply increases. Anticipate going into 1st weeks April to vax teachers, child care & school staff.

Tuesday Media Briefing (cont'd.)

AHS Secretary Mike Smith

- All depends on federal supply.
- On or about March 8: also expand law enforcement, 9-1-1 call takers; staff in correctional facilities.
- State DOC: J & J on site or option of other vax through Walgreens (will also give list of eligible staff).
- Expect 60+ later this month, and others in the weeks thereafter.
- *"There is now clear light at the end of the pandemic tunnel."*

Tuesday Media Briefing (cont'd.)

VDH Commissioner Levine

- Case updates
- Bromley/Stratton (limited snapshot – offered to all): 264 tested at both (VTers & OOS) total 8 pos., 4 to be conf. w/PCR. (prev. WE: few pos./227)
- Takeaway: *"no high rates of cases being brought into VT."*
- Ski area testing now complete; regular testing avail. Stratton/Manchester.
- Cont. to monitor college campuses: expected more cases spring semester.
  - Norwich: no new cases almost 1 wk.
  - UVM: recent testing shows decrease new case rates. We support 2X/wk. testing. Admin. strengthened sanctions; created outdoor spaces; improved quar. facilities.
- Continue to monitor Franklin Co. – showing signs of leveling off.

Tuesday Media Briefing (cont'd.)

VDH Commissioner Levine

- SEE list of high-risk conditions on web site; do NOT need HCP verification.
- FDA EUA J & J vaccine & ACIP recommendation: "will be a game changer – so that more of us can get vaccinated more quickly."
- Uses adenovirus vector can't replicate in body - instructs to make spike protein; body makes Abs. Phase 3 study enrolled 44K participants on 3 continents during time of high COVID-19 prev. while variants emerging.
- Data: 72% eff rate against moderate illness; 85% against severe; 100% effective against hosp./death. Irrespective of variants; performance across demographics.

Tuesday Media Briefing (cont'd.)

Modeling – Commissioner Pieciak:

- National decline in cases halted, but VT cont. slow/steady improvement in all key metrics (fewer deaths in Feb. than previous 2 months).
- Natl. 7d. average cases relatively flat this week, but natl. models forecast decreasing in cases in future weeks. U.S. death rate: 7d. av. down 19% past 2 weeks
- Northeast: just under 83K (8% incr. wk/wk). VT & NH only 2 in region w/cases improved. Regional forecast anticipates declining case over next few weeks.

Tuesday Media Briefing (cont'd.)

Modeling – Commissioner Pieciak:

- VT: broad improvement metrics throughout Feb. cases/hosps/d./pos. all down.
- 694 cases this week (down 35 from previous wk.); cases decreased among most vulnerable.
- Older (most vaccinated) population: cases decreasing more
- Recent fatalities: many infected weeks ago when case counts higher & vax percentages lower.
- 2 counties stand out: Bennington & Franklin w/higher case cts. But improving.
- Higher ed: best week 39 cases/~21K tests this past week. 456 total in VT.
- Hospitalizations dropping – 7d. av. falling rapidly; ICU beds lagging slightly.
- VT forecast: expect fall in cases throughout March/April (but no guarantee)

Tuesday Media Briefing (cont'd.)

Modeling – Commissioner Pieciak:

- Vax progress: # administered also increasing >2K/day on 7d. average for 1st time.
- VT 2nd in Northeast & 11th nationally doses administered
- VT 9th in U.S. for population fully vaccinated.

Tuesday Media Briefing (cont'd.)

Governor Scott (post White House call)

- Pfizer & Moderna next week: 700 additional doses for VT. At least 15K/wk. for next 3 wks.
- Federal pharmacy program also slight increase = 300 doses for VT.
- By end March, expect increase in Pfizer & Moderna but not J & J
- J & J: VT rec'd. 1st round allocation (slightly different from advertised – trying to clarify) – expected 3K but believe we have 5K. But will NOT receive J & J next week & no guarantee in 3rd week. But by end March, 4-6K/wk.
- J & J and Merck to team up to produce J & J vaccine.

Media Briefing Q & A (3/2/21)

- Comm. Levine: “many suggestions” being made re: J & J (e.g., rural; other pops. less likely to get 2nd dose). Most states will integrate into general vax program to get as many vaccinated as quickly as possible
  - 2nd dose from Pfizer, Moderna – not sure everyone will be 100% compliant; will always be people who don’t show for 2nd dose. But data shows big boost from 2nd dose, so why not follow through?
  - J & J study looked at 2 & 4 wks. post-vaccine: optimal efficacy was at 4-week point. Suggests consider most optimally protected at 4 weeks.
- Gov. Scott: “anyone w/in the footprint of the school building” will be eligible for vaccine under new expansion – and if part of staff in the system (e.g., coaches). Includes staff of independent schools.

Media Briefing Q & A (3/2/21)

- **Q**: Impediment to return to full IP is guidance, esp. distancing. Gov. Scott: huge hurdle that we're getting beyond. If we can all agree to the goal, learned from CDC – they discussed & said continuing to wear masks is essential. Reason for 6 ft. distance was for those located in high transmission areas – mitigate when mask not worn. Others, get creative – this is guidance only. If can't be done, find other ways and make sure to maintain 6 ft. distance between teachers & students. Open windows/doors, utilize fans. I believe we'll hear more from CDC in coming days.
- **Q**: Does J & J news change anything in teacher vax plan? Gov.: may create "a wrinkle" (tho we believe we have more than they think we have).
  - Smith: "we'll call an audible" – use what's in storage, incl. recaptured from LTC federal program. Starting deliberately/slowly, then ramp up.

Media Briefing Q & A (3/2/21)

- **Q**: will people get to choose which vax? Gov: will consider once we und. supply. *"We would like people to have a choice."*
- **Q**: Did J & J protect against long-hauler sxs? Comm. Levine: no data at this point. EUAs usually come after 2 mos. (but definition of long-haul is symptoms ≥3-4 mos.), so need more time.
- **Q**: sounds like you're concerned people won't want J & J? Gov.: we don't know that. Just got it – will know more re: acceptance rate after a week. If I had a choice, would take J & J: one shot, more flexibility.
- Comm. Levine: if this were 1st vax, all would have said "incredible stuff." If it were available to me, I would take it right now. Moderate disease in study trial for J & J: more equiv. to mild sxs in trials for other 2 vaccines.
- Gov: it could be demand for J & J will exceed supply.

Media Briefing Q & A (3/2/21)

- **Q**: Regarding full IP instruction: where do **students who opted into fully remote fit in**? Gov.: need to answer in next week or so – on the table. Will likely reach out to teachers, supts., principals, families to see if changes their perspective. Secy. French: will try to understand interest level and capacity in the Districts.
- **Q**: under 16 yo – why not included? Gov.: not through trials yet (maybe fall?)
- **Q**: impact of vaccine on masking, etc.? Gov: virus doesn't disappear. Comm. Levine: many of us in public health talking about fall/winter re: perhaps masking less mandatory. Possibly July for **outdoor** masking not necessary (but not promising!) since less transmissible.
  - Many factors: natural immunity from illness, vaccine-mediated immunity, variant strains "really not making a big fuss right now"; need to cont. to monitor data.
- **Q**: Coaches: some not empl. by schools – eligible? **A**: yes.

Save the Date!

- What? **Child maltreatment conference**
- Who? **James Metz, MD MPH** & other expert speakers
- When? **April 29**, 8 am – 12:15 pm via live stream
- How? **Register at:**

http://campaign.r20.constantcontact.com/render?ca=3cdb8290-cfe5-4dbb-b73b-29ecabed13f0&preview=true&m=1130384660698&id=preview

Recognizing and Responding to Child Maltreatment
Promoting Child Abuse Awareness in VT Conference

Thursday, April 29, 2021
8:00am -12:15pm
LIVE STREAM

This conference will help the professional to recognize sentinel injuries, sexual abuse and neglect. Participants will learn about the mental health implications of trauma and abuse and will learn strategies for effective reporting.

James Metz, MD, MPH - Course Director
Assistant Professor, Pediatrics
Division Chief, Child Abuse Medicine
UVM Larner College of Medicine

"Recognizing Sentinel Injuries" and "Child Neglect"

In Case You Missed It

- **CDC COCA Call:** Tuesday, March 2, 2021; 2:00 PM – 3:00 PM ET - What Clinicians Need to Know about J & J Janssen COVID-19 Vaccine
  - **Zoom link:** https://www.zoomgov.com/j/1603748312?pwd=anlmUURkSEtmdzBLSmNOV0pJSzZUQT09
  - **Passcode: 893944 – Telephone:** US: +1 669 254 5252 or; +1 646 828 7666 or; +1 551 285 1373 or; +1 669 216 1590
- Washington Post: Israel's success in vaccine distribution
- NYT editorial: addressing vaccine hesitancy
- Burlington Free Press: tracking vaccine side effects (e.g., VAERS data) among Vermonters.

VT AOE Update

- Recovery Guidance document now available at: https://education.vermont.gov/sites/aoe/files/documents/edu-guidance-education-recovery-no1.pdf
- AOE Deputy Secretary Heather Bouchey will join our call Monday, March 15, 2021
- Please reach out to your local school/district administrators, school nurses, COVID coordinators and VDH school liaisons to offer assistance.

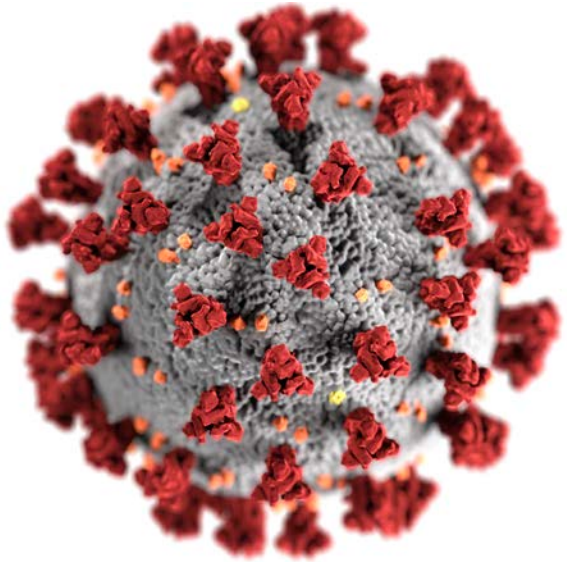
Save the Date: Health Equity Interactive Session

- Program of Northern Vermont Area Health Education Center (AHEC)
- Stacie L. Walton, MD, MPH, clinical/ academic pediatrician; medical consultant for HCPs/institutions for >25 years; recently retired from Kaiser Permanente (Diversity Champion)
- Details in tonight's email

(Thank you, Melissa Kaufold)

VCHIP/CHAMP/VDH COVID19 Update: Pregnant and Lactating Women

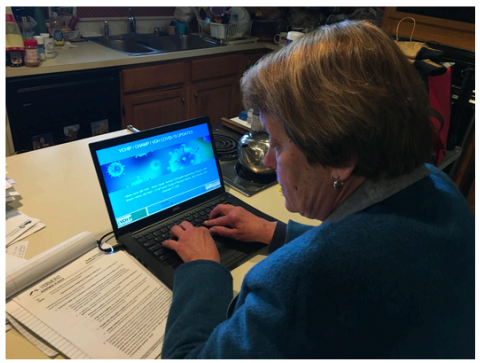
March 3, 2021



Kelley McLean, MD
Associate Professor, Maternal Fetal Medicine
University of Vermont

Showing Up: VCHIP Leverages Network to Help Vermont Providers during Pandemic

January 4, 2021 by Jennifer Nachbur



Wendy Davis, M.D., professor of pediatrics, working on her computer during one of the tri-weekly VCHIP-CHAMP-VDH COVID-19 Update calls. (Courtesy photo)

Vermonters have a reputation for showing up for their community – whether there's a pandemic or not. That's also true for the faculty and staff of the Vermont Child Health Improvement Program (VCHIP), who have underscored over the past nine months just how important their role is to ensuring providers get access to critical resources and tools that allow them to deliver quality care.

Following the state's first confirmed case of COVID-19 on March 7, the Vermont Department of Health (VDH) set up an 8 a.m. to 5 p.m. hotline and was quickly inundated with calls from medical professionals and community members alike. Within a span of about 48 hours, well child visits moved to telehealth, which led to new workflows, new technology, and reimbursement issues.

A regular partner with VDH, VCHIP representatives, including Executive Director Judy Shaw, Ed.D., M.P.H., R.N., Professor of Pediatrics Wendy Davis, M.D., and Associate Professor of Pediatrics Breena Holmes, M.D., realized that instead of helping staff phone calls, they could leverage VCHIP's CHAMP (Child Health Advances Measured in Practice) program to help share just-in-time and sorely-needed COVID-19 information with providers in their network – and beyond.

Answering the call for help with CHAMP

Disclosures

- **None**

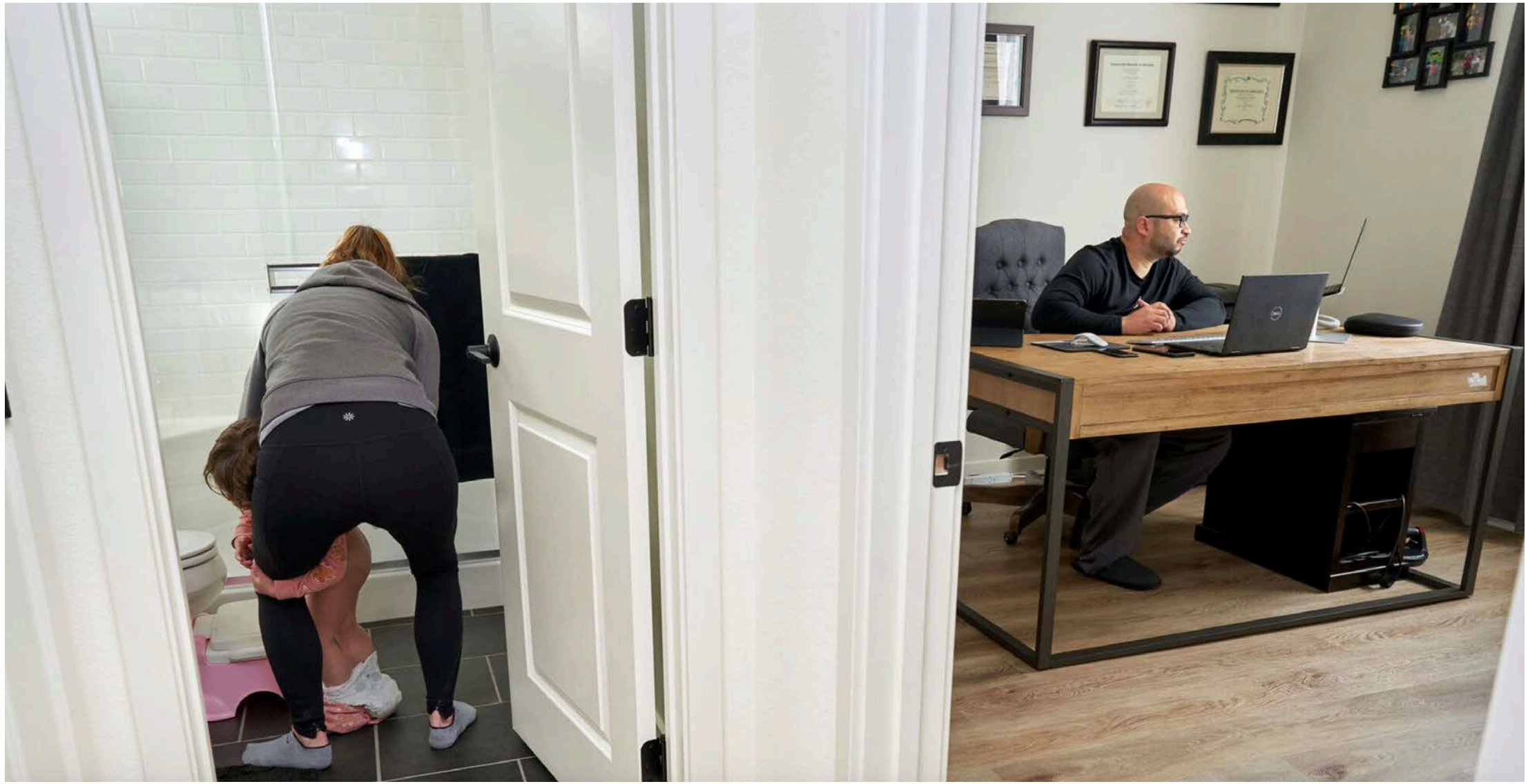
Disclosures

- **Not breastfeeding or lactating**

The New York Times

THE PRIMAL SCREAM

THREE AMERICAN MOTHERS, ON THE BRINK



Pandemic Ripple Effects

- Almost 1 million mothers have left the workforce
  - Black mothers, Hispanic mothers and single mothers are among the hardest hit.

"Just before the pandemic hit, for the first time ever, for a couple months, we had more women employed than men"

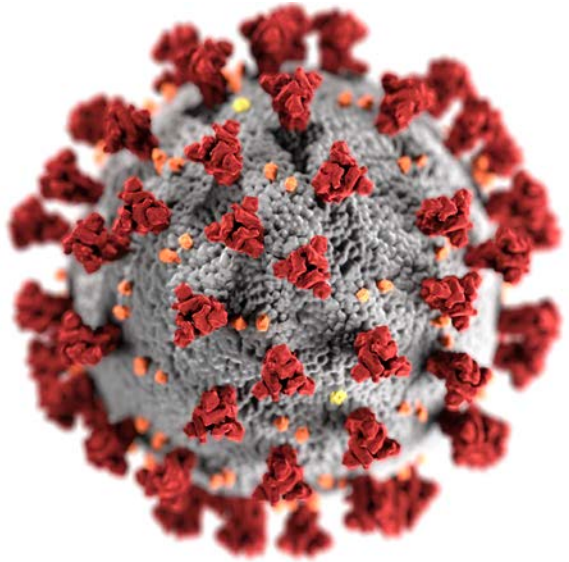
-Michael Madowitz, economist, Center for American Progress

"And now we are back to late 1980s levels of women in the labor force."
"Covid took a crowbar into gender gaps and pried them open"

-Betsey Stevenson, economist, University of Michigan.

New York Times Feb 2021

COVID19 Update: Pregnant and Lactating Women



Society for Maternal•Fetal Medicine

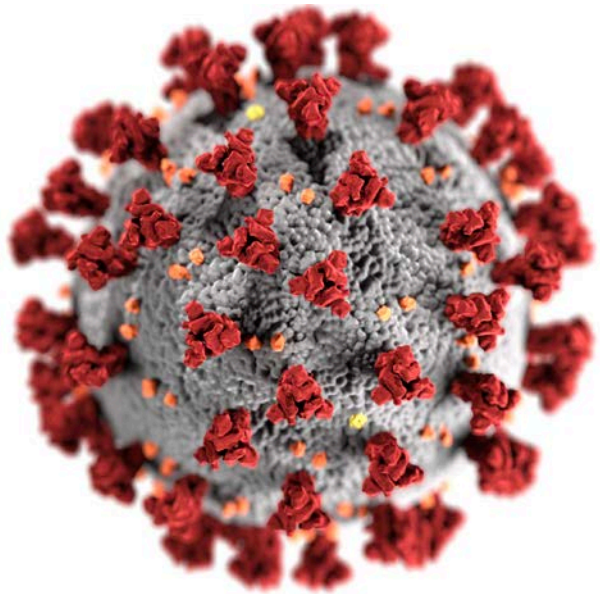
High-risk pregnancy experts

Join us tomorrow from 12:00 to 1:00pm (ET) for a webinar titled, "Updates in COVID-19 in Pregnancy," with Dr. Torre Halscott. Please register in advance by clicking the button below. If you need assistance or have questions, contact Alexis Hooper.

The MFM Fellow Lecture Series webinars are typically available at no cost to SMFM members. **This week, we are making the webinar open access**, so that non-members can also view it at no cost. Please share this email with your colleagues who may be interested in the latest on COVID-19 and pregnancy.

Register in Advance

COVID19 Infection in Pregnancy



COVID19 Infection in Pregnancy

- Compared to age-matched, non-pregnant individuals, pregnant women are at **increased risk of hospitalization**
- 3-fold adjusted RR of needing **intensive care** (10.5 vs 3.9/1000 cases) and **mechanical ventilation** (2.9 vs 1.1/1000 cases)
- Pregnant women with laboratory- confirmed severe or critical COVID-19 disease have higher adjusted relative risks of cesarean delivery (1.57 [95% CI, 1.30-1.90]), postpartum hemorrhage (2.04 [95% CI, 1.19-3.47]), hypertensive disorders of pregnancy (1.64 [95% CI, 1.21-2.23]), and preterm birth (3.53 [95% CI, 2.42-5.15])

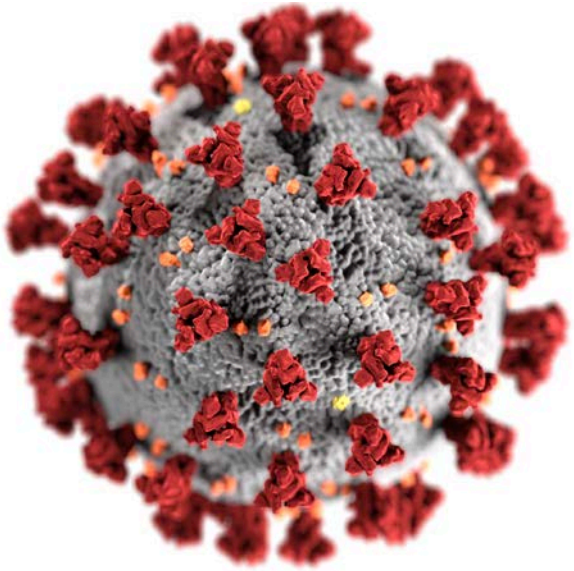
COVID19 Infection in Pregnancy

- The apparent increased risk of severe disease in pregnancy is further exacerbated in pregnant women who are older, have a higher BMI, and who have medical comorbidities
- Evidence is emerging that racial and ethnic disparities are also related to the increased morbidity and mortality among pregnant people.

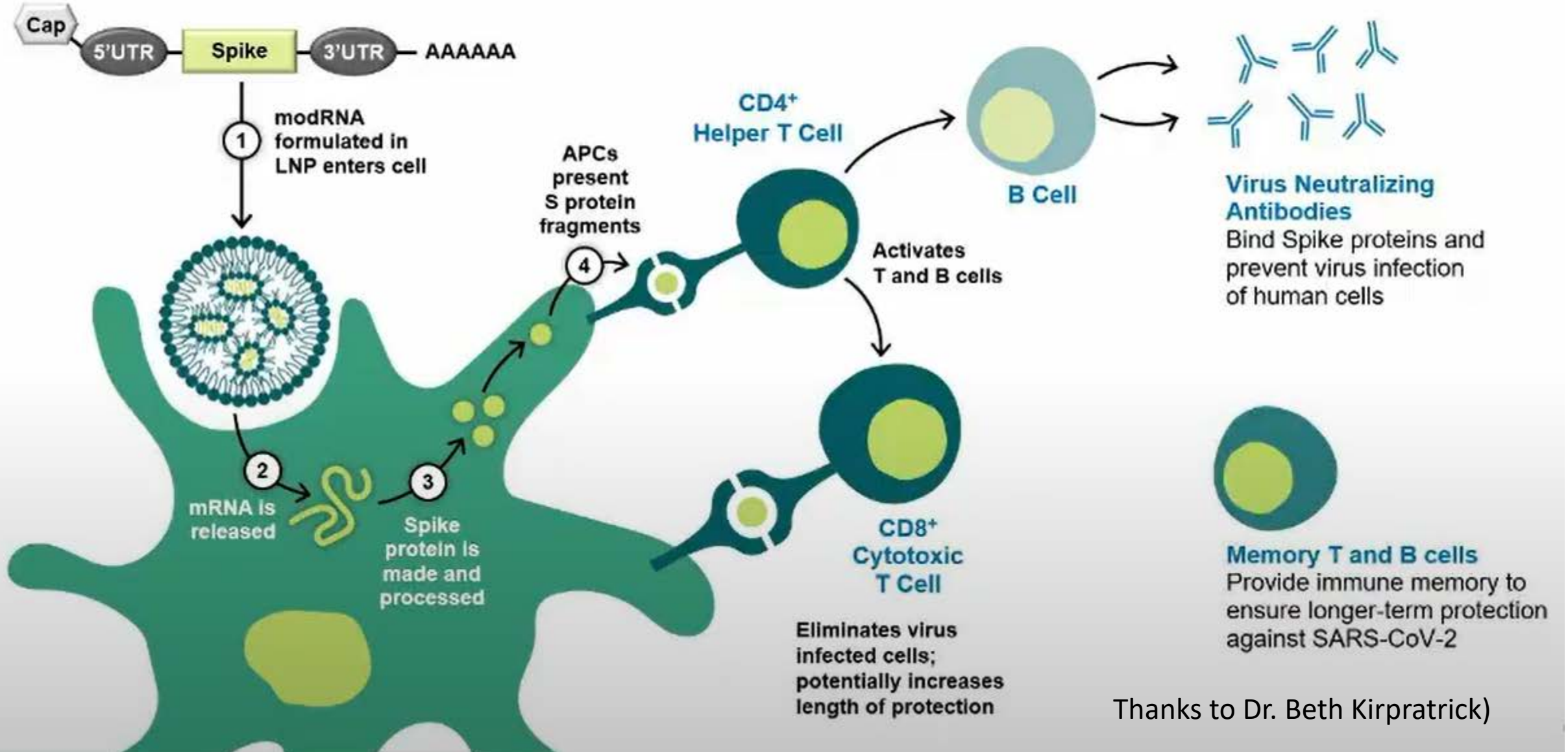
COVID19 Infection in Pregnancy

- Bottom line(s):
  - Most pregnant women will have mild or asymptomatic disease
  - *However*, we now know that pregnant women do indeed face increased risk of hospitalization, mechanical ventilation, and critical illness.
  - The risk of pregnancy complications appear to largely exist in the context of severe maternal illness- including preterm birth.
  - <u>The utility, safety, and effectiveness of the available vaccines in pregnancy remains unknown.</u>

Vaccination of Pregnant Women against COVID19



Mode of Action of the BNT162 Vaccine Candidates



Thanks to Dr. Beth Kirpratrick)

mRNA vaccines:
Noteworthy characteristics

(1)mRNA is not stable and is naturally degraded in the cell when transcription job is done (days)

(2) mRNA does not enter the nucleus and does not interact with DNA (no risk of insertional mutation, an issue with DNA based vaccines)

(3) mRNA is NOT infectious

(4) ***Given how mRNA vaccines act locally (at the site of injection) and are rapidly degraded and removed by lymphatic system, it is unlikely that the vaccine would reach and cross the placenta (G. Swamy, MD, SMFM)***

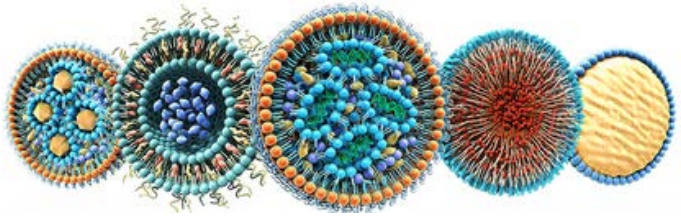
mRNA vaccines:

Biologic Plausibility of Fetal Harm

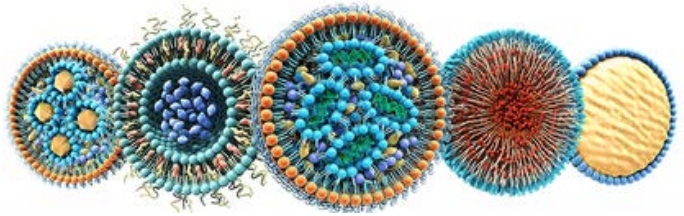
(1)mRNA is not stable and is a large molecule with a negative charge: even if it makes it to the placental interface, the biochemical characteristics suggest it would not cross the placental interface

(2)The immune response to SARS-CoV-2 and the mRNA vaccines with covid and the vaccine are very similar: Ab and T cell response to the Spike protein. No biologic reason to think the response to the antigen would be worse than the viral effects-which are largely related to maternal disease not the virus per se

***But what about that carrier???**



Lipid Nanoparticles



- Lipid nanoparticles are spherical vesicles made of ionizable lipids, which are positively charged at low pH (enabling RNA complexation) and neutral at physiological pH
- optimizing lipid nanoparticle formulations for nucleic acid delivery reflects years and years of work- but widespread use in humans has only just begun

"Achieving nanocarriers with low or no toxicity for the organism and the environment is one of the biggest challenges in designing drug delivery nanosystems".

"Ideally, the drug carrier should be rapidly removed from the body after the drug has been released. Lipid-based NPs sizes are far over the renal filtration threshold (Yang et al., 2019). Once in the bloodstream, they have to be opsonized by serum proteins and subsequently uptaken by the MPS in specialized organs (i.e., liver, kidney, spleen, lungs, and lymph nodes) for their efficient elimination from the body (Di Ianni et al., 2017).

Montoto et al. Front. Mol. Biosci., 30 October 2020

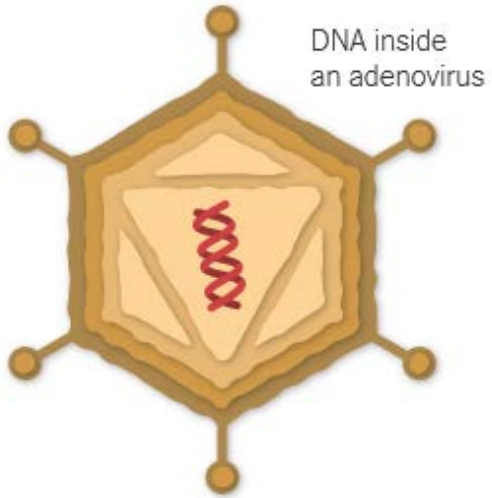
Emergency Use Authorization Fact Sheet

- The EUA Fact Sheet for Recipients and Caregivers both Pfizer-BioNtech and Moderna vaccines states “If you are pregnant or breastfeeding, discuss your options with your healthcare provide

A Word on the Newest Player..... **JNJ-78436735** or **Ad26.COV2.S**

- Feb 27, 2021: Johnson and Johnson vaccine is issued emergency use authorization (EUA) by the FDA
- Utilizes an adenovirus vector to deliver double stranded DNA→codes for the SARS-CoV-2 spike protein

The same adenovirus vector platform has been used for other clinical vaccines in pregnant people, including Ebola, HIV, and RSV adenoviral vaccine studies, with no adverse pregnancy outcomes



What are Current Society Recommendations??

Pre-pregnancy/Planning

AMERICAN SOCIETY FOR REPRODUCTIVE MEDICINE (ASRM)
PATIENT MANAGEMENT AND CLINICAL RECOMMENDATIONS DURING THE CORONAVIRUS (COVID-19) PANDEMIC

UPDATE No. 11 – COVID-19 Vaccination
December 16, 2020

- **The Task Force does not recommend withholding the vaccine from patients who are planning to conceive, who are currently pregnant, or who are lactating** (1,2,3). These recommendations are in line with those of the Advisory Committee for Immunization Practices (ACIP) of the U.S. Centers for Disease Prevention and Control (CDC), the American College of Obstetricians and Gynecologists (ACOG), and the Society for Maternal-Fetal Medicine (SMFM).

- **Patients undergoing fertility treatment and pregnant patients should be encouraged to receive vaccination based on eligibility criteria**. Since the vaccine is not a live virus, there is no reason to delay pregnancy attempts because of vaccination administration or to defer treatment until the second dose has been administered.

- **A shared decision-making model between patients and providers should be used when considering vaccination and should take into consideration the ethical principles of autonomy, beneficence, and non-maleficence.** Consideration of local COVID-19 transmission and risk of acquisition, personal risk of contracting COVID-19, risks of COVID-19 to the patient and potential risks to a fetus, efficacy of the vaccine and known side effects, and the lack of data about the vaccine during pregnancy should all be taken into consideration as patients make decisions regarding vaccination. Some individuals may elect to defer conception attempts until both doses of vaccine have been administered.

https://www.asrm.org/globalassets/asrm/asrm-content/news-and-publications/covid-19/covidtaskforceupdate11.pdf

Pre-pregnancy/Planning

AMERICAN SOCIETY FOR REPRODUCTIVE MEDICINE (ASRM)
PATIENT MANAGEMENT AND CLINICAL RECOMMENDATIONS DURING THE CORONAVIRUS (COVID-19) PANDEMIC

UPDATE No. 11 – COVID-19 Vaccination
December 16, 2020

Summary:
Non-pregnant women WERE in the trials
Take prenatal vitamins
Get COVID vaccine

- **Because COVID-19 mRNA vaccines are not composed of live virus, they are not thought to cause an increased risk of infertility, first or second trimester loss, stillbirth, or congenital anomalies.** It should be noted that pregnant and lactating women were excluded from the initial phase III trials of these two vaccines, so specific safety data in these populations are not yet available and further studies are planned. However, the mechanism of action of mRNA vaccines and existing safety data provide reassurance regarding the safety of COVID-19 mRNA vaccines during pregnancy. The FDA EUA letter permits the vaccination of pregnant and breastfeeding individuals with a requirement that the company engage in post-authorization observational studies in pregnancy (9).

- **While COVID-19 vaccination can cause fever in some patients (up to 16% of those vaccinated and mostly after the second dose), this risk should not be a concern when deciding whether to vaccinate a pregnant individual or a patient desiring pregnancy.** While fever in pregnancy (particularly the 1st trimester) has been associated with an increased risk of neural tube defects, a recent study demonstrated the association no longer remained significant if the patient is taking >400 mcg of folic acid daily (10). Another large Danish cohort study did not demonstrate any increased risk of congenital anomalies of those who reported fever in the first trimester (11). Additionally, the most common symptom of COVID-19 infection itself is fever (83-99% of affected patients). Patients who experience fever following vaccination should take an antipyretic medication, like acetaminophen (12).

- **Patients who conceive in the window between the first and second dose of the vaccine should be offered the second dose of the vaccine at the appropriate interval.**

- **Physicians should promote vaccination to patients, their communities, and to the public.** Preliminary data suggests that those populations at greatest risk of severe disease from COVID-19 may also be the most hesitant to be vaccinated, and specific efforts to increase vaccine uptake in these communities should be undertaken.

https://www.asrm.org/globalassets/asrm/asrm-content/news-and-publications/covid-19/covidtaskforceupdate11.pdf

CDC ACIP Recommendations about Pfizer Vaccine in Pregnancy

- If pregnant people are part of a group that is recommended to receive a COVID-19 vaccine (e.g., healthcare personnel), they may choose to be vaccinated.
- A conversation between the patient and their clinical team may assist with decisions regarding the use of vaccines approved under EUA for the prevention of COVID-19.
- While a conversation with a healthcare provider may be helpful, it is not required prior to vaccination.
- There is no recommendation for routine pregnancy testing before receipt of a COVID-19 vaccine. Those who are trying to become pregnant do not need to avoid pregnancy after Pfizer-BioNTech COVID-19 vaccination.


ACOG
The American College of
Obstetricians and Gynecologists

- ACOG recommends that COVID-19 vaccines should not be withheld from pregnant individuals who meet criteria for vaccination based on ACIP-recommended priority groups.
- COVID-19 vaccines should be offered to lactating individuals similar to non-lactating individuals when they meet criteria for receipt of the vaccine based on prioritization groups outlined by the ACIP.
- Individuals considering a COVID-19 vaccine should have access to available information about the safety and efficacy of the vaccine, including information about data that are not available. A conversation between the patient and their clinical team may assist with decisions regarding the use of vaccines approved under EUA for the prevention of COVID-19 by pregnant patients. Important considerations include:
    - the level of activity of the virus in the community
    - the potential efficacy of the vaccine
    - the risk and potential severity of maternal disease, including the effects of disease on the fetus and newborn
    - the safety of the vaccine for the pregnant patient and the fetus.

- Vaccines currently available under EUA have not been tested in pregnant women. Therefore, there are no safety data specific to use in pregnancy. See details about the Food and Drug Administration's (FDA) EUA process below.

ACOG has representation on the ACIP, including on the ACIP COVID-19 working groups. ACIP has made the following recommendations for prioritization of COVID-19 vaccine allocation:

Phase 1a: Health care workers and long-term care facility residents (CDC 2020)
Phase 1b: Persons aged ≥75 years and frontline essential workers (CDC 2020)
Phase 1c: Persons aged 65-75 years, persons aged 16-64 years with high-risk* medical conditions (including pregnancy), and other essential workers (CDC 2020)

*High-risk medical conditions outlined by the CDC include:

- Pregnancy
- Cancer
- Chronic kidney disease
- COPD (chronic obstructive pulmonary disease)
- Down Syndrome
- Heart conditions, such as heart failure, coronary artery disease, or cardiomyopathies
- Immunocompromised state (weakened immune system) from solid organ transplant
- Obesity (body mass index [BMI] of 30 kg/m2 or higher but < 40 kg/m2)
- Severe Obesity (BMI ≥ 40 kg/m2)
- Sickle cell disease
- Smoking (current or history)
- Type 2 diabetes mellitus

Clinical | Jan 27, 2021

ACOG and SMFM Joint Statement on WHO Recommendations Regarding COVID-19 Vaccines and Pregnant Individuals

Washington, DC – The American College of Obstetricians and Gynecologists (ACOG) and the Society for Maternal-Fetal Medicine (SMFM) are aware of the World Health Organization's (WHO) recommendation to withhold COVID-19 vaccines from pregnant individuals unless they are at high risk of exposure. ACOG and SMFM continue to stress that both COVID-19 vaccines currently authorized by the U.S. Food and Drug Administration should not be withheld from pregnant individuals who choose to receive the vaccine. ACOG's and SMFM's current guidance on the COVID-19 vaccine in pregnant patients remains in place.

Despite efforts by ACOG and SMFM to advocate for their inclusion, clinical trials that informed the emergency use authorization (EUA) of the vaccines did not include pregnant individuals. However, preliminary developmental and reproductive toxicity (DART) studies for both the Pfizer-BioNtech and Moderna vaccines are encouraging, with no safety signals reported. DART animal studies provide the first safety data to help inform the use of these vaccines in pregnancy until there are more data in this specific population. These studies do not indicate any adverse effects on female reproduction or fetal/embryonal development. ACOG and SMFM strongly urge manufacturers and federal agencies to collect and report data regarding the use of these vaccines in pregnancy.

Data have demonstrated that symptomatic pregnant individuals with COVID-19 are at increased risk of more severe illness and death compared with nonpregnant peers. Many pregnant individuals have medical conditions known to put them at further increased risk of severe illness and complications. Therefore, given clear evidence of the dangers of COVID-19 in pregnancy, an absence of data demonstrating adverse effects associated with the vaccine in pregnancy, and in the interest of patient autonomy, ACOG and SMFM recommend that pregnant individuals be free to make their own informed decisions regarding COVID-19 vaccination. This decision should consider a number of factors, including the available information about the safety and efficacy of the vaccine and consideration of a lack of data regarding the use of the vaccine during pregnancy. Additional considerations include the level of activity of the pandemic in the community, the potential efficacy of the vaccine, and the potential risk and severity of maternal disease. While pregnant individuals are encouraged to discuss vaccination considerations with their clinical care team when feasible, documentation of such a discussion should not be required prior to receiving a COVID-19 vaccine.

As physicians who care for pregnant individuals, and as vaccine rollout expands to other eligible populations, ACOG and SMFM continue to firmly assert that pregnant individuals should be given the opportunity to make their own decision as to whether to receive the COVID-19 vaccine and that barriers should not be put in place to prevent access and hinder the ability of pregnant people to protect themselves from a virus that could potentially be life-threatening.

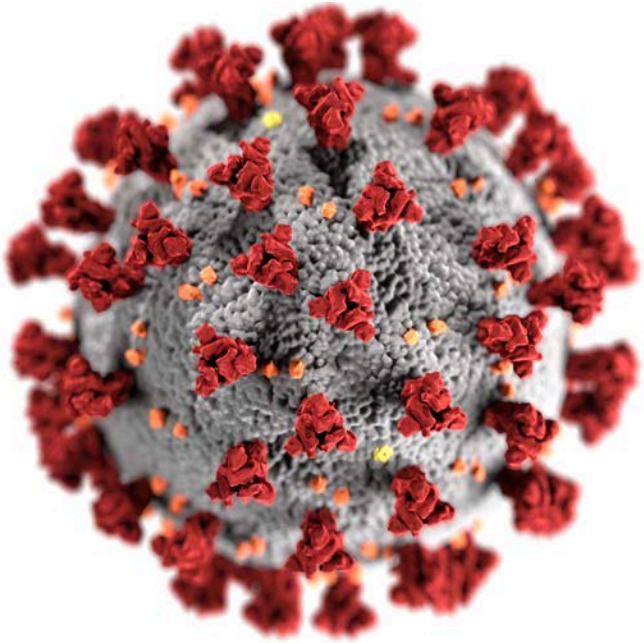
Society for Maternal-Fetal Medicine

ACOG
The American College of Obstetricians and Gynecologists

Pregnancy Summary: CDC/ACIP, SMFM, ACOG, ASRM all agree

- Vaccine should be offered (if would be offered without pregnancy)
- Women who decline should be supported *(for women who decline discuss postpartum vaccination)*
- While no data, no one will recommend. However, the theoretical risk is low due to minimal circulation of the lipid nanoparticles; mRNA is large, highly charged, and degraded rapidly-extremely unlikely to interact with placenta
- MM note: the risk of COVID in pregnancy is real, and sequelae of preterm birth well established, every construct for fetal risk is highly theoretical
- MM note: passive immunity to the fetus is well described in general; unknown in COVID

Vaccination of Lactating Women against COVID19



CDC ACIP Recommendations about Pfizer Vaccine in Lactation

- There are no data on the safety of COVID-19 vaccines in lactating people or the effects of mRNA vaccines on the breastfed infant or milk production/excretion.
- mRNA vaccines are not thought to be a risk to the breastfeeding infant. A lactating person who is part of a group recommended to receive a COVID-19 vaccine (e.g., healthcare personnel) may choose to be vaccinated.

SMFM Recommendations about COVID-19 mRNA Vaccine in Lactation

- Vaccination is recommended for lactating persons.
- Counseling should balance the lack of data on vaccine safety and a person's individual risk for infection and severe disease.
- The theoretical risks regarding the safety of vaccinating lactating people do not outweigh the potential benefits of the vaccine.

ACOG

Lactating Individuals

ACOG recommends COVID-19 vaccines be offered to lactating individuals similar to non-lactating individuals when they meet criteria for receipt of the vaccine based on prioritization groups outlined by the ACIP. While lactating individuals were not included in most clinical trials, COVID-19 vaccines should not be withheld from lactating individuals who otherwise meet criteria for vaccination. Theoretical concerns regarding the safety of vaccinating lactating individuals do not outweigh the potential benefits of receiving the vaccine. There is no need to avoid initiation or discontinue breastfeeding in patients who receive a COVID-19 vaccine.

American Academy of Pediatrics

Q: Are there any data from volunteers who happened to get pregnant or who were breastfeeding during vaccine trials? Any effects of COVID vaccine on pregnancy, the developing fetus, or infants?

A: No pregnancy related data have yet been released. Typically, in large trials, there are some inadvertent pregnancies. They will be followed for birth outcomes. Pregnancy and breastfeeding will probably not be contraindications to receiving COVID-19 vaccine; however, there is no safety data in the pregnant woman, her fetus or infants at this time. While these vaccines were not specifically tested in breastfeeding women, it is not likely (based on the mechanisms of action of the vaccines in US trials) that there would be any risk to the child.

“mRNA vaccines are not considered live virus vaccines and are not thought to be a risk to the breastfeeding infant,” Dr. Mbaeyi said (CDC Medical Officer, AAP website)

Lactation Summary

- Should be offered
- Slightly stronger language re: safety and encouraging vaccination
- No need to delay or interrupt breastfeeding

VAERS Vaccine Adverse Event Reporting System
www.vaers.hhs.gov

Report an Adverse Event to VAERS

VAERS is a passive reporting system, meaning it relies on individuals to send in reports of their experiences. Anyone can submit a report to VAERS, including parents and patients.

Click here for guidance to healthcare providers on reporting adverse events to VAERS after COVID-19 vaccination

Healthcare providers are **required by law** to report to VAERS:

- Any adverse event listed in the VAERS Table of Reportable Events Following Vaccination that occurs within the specified time period after vaccinations
- An adverse event listed by the vaccine manufacturer as a contraindication to further doses of the vaccine

Healthcare providers are strongly **encouraged** to report to VAERS:

- Any adverse event that occurs after the administration of a vaccine licensed in the United States, whether it is or is not clear that a vaccine caused the adverse event
- Vaccine administration errors

Vaccine manufacturers are required to report to VAERS all adverse events that come to their attention.

What adverse events should healthcare providers report to Vaccine Adverse Event Reporting System (VAERS) after COVID-19 vaccination?

VAERS Vaccine Adverse Event Reporting System
www.vaers.hhs.gov

Healthcare professionals are **encouraged** to report any clinically significant adverse event following vaccination to VAERS, even if they are not sure if vaccination caused the event.

Healthcare providers are **required** to report the following adverse events after COVID-19 vaccination, and other adverse events if later revised by CDC, to VAERS:

- Vaccination administration errors, whether or not associated with an adverse event
- Severe COVID-19 illness (e.g., resulting in hospitalization)
- Serious adverse events (AEs) regardless of causality. Serious AEs are defined as:
    1. Death;
    2. A life-threatening adverse event;
    3. Inpatient hospitalization or prolongation of existing hospitalization;
    4. Persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
    5. A congenital anomaly/birth defect;
    6. Cases of observed Multisystem Inflammatory Syndrome.

- Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the patient and may require medical or surgical intervention to prevent one of the outcomes listed above.

Also report any additional select adverse events and/or any revised safety reporting requirements per FDA's conditions of authorized use of vaccine(s) throughout the duration of any COVID-19 Vaccine being authorized under an Emergency Use Authorization (EUA).

Item 8

Pregnant at time of vaccination?:
(*If yes, describe the event, any pregnancy complications, and estimated due date if known in item 18*)

○ Yes ○ No ○ Unknown

How to report an adverse event to VAERS

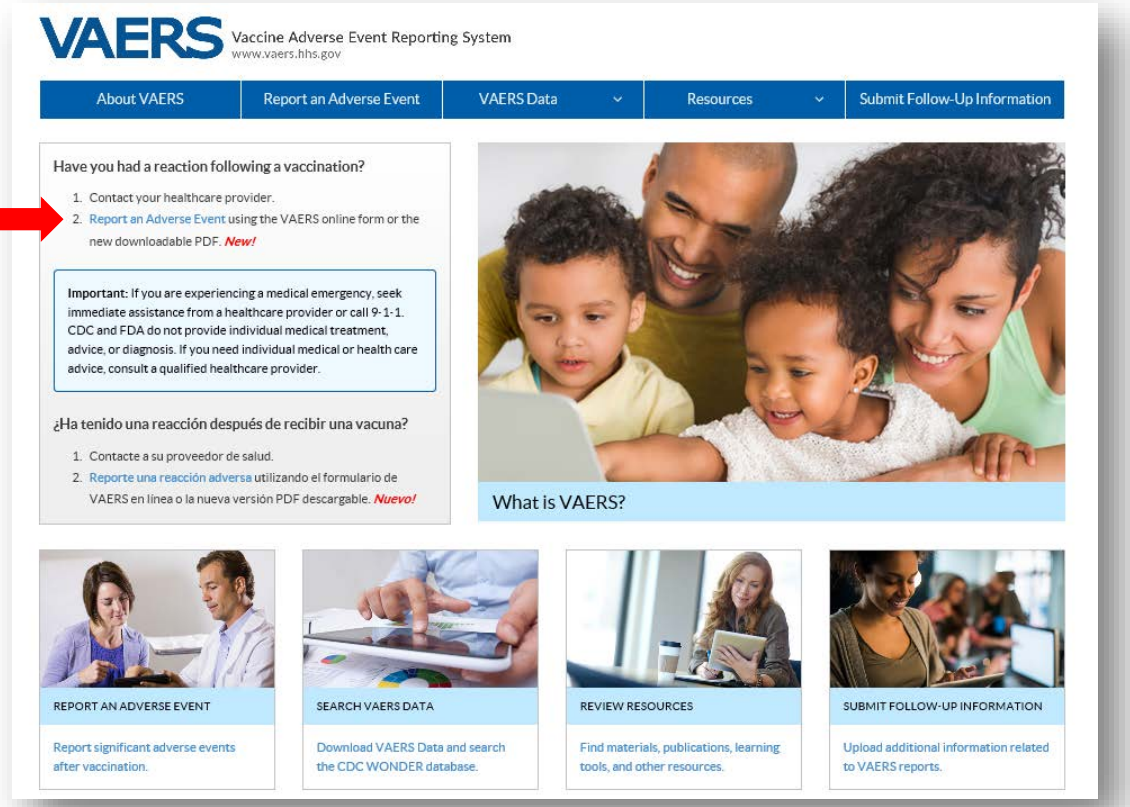
- Go to vaers.hhs.gov.
- Submit a report online.

For help:

call
1-800-822-7967

email
info@VAERS.org

video instructions
https://youtu.be/sbCWhcQADFE



VAERS is the nation's early warning system for vaccine safety

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

1. Text message check-ins from CDC (daily 1st week; weekly thru 6 weeks; then 3, 6, and 12 mo.)

   Vaccine recipient completes web survey

This Photo by Unknown Author is licensed under CC BY-SA

Vaccine recipient

v-safe after vaccination health checker

2. Clinically important event(s) reported

✓ **Received medical care**

Call center

This Photo by Unknown Author is licensed under CC BY-SA

3. A VAERS customer service representative conducts active telephone follow-up on a medically attended health impact event and takes a report if appropriate

CDC CENTERS FOR DISEASE CONTROL AND PREVENTION ↔ FDA

V-safe pregnancy registry

- **V-safe** participants who report pregnancy following COVID-19 vaccination are actively contacted to enroll in pregnancy registry*
- Participants are contacted once per trimester, after delivery, and when the infant is 3 months old†
- Outcomes of interest include miscarriage and still birth, pregnancy complications, maternal intensive care unit admission, adverse birth outcomes, neonatal death, infant hospitalizations, and birth defects

* Must be registered in **v-safe** and have been pregnant at the time of COVID-19 vaccine receipt or within 30 days of vaccination; enrollment may discontinue when sufficient enrollment numbers are achieved

† Phone surveys are conducted along with maternal and infant medical record review

COVID-19 vaccine safety update

Advisory Committee on Immunization Practices (ACIP)
March 1, 2021

Tom Shimabukuro, MD, MPH, MBA
CDC COVID-19 Vaccine Task Force
Vaccine Safety Team

v-safe℠ after vaccination health checker

Summary of v-safe data as of February 16, 2021

	Pfizer-BioNTech	Moderna	Total
People receiving 1 or more doses in the United States*	28,374,410	26,738,383	55,220,364
Registrants completing at least 1 v-safe health check-in	1,776,960	2,121,022	3,897,982
Pregnancies reported to v-safe†	16,039	14,455	30,494

* COVID Data Tracker as of Feb 16, 2021 (107,571 doses with manufacturer not identified)
† Self-reported during a **v-safe** health check-in

CDC

V-safe pregnancy registry enrollment as of February 19, 2021

Registry participants to date (N = 1,949)	
Enrolled	1,815
Not eligible*	103
Refused/declined†	31

- In the enrolled population, there have been 275 completed pregnancies, including 232 live births
  - Other outcomes include miscarriage, stillbirth, ectopic/tubal, other

* Eligibility assessment determines whether vaccination was during pregnancy or within 30 days of last menstrual period

† Refused indicates those for whom eligibility could not be fully assessed because participant chose not to engage with pregnancy registry team; declined indicates those who were eligible to participate but chose not to enroll

Most commonly reported adverse events to VAERS after COVID-19 vaccines through February 16, 2021*

Pfizer-BioNTech

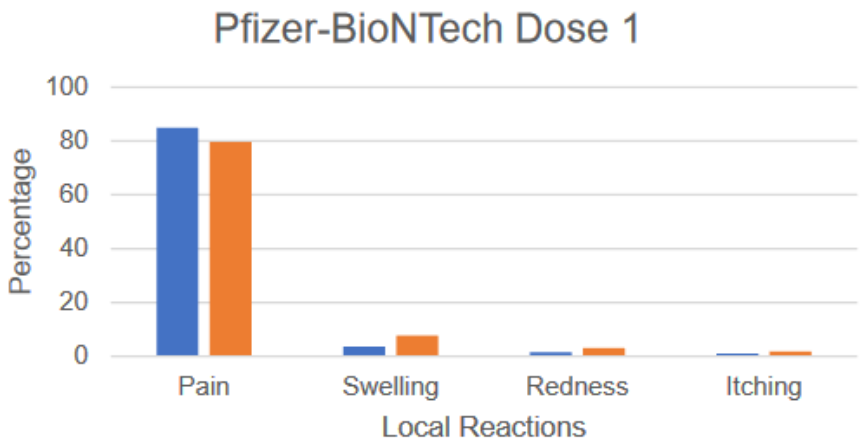
Adverse event†	N (%)
Headache	2,322 (20.0)
Fatigue	1,801 (15.5)
Dizziness	1,659 (14.3)
Pyrexia	1,551 (13.4)
Chills	1,508 (13.0)
Nausea	1,482 (12.8)
Pain	1,464 (12.6)
SARS-CoV-2 Test Positive	1,002 (8.6)
Injection Site Pain	997 (8.6)
Pain in Extremity	923 (8.0)

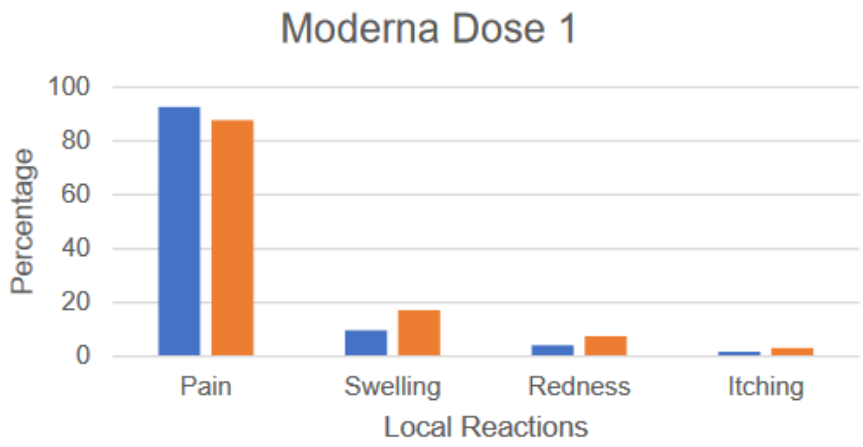
Moderna

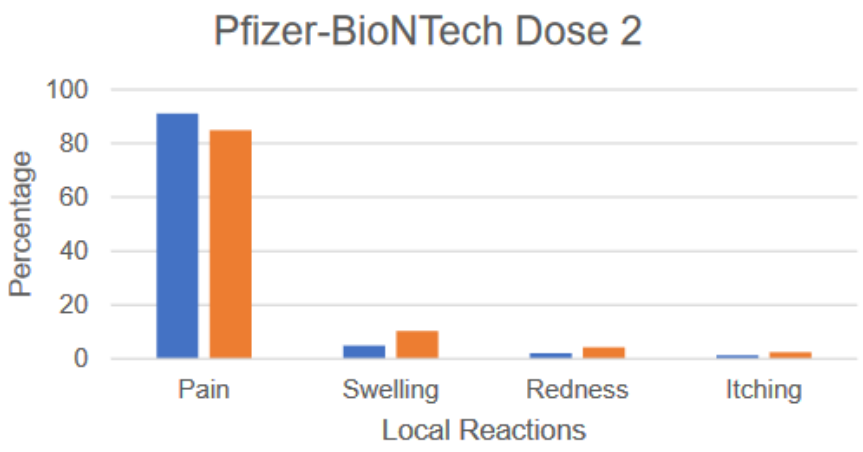
Adverse event†	N (%)
Headache	1,353 (23.4)
Pyrexia	1,093 (18.9)
Chills	1,056 (18.3)
Pain	945 (16.3)
Fatigue	888 (15.4)
Nausea	884 (15.3)
Dizziness	792 (13.7)
Injection Site Pain	671 (11.6)
Pain in Extremity	576 (10.0)
Dyspnoea	487 (8.4)

- No empirical Bayesian data mining alerts (EB05 ≥2) detected for any adverse event-COVID-19 vaccine pairs (most recent weekly results)

V-safe: Day 1 post-vaccination local reactions in pregnant and non-pregnant women aged 16-54 years*





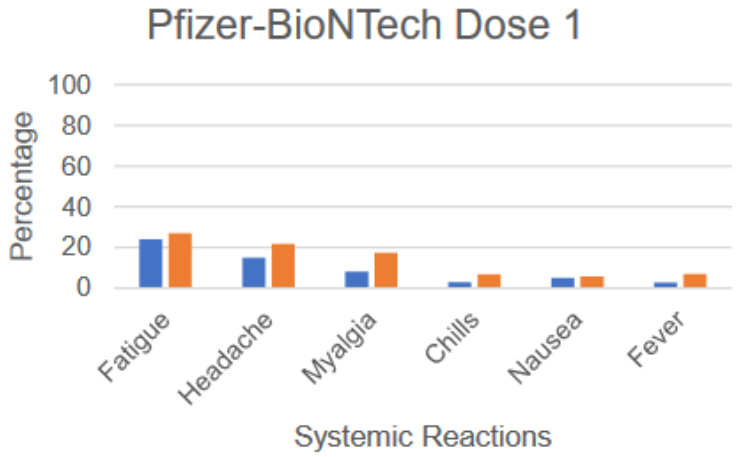


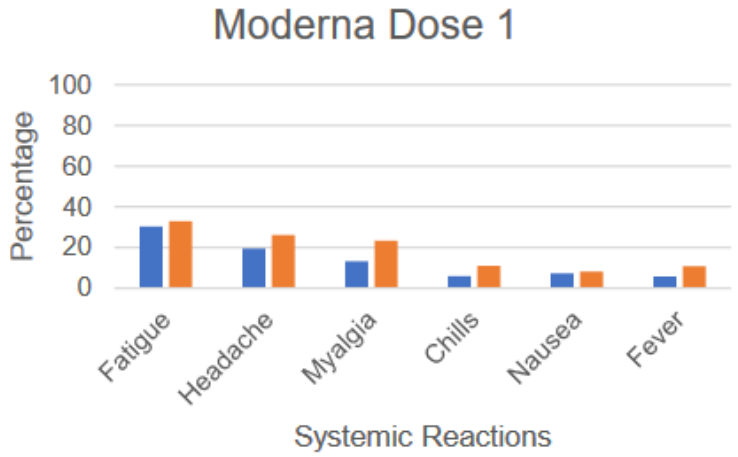
Pregnant (self-report)
Not pregnant

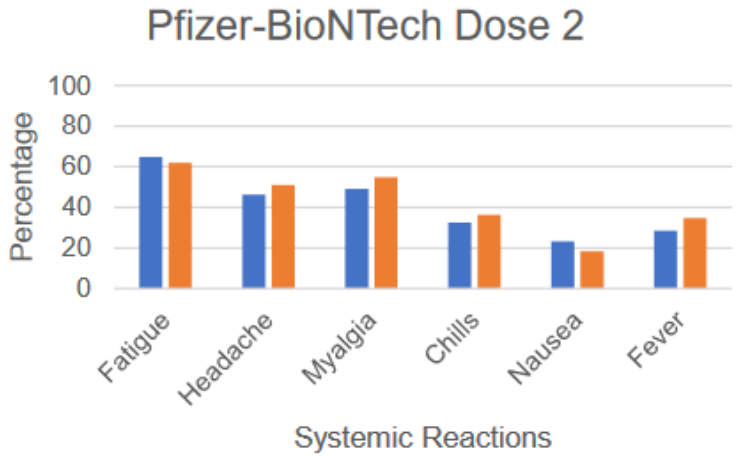
v-safe℠ after vaccination health checker

* Source: CDC unpublished **v-safe** data through January 13, 2021

V-safe: Day 1 post-vaccination local reactions in pregnant and non-pregnant women aged 16-54 years*







Pregnant (self-report)
Not pregnant

v-safe℠ after vaccination health checker

* Source: CDC unpublished **v-safe** data through January 13, 2021

V-safe pregnancy registry outcomes of interest in COVID-19 vaccinated pregnant women as of February 18, 2021*

Outcomes	Background rates*	V-safe pregnancy registry overall
Pregnancy outcome		
Miscarriage (<20 weeks)	26%	15%†
Stillbirth (≥ 20 weeks)	0.6%	1%
Pregnancy complications		
Gestational diabetes	7-14%	10%
Preeclampsia or gestational hypertension§	10-15%	15%
Eclampsia	0.27%	0%
Intrauterine growth restriction	3-7%	1%
Neonatal		
Preterm birth	10.1%	10%
Congenital anomalies‡	3%	4%
Small for gestational age^	3-7%	4%
Neonatal death	0.38%	0%

* Sources listed on slide 33; † 93% of these were pregnancy losses <13 weeks of age; § Pre-eclampsia or gestational hypertension diagnosed during pregnancy and/or during delivery; ‡ Congenital anomalies (overall) diagnosed after delivery only; ^ Birthweight below the 10th percentile for gestational age and sex using INTERGROWTH-21st Century growth standards

Characteristics of COVID-19 vaccine pregnancy reports to VAERS through February 16, 2021* (N=154)

CDC + FDA

VAERS

Characteristic	
Maternal age in years, median (range)	33 (16–51)
Gestational age in weeks at time of vaccination when reported, median (range)	13 (2–38)
Trimester of pregnancy at time of vaccination	**n (%)**
First (0-13 weeks)	60/118 (51)
Second (14-27 weeks)	36/118 (31)
Third (28+ weeks)	22/118 (19)
Vaccine	
Pfizer-BioNTech	97 (63)
Moderna	56 (36)
Unreported	1 (0.6)

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CDC Centers for Disease Control and Prevention

Adverse events in pregnant women following COVID-19 vaccine reported to VAERS through February 16, 2021* (N=154)

CDC + FDA

VAERS

Adverse events	N (%)
Pregnancy/neonatal specific conditions	**42 (27)**
Spontaneous abortion/miscarriage†	29
Premature rupture of membranes	3
Fetal hydrops	2
Neonatal death in 22-week preterm birth	1
Premature delivery	1
Gestational diabetes	1
Vaginal bleeding	1
Stillbirth	1
Shortened cervix	1
Leakage amniotic fluid	1
Calcified placenta	1
Non-pregnancy specific adverse events (top 10) Headache (31), fatigue (29), chills (21), pain in extremity (17), nausea (15), dizziness (14), pain (14), pyrexia (13), injection site pain (13), injection site erythema (10)	**112 (73)**

* Reports received and processed through February 16, 2021

† Frequency of clinically recognized early pregnancy loss for women aged 20–30 years, 9–17%; age 30, 20%; age 40, 40%; age 45, 80%. ACOG Practice Bulletin No. 200: Early Pregnancy Loss. Obstet Gynecol. 2018132(5):e197-e207

DEPARTMENT OF HEALTH & HUMAN SERVICES USA

CDC Centers for Disease Control and Prevention

Other CDC COVID-19 maternal vaccination safety activities

- Vaccine Safety Datalink (VSD)
  - COVID-19 vaccination coverage in pregnant women
  - Risk of miscarriage and stillbirth following COVID-19 vaccination
  - Safety in pregnancy
    - Acute adverse events in pregnancy, longer-term safety assessment of acute adverse events, pregnancy complications and birth outcomes, and infant follow-up for the first year of life
- Clinical Immunization Safety Assessment (CISA) Project
  - Prospective observational cohort study
    - Adverse pregnancy and birth outcomes, serious adverse events, local and systemic reactogenicity, infant health outcomes for first 3 months of life

Maternal vaccination safety summary

- Pregnant women were not specifically included in pre-authorization clinical trials of COVID-19 vaccines
  - Post-authorization safety monitoring and research are the primary ways to obtain safety data on COVID-19 vaccination during pregnancy
- Substantial numbers of self-reported pregnant persons (>30,000) have registered in **v-safe**
- The reactogenicity profile and adverse events observed among pregnant women in **v-safe** did not indicate any safety problem
- Most (73%) reports to VAERS among pregnant women involved non-pregnancy-specific adverse events (e.g., local and systemic reactions)
- Miscarriage was the most frequently reported pregnancy-specific adverse event to VAERS; numbers are within the known background rates based on presumed COVID-19 vaccine doses administered to pregnant women

Decision Tool (not validated but pretty good)

I'm pregnant. Should I get the COVID vaccine?

For most people, getting the COVID vaccine as soon as possible is the safest choice.

However, trials testing the vaccine in pregnant and breastfeeding women have not been completed.

The information below will help you make an informed choice about whether to get the COVID vaccine while you are pregnant or trying to get pregnant.

Your options:

- Get the COVID vaccine as soon as it is available
- Wait for more information about the vaccine in pregnancy

What are the benefits of getting the COVID Vaccine?

1. COVID is dangerous. It is *more* dangerous for pregnant women.

- COVID patients who are pregnant are 5 times more likely to end up in the intensive care unit (ICU) or on a ventilator than COVID patients who are not pregnant.[1]
- Preterm birth may be more common for pregnant women with severe COVID, but other obstetric complications such as stillbirth do not appear to be increased.[2]
- Pregnant women are more likely to die of COVID than non-pregnant women with COVID who are the same age.[3,4]

2. The COVID vaccine will prevent 95% of COVID infections.

- As COVID infections go up in our communities, your risk of getting COVID goes up too.
- Getting the vaccine will prevent you from getting COVID and will help keep you from giving COVID to people around you.

3. The COVID vaccine cannot give you COVID.

- The COVID vaccine has no live virus.[5]
- The COVID vaccine does NOT contain ingredients that are known to be harmful to pregnant women or to the fetus.
- Many vaccines are routinely given in pregnancy and are safe (for example: tetanus, diphtheria, and flu).

More details about how the vaccine works can be found on page 5.

What are the risks of getting the COVID vaccine?

1. The COVID vaccine has not yet been tested in pregnant women.

- The vaccine was tested in over 20,000 people, and there were no serious side effects. However, it was not tested in pregnant women.
- We do not have data on whether the vaccine works as well in pregnancy as it did in the study of non-pregnant individuals.
- We do not have data on whether there are unique downsides in pregnancy, like different side effects or an increased risk of miscarriage or fetal abnormalities.

2. People getting the vaccine will probably have some side effects.

- Although there were no serious side effects reported, many people had some side effects. The side effects of the vaccine were:
  - injection site reactions like sore arm (84%)
  - fatigue (62%)
  - headache (55%)
  - muscle pain (38%)
  - chills (32%)
  - joint pain (24%)
  - fever (14%)
- About 1% of people will get a high fever (over 102°F). A persistent high fever during the first trimester of pregnancy might increase the risk of congenital defects or miscarriage. For those reasons, you may choose to delay your COVID vaccine until after the first trimester.
- The CDC recommends using Tylenol (acetaminophen) during pregnancy if you have a high fever.

What do the experts recommend?

COVID is very dangerous and can spread very easily. Because of this, ***"the Pfizer-COVID vaccine is recommended for persons 16 years of age and older in the U.S. population under the FDA's Emergency Use Authorization."*** (CDC)[6]

However, because there are no studies of pregnant women yet, there are no clear recommendations for pregnant women. This is standard for a new drug and is not due to any particular concern with this vaccine.

The **Society for Maternal-Fetal Medicine** ***strongly recommends*** that pregnant individuals have access to COVID vaccines. They recommend that each person have a discussion with their healthcare professional about their own personal choice.[7]

The **American College of Obstetricians and Gynecologists** recommends that the COVID vaccine should ***not*** be withheld from pregnant individuals who meet criteria for vaccination.[8]

What else should I think about to help me decide?

1 Make sure you understand as much as you can about COVID and about the vaccine. Ask a trusted source, like your midwife or doctor. Page 5 has more information about the vaccine.

2 Think about your own personal risk.

Look at the columns below and think about *your* risk of getting COVID (Left). Think about your safety - are you able to stay safe (Right)?

The risks of getting sick from COVID are higher if…	If you are not at higher risk for COVID and…
☐ You have contact with people outside your household who do not wear masks	☐ …you are always able to wear a mask
☐ You are 35 years old or older	☐ …you and the people you live with can socially distance from others for your whole pregnancy
☐ You are overweight	☐ …your community does NOT have high or increasing COVID cases
☐ You have other medical problems such as diabetes, high blood pressure, or heart disease	☐ …you think the vaccine itself will make you very nervous (you are more worried about the unknown risks than about getting COVID)
☐ You are a smoker	☐ …you have had a severe allergic reaction to a vaccine
☐ You are a racial or ethnic minority, or your community has a high rate of COVID infections	
☐ You are healthcare worker[9]	
If you are at a higher risk of getting COVID, it probably makes sense to get the vaccine.	**… it might make sense for you to wait for more information.**

Baystate Health | University of Massachusetts Medical School UMASS

Updated December 14, 2020

What about breastfeeding?

The **Society for Maternal-Fetal Medicine** reports that there is no reason to believe that the vaccine affects the safety of breastmilk.[7] When we have an infection or get a vaccine, our bodies make antibodies to fight the infection. Antibodies formed from vaccines given during pregnancy do pass into the breastmilk and then to the baby to help prevent infections. Since the vaccine does not contain the virus, there is no risk of breastmilk containing the virus.

Summary

1. COVID seems to cause more harm in pregnant women than in women of the same age who are not pregnant.
2. The risks of getting the COVID vaccine during pregnancy are thought to be small but are not totally known.
3. You should consider your own personal risk of getting COVID. If your personal risk is high, or there are many cases of COVID in your community, it probably makes sense for you to get the vaccine while pregnant.
4. Whether to get the vaccine during pregnancy is your choice.

What do pregnant doctors think?

We know COVID can be terrible in pregnancy, and we know the vaccine doesn't contain live virus. As someone who is approaching my third trimester and working on the front lines of this disease, for me the choice is clear, I intend to be first in line as soon as they will let me have one. (Pregnant Emergency Department Doctor)

I am a little nervous about getting something that hasn't been tested in pregnant patients. Early pregnancy is a nerve-wracking time, even without the unknown of a new vaccine. So, I went over the risks and benefits of getting or not getting it as a front-line worker - with myself, my partner, and my doctors. We ended up deciding I should get the vaccine. (Pregnant Emergency Department Doctor)

I am still breastfeeding my baby, and I think the risk of exposing my infant and other children and partner to COVID is far greater than any theoretical risk this novel vaccine may have. I've decided to get vaccinated whenever it becomes available. (Breastfeeding OB/GYN Doctor)

Do you have more questions? Call your doctor or midwife to talk about your own personal decision.

Thoughts about this tool?

Was this decision aid helpful? Please take a moment to give us feedback about this decision aid at https://is.gd/COVIDVac or by scanning the QR code below. We need your help!

Feedback about your experience with the vaccine

If you decide to get the vaccine, you will get a "V-safe information sheet" with instructions about the V-safe website and app for reporting symptoms after your vaccine. This will help researchers track side effects and learn more about how well the vaccine works.

More information about the COVID Vaccine

How does the COVID vaccine work?

- The Pfizer COVID vaccine is an mRNA vaccine (messenger RNA).
- mRNA is not new - our bodies are full of it. mRNA vaccines been studied for the past two decades.
- mRNA vaccines mimic how viruses work. The mRNA is like a recipe card that goes into your body and makes one recipe for a brief time. The recipe is for a small part of the virus (the spike protein).
- When this spike protein is released from cells, the body recognizes it as foreign and the immune system responds. This immune response causes the side effect symptoms (like aches and fever) but leads to improved immunity.
- mRNA breaks down quickly, so it only lasts a brief time.
- This is also how the other viruses like a cold virus work – viruses use our body and cells to make their proteins. Then our immune system attacks those proteins to keep us healthy.
- There is no live virus in this vaccine and there is no way for the vaccine to give people COVID.[5]

What did the research show?

We know that the Pfizer vaccine trial of over 40,000 people has shown that the vaccine lowers a person's chance of getting COVID and severe COVID. In this study, 20,000 people got the vaccine and 20,000 people got a placebo (like a sugar pill).

- After one dose, the vaccine appears to be 50% effective. After 2 doses, the vaccine is 95% effective.
- In other words, **for every 100 people who got COVID in the placebo group, only 5 people got COVID in the vaccine group.**
- There were 9 cases of severe COVID in the placebo group and 1 case in the vaccine group.
- There were no serious safety concerns.

Intended Use: This decision aid is intended for use by pregnant women (and women planning on becoming pregnant) who are considering getting the COVID-19 vaccine, as well as their healthcare providers, and their friends and family. It was created by the *Shared Decision-Making: COVID Vaccination in Pregnancy* working group at the University of Massachusetts Medical School – Baystate. This group consists of experts in the fields of OB/GYN, Maternal-Fetal Medicine, Shared Decision-Making and risk communication, Emergency Medicine, and current COVID-19 research. Questions should be directed to Dr. Elizabeth Schoenfeld, Elizabeth.Schoenfeld@bhs.org. Feedback regarding the utility of this decision aid can be directed through the survey (see link on page 5).

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Updated December 14, 2020

1. DeBolt CA, et al. Pregnant women with severe or critical COVID-19 have increased composite morbidity compared to non-pregnant matched controls. Am J Obstet 2020 Nov doi: 10.1016/j.ajog.2020.11.022
2. Adhikari EH, et al. Pregnancy outcomes among women with and without severe acute respiratory syndrome coronavirus 2 infection. JAMA Network Open 2020 Nov 3(11):e2029256
3. DiMascio D, WAPM working group on COVID-19. Maternal and Perinatal Outcomes of Pregnancy Women with SARS-coV-2 infection. Ultrasound Obstet Gynecol. 2020 Sept. doi: 10.1002/uog.23107.
4. Centers for Disease Control and Prevention. Update: Characteristics of Symptomatic Women of Reproductive Age with Laboratory-Confirmed SARS-CoV-2 Infection by Pregnancy Status — United States, January 22–October 3, 2020. November 2020:1-7.
5. Abbasi J. COVID-19 and mRNA Vaccines—First Large Test for a New Approach. *JAMA*. 2020;324(12):1125–1127. doi:10.1001/jama.2020.16866
6. https://www.cdc.gov/vaccines/acip/recs/grade/covid-19-pfizer-biontech-etr.html (Accessed Dec14, 2020)
7. SMFM statement on COVID vaccination in pregnancy: https://www.smfm.org/publications/339-society-for-maternal-fetal-medicine-smfm-statement-sars-cov-2-vaccination-in-pregnancy
8. https://www.acog.org/en/clinical/clinical-guidance/practice-advisory/articles/2020/12/vaccinating-Pregnant-and-Lactating-Patients-Against-COVID-19 (Accessed December 14, 2020)
9. Mutambudzi M, Niedwiedz C, Macdonald EB, *et al*. Occupation and risk of severe COVID-19: prospective cohort study of 120 075 UK Biobank participants. *Occupational and Environmental Medicine* Published Online First: 09 December 2020. doi: 10.1136/oemed-2020-106731

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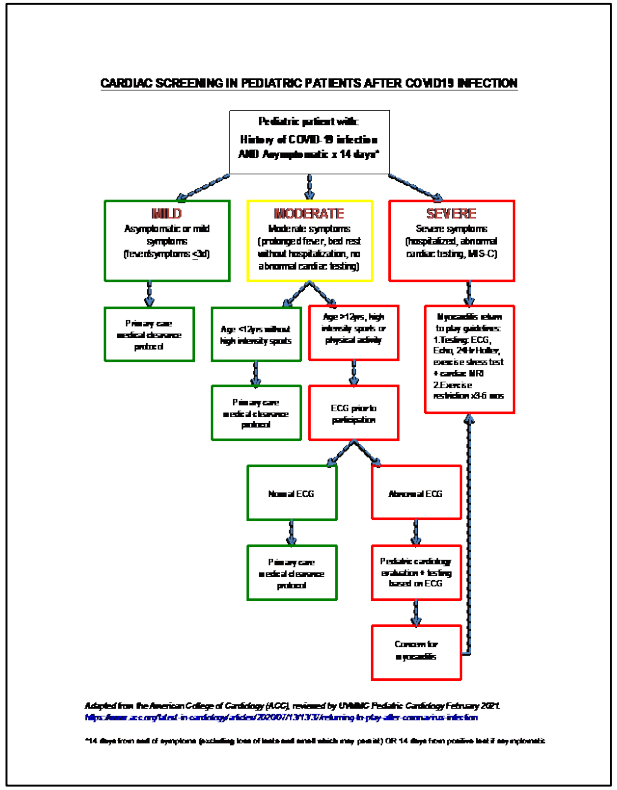
Updated December 14, 2020

Thank you!!

3 DOCUMENTS

1) Cardiac screening:



CARDIAC SCREENING IN PEDIATRIC PATIENTS AFTER COVID19 INFECTION

Pediatric patient with:
History of COVID-19 infection
AND Asymptomatic x 14 days*

MILD
Asymptomatic or mild symptoms (fever/symptoms ≤3d)

MODERATE
Moderate symptoms (prolonged fever, bed rest without hospitalization, no abnormal cardiac testing)

SEVERE
Severe symptoms (hospitalized, abnormal cardiac testing, MIS-C)

Primary care medical clearance protocol

Age <12yrs, without high intensity sports

Age >12yrs, high intensity sports or physical activity

Primary care medical clearance protocol

ECG prior to participation

Myocarditis return to play guidelines:
1.Testing: ECG, Echo, 24-hr Holter, exercise stress test + cardiac MRI
2.Exercise restriction x3-6 mos

Normal ECG

Abnormal ECG

Primary care medical clearance protocol

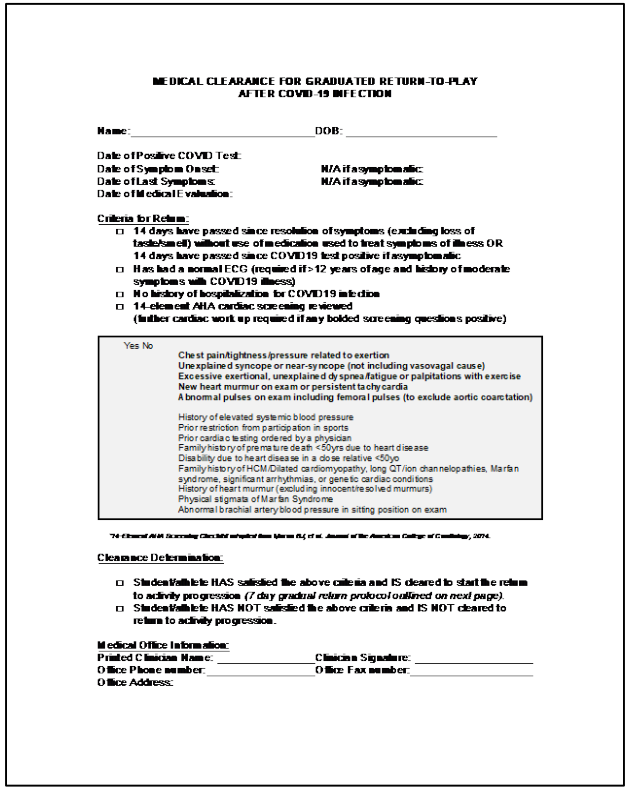
Pediatric cardiology evaluation + testing based on ECG

Concern for myocarditis

Adapted from the American College of Cardiology (ACC), reviewed by UVaMC Pediatric Cardiology February 2021.
https://www.acc.org/latest-in-cardiology/articles/2020/07/31/13/07/returning-to-play-after-coronavirus-infection

*14 days from onset of symptoms (excluding loss of taste and smell which may persist) OR 14 days from positive test if asymptomatic

2) Medical Clearance:



MEDICAL CLEARANCE FOR GRADUATED RETURN-TO-PLAY AFTER COVID-19 INFECTION

Name:_____ **DOB:** _____

Date of Positive COVID Test:
Date of Symptom Onset: **N/A if asymptomatic:**
Date of Last Symptoms: **N/A if asymptomatic:**
Date of Medical Evaluation:

Criteria for Return:

- ☐ **14 days have passed since resolution of symptoms (excluding loss of taste/smell) without use of medication used to treat symptoms of illness OR 14 days have passed since COVID19 test positive if asymptomatic**
- ☐ **Has had a normal ECG (required if >12 years of age and history of moderate symptoms with COVID19 illness)**
- ☐ **No history of hospitalization for COVID19 infection**
- ☐ **14-element AHA cardiac screening reviewed (further cardiac work up required if any bolded screening questions positive)**

Yes	No	
		Chest pain/tightness/pressure related to exertion
		Unexplained syncope or near-syncope (not including vasovagal cause)
		Excessive exertional, unexplained dyspnea/fatigue or palpitations with exercise
		New heart murmur on exam or persistent tachycardia
		Abnormal pulses on exam including femoral pulses (to exclude aortic coarctation)
		History of elevated systemic blood pressure
		Prior restriction from participation in sports
		Prior cardiac testing ordered by a physician
		Family history of premature death <50yrs due to heart disease
		Disability due to heart disease in a close relative <50yo
		Family history of HCM/Dilated cardiomyopathy, long QT/ion channelopathies, Marfan syndrome, significant arrhythmias, or genetic cardiac conditions
		History of heart murmur (excluding innocent/resolved murmurs)
		Physical stigmata of Marfan Syndrome
		Abnormal brachial artery blood pressure in sitting position on exam

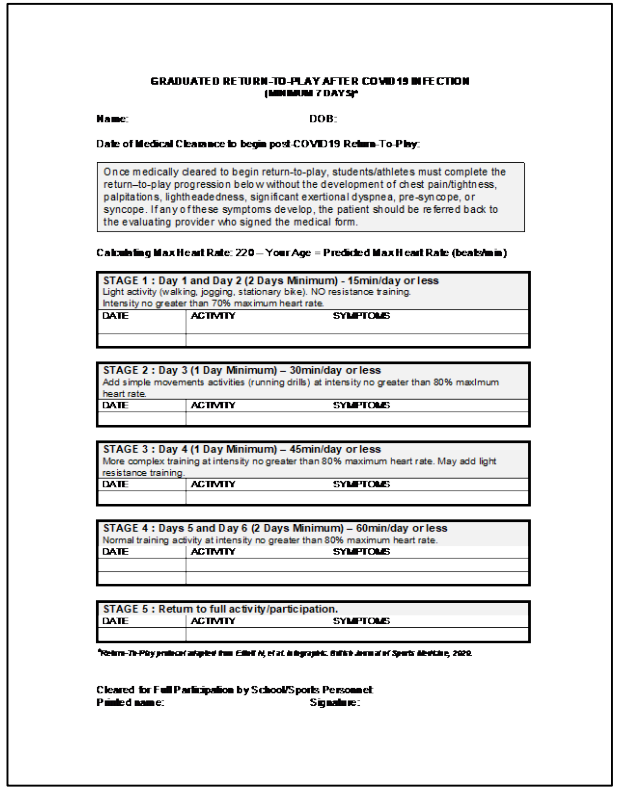
*14-Element AHA Screening Checklist adapted from Upton PA, et al. Journal of the American College of Cardiology, 2014.

Clearance Determination:

- ☐ **Student/Athlete HAS satisfied the above criteria and IS cleared to start the return to activity progression *(7 day gradual return protocol outlined on next page).***
- ☐ **Student/Athlete HAS NOT satisfied the above criteria and IS NOT cleared to return to activity progression.**

Medical Office Information:
Printed Clinician Name: _____ **Clinician Signature:** _____
Office Phone number: _____ **Office Fax number:** _____
Office Address:

3) Return-to-play:



GRADUATED RETURN-TO-PLAY AFTER COVID19 INFECTION
(MINIMUM 7 DAYS)*

Name: **DOB:**

Date of Medical Clearance to begin post-COVID19 Return-To-Play:

Once medically cleared to begin return-to-play, students/athletes must complete the return–to-play progression below without the development of chest pain/tightness, palpitations, lightheadedness, significant exertional dyspnea, pre-syncope, or syncope. If any of these symptoms develop, the patient should be referred back to the evaluating provider who signed the medical form.

Calculating Max Heart Rate: 220 – Your Age = Predicted Max Heart Rate (beats/min)

STAGE 1 : Day 1 and Day 2 (2 Days Minimum) - 15min/day or less
Light activity (walking, jogging, stationary bike). NO resistance training.
Intensity no greater than 70% maximum heart rate.

DATE	ACTIVITY	SYMPTOMS

STAGE 2 : Day 3 (1 Day Minimum) – 30min/day or less
Add simple movements activities (running drills) at intensity no greater than 80% maximum heart rate.

DATE	ACTIVITY	SYMPTOMS

STAGE 3 : Day 4 (1 Day Minimum) – 45min/day or less
More complex training at intensity no greater than 80% maximum heart rate. May add light resistance training.

DATE	ACTIVITY	SYMPTOMS

STAGE 4 : Days 5 and Day 6 (2 Days Minimum) – 60min/day or less
Normal training activity at intensity no greater than 80% maximum heart rate.

DATE	ACTIVITY	SYMPTOMS

STAGE 5 : Return to full activity/participation.

DATE	ACTIVITY	SYMPTOMS

*Return-To-Play protocol adapted from Elliott N, et al. Infographic. British Journal of Sports Medicine, 2020.

Cleared for Full Participation by School/Sports Personnel
Printed name: **Signature:**

Questions/feedback under consideration

Schools

- Categorizing what activities are appropriate at different stages in the protocol (PE, recess, intramural sports, school sports)
- Who is monitoring the child during the 7-day protocol? (School nurses, Athletic Trainers, PE teachers)
- What is school role w/protocol for monitoring and documenting return-to-play?
  - When should this protocol be enforced in schools and for what activities?
- What if students had COVID-19 in the past and have already returned-to-play/sports/physical activity?
- School needs rationale to explain/enforce this protocol to families/ coaches/staff

Questions/feedback under consideration (cont'd.)

Childcare and out-of-school time

- Categorizing what activities are appropriate at different stages in the protocol – general/outdoor play, active field trips (hiking, rowing, snowshoeing, skiing), going for walk, open gym
- Who is monitoring the child during the 7-day protocol?
- What is the role of the childcare or out-of-school facility in monitoring and documenting return-to-play protocol?

Questions/feedback under consideration (cont'd.)

Families

- Categorizing what activities appropriate at different stages in protocol (Outdoor activities [hiking, sledding, skiing, biking, going for walks], general play with other children, lessons, club sports, fitness activities)
- What is the parent role in monitoring the child.
  - Who does math for the max HR & percentages to be achieved at each stage?
  - Who will teach to take heart rate of child?
- Risk of myocarditis will be a new concept for families, discuss risk to families, symptoms, is it safe to have kids participating in activity.
  - Quelling anxiety around safety of going to school with risk of getting Covid-19 and having outcomes like myocarditis
- Protocol should be explainable at 5th grade literacy level for families/ non-healthcare providers

Happening Now

- Big Change Roundup: bigchangeroundup.org
  - Largest fundraiser for the UVMCH; funds raised support patients and families (e.g.) some child life services; new program startup (e.g., Transgender Program; safe sleep program on Mother Baby Unit); injury prevention initiatives; food insecurity initiative (CSC); support for inpt. families (ferry passes, gas cards, meal vouchers)
- Please help promote personally & through your practices/ orgs.
- **3/19-3/21:** Big Change Roundup Drive Thru Collections (3 loc.)
- **3/26/2021:** Big Change Roundup Final Total Announcement (counted off air/off-site)

Questions/Discussion

- Q & A Goal: monitor/respond in real time; record/disseminate/revisit later as needed.
- **For additional questions, please e-mail:** vchip.champ@med.uvm.edu
  - **What do *you* need** – how can we be helpful (specific guidance)?
- **VCHIP CHAMP VDH COVID-19 website:** https://www.med.uvm.edu/vchip/projects/vchip_champ_vdh_covid-19_updates
- Next CHAMP call – ***Friday, March 5, 2021 – 12:15 – 12:45 pm (Lee/Raszka update!)***
- Generally back to **Monday/Wednesday/Friday** schedule
- Please tune in to VMS call with VDH Commissioner Levine:

  ***Thursday, March 4, 2021* – *12:30-1:00 p.m.* – Zoom platform & call information:**
- **Join *Zoom* Meeting:** https://us02web.zoom.us/j/86726253105?pwd=VkVuNTJ1ZFQ2R3diSVdqdlJ2ZG4yQT09
  - Meeting ID: 867 2625 3105 / Password: 540684
- One tap mobile - +1 646 876 9923,,86726253105#,,,,0#,,540684#