COVID 19
Vaccines and Outpatient Options

Tanner Clinic 12/15/20

Key Topics

1. Pfizer Vaccine Approved and distribution is starting
2. Monoclonal antibodies approved for high risk outpatients with COVID
3. Home monitoring options for COVID
4. Data for Outpatient Treatments for COVID

Pfizer COVID vaccine

Moderna likely approval this week by VRBAC and ACIP

Administration

- 2-dose series administered intramuscularly 3 weeks apart
- Administration of 2nd dose within 4-day grace period (e.g., day 17-21) considered valid
- If >21 days since 1st dose, 2nd dose should be administered at earliest opportunity (but no doses need to be repeated)
- Both doses are necessary for protection; efficacy of a single dose has not been systematically evaluated

Background

- Systemic signs and symptoms following COVID-19 vaccination can include fever, fatigue, headache, chills, myalgia, and arthralgia. Most are
  - mild to moderate in severity
  - occur within the first 3 days of vaccination
  - resolve within 1-2 days of onset
- Systemic adverse reactions were more commonly reported after the second dose than after the first dose and were generally more frequent and severe in persons aged 18–55 years than in those aged >55 years.*
- Cough, shortness of breath, rhinorrhea, sore throat, or loss of taste or smell are not consistent with post-vaccination symptoms.

* https://www.cdc.gov/mmwr/volumes/69/wr/mm6950e2.htm

Reactogenicity

Systemic symptoms more common after **second** dose

Data from published Phase I/II trials

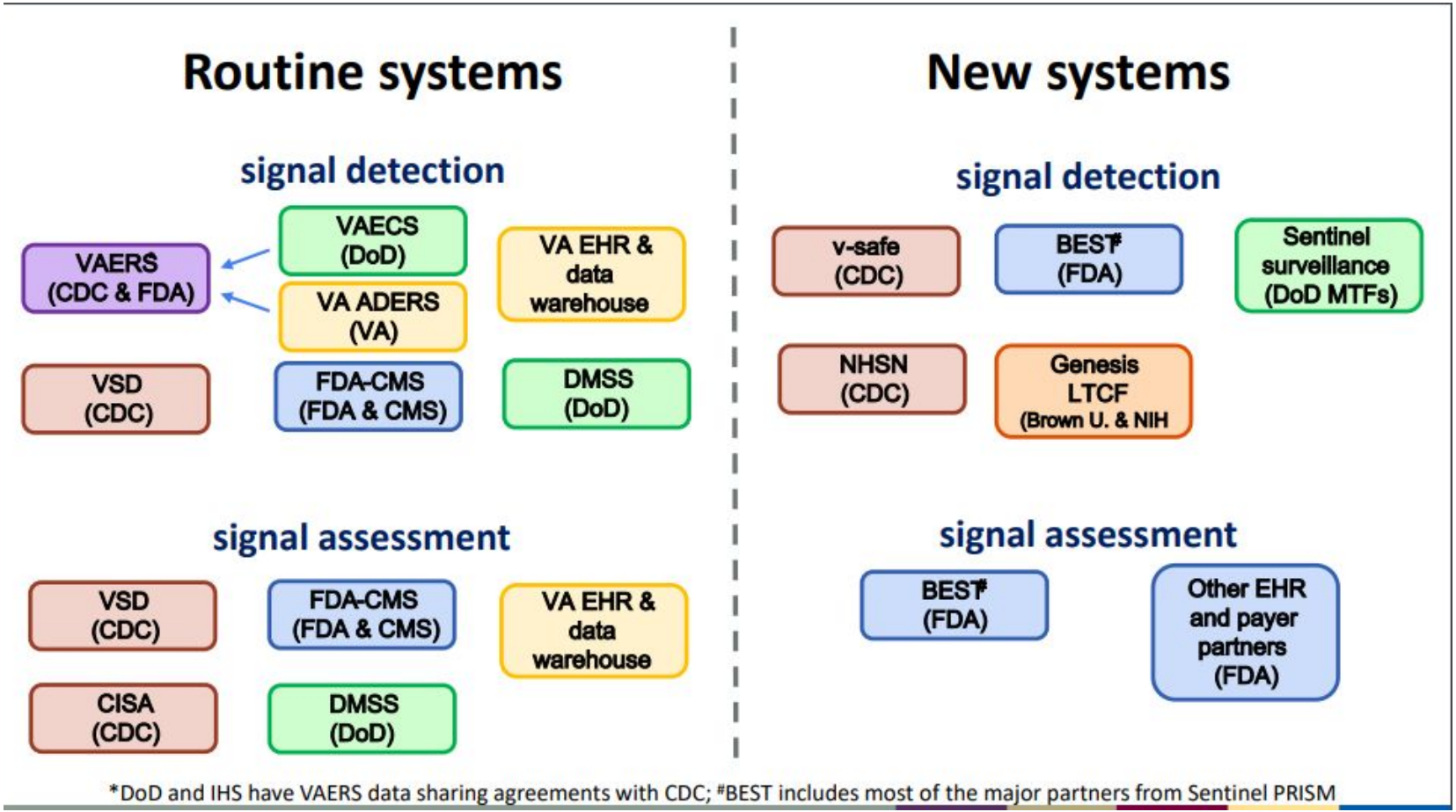
Moderna[1] Adults 18–55 years of age

100µg	Post-dose 1			Post-dose 2		
N=15	**Mild**	**Moderate**	**Severe**	**Mild**	**Moderate**	**Severe**
Fever	—	—	—	5 (33%)	1 (7%)	—
Headache	4 (27%)	—	—	5 (33%)	4 (27%)	—
Myalgia	1 (7%)	—	—	2 (13%)	6 (40%)	—

Pfizer[2]

30µg	Post-dose 1			Post-dose 2		
N=12	**Mild**	**Moderate**	**Severe**	**Mild**	**Moderate**	**Severe**
Fever	1 (8%)	1 (8%)	—	—	2 (17%)	—
Headache	3 (25%)	1 (8%)	2 (17%)	6 (50%)	2 (17%)	—
Myalgia	1 (8%)	1 (8%)	1 (8%)	4 (33%)	3 (25%)	—

[1]Jackson et al. An mRNA Vaccine against SARS-CoV-2- Preliminary report. NEJM 2020;20:1920-1931.
[2]Walsh et al. Safety and immunogenicity of two RNA-Based COVID-19 vaccine candidates. NEJM 2020; online publication Oct 14.



*DoD and IHS have VAERS data sharing agreements with CDC; #BEST includes most of the major partners from Sentinel PRISM

Active Safety Monitoring for COVID-19 Vaccines

- **V-safe** is a new CDC smart-phone based monitoring program for COVID-19 vaccine safety
  - Uses text messaging and web surveys to check-in with vaccine recipients after vaccination
  - Participants can report any side effects or health problems after COVID-19 vaccination
  - Includes active telephone follow-up by CDC for reports of significant health impact

cdc.gov/vsafe

CDC asks that:

- Healthcare providers help us get as many people to use **v-safe** as possible
  - give a one-page **info sheet** to patients at the time of vaccination
  - counsel patients on the importance of enrolling in **v-safe**
- CDC has created an electronic version of the **v-safe** info sheet for a toolkit for distribution to public health and healthcare partners

Get vaccinated.
Get your smartphone.
Get started with v-safe.

What is v-safe?

V-safe is a smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins after you receive a COVID-19 vaccination. Through ***v-safe***, you can quickly tell CDC if you have any side effects after getting the COVID-19 vaccine. Depending on your answers, someone from CDC may call to check on you. And ***v-safe*** will remind you to get your second COVID-19 vaccine dose if you need one.

Your participation in CDC's ***v-safe*** makes a difference—it helps keep COVID-19 vaccines safe.

How can I participate?

Once you get a COVID-19 vaccine, you can enroll in ***v-safe*** using your smartphone. Participation is voluntary and you can opt out at any time. To opt out, simply text "STOP" when ***v-safe*** sends you a text message. You can also start ***v-safe*** again by texting "START."

How long do v-safe check-ins last?

During the first week after you get your vaccine, ***v-safe*** will send you a text message each day to ask how you are doing. Then you

v-safe
after vaccination
health checker

Use your smartphone to tell CDC about any side effects after getting the COVID-19 vaccine. You'll also get reminders if you need a second vaccine dose.

Special Considerations….

Persons with known current SARS-CoV-2 infection

- Vaccination should be deferred until recovery from acute illness (if person had symptoms) *and* criteria have been met to discontinue isolation
- No minimal interval between infection and vaccination
- However, current evidence suggests reinfection uncommon in the 90 days after initial infection and thus persons with documented acute infection in the preceding 90 days may defer vaccination until the end of this period, if desired

https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-in-home-patients.html
https://www.cdc.gov/coronavirus/2019-ncov/hcp/duration-isolation.html

Pregnant women

- There are no data on the safety of COVID-19 vaccines in pregnant women
  - Animal developmental and reproductive toxicity (DART) studies are ongoing
  - Studies in humans are ongoing and more planned

- mRNA vaccines and pregnancy
  - Not live vaccines
  - They are degraded quickly by normal cellular processes and don't enter the nucleus of the cell

- COVID-19 and pregnancy
  - Increased risk of severe illness (ICU admission, mechanical ventilation and death)
  - Might be an increased risk of adverse pregnancy outcomes, such as preterm birth

- If a woman is part of a group (e.g., healthcare personnel) who is recommended to receive a COVID-19 vaccine and is pregnant, she may choose to be vaccinated. A discussion with her healthcare provider can help her make an informed decision.

https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/pregnancy-breastfeeding.html

Considerations to minimize the impact of post-vaccination systemic signs and symptoms on healthcare staffing

- Vaccinating HCP preceding 1-2 days off, during which they are not required to be in the facility.
- Staggering delivery of vaccine to HCP in the facility so that not all HCP in a single department, service, or unit are vaccinated at the same time.

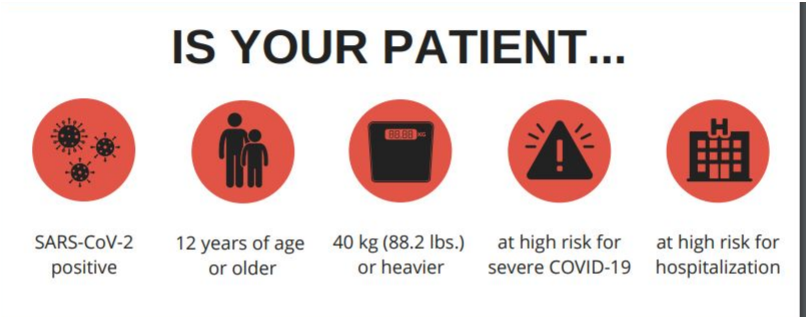
Signs and symptoms that may be from either COVID-19 vaccination, SARS-CoV-2 infection, or another infection

- Signs and Symptoms
  - Presence of ANY systemic signs and symptoms (e.g., fever, fatigue, headache, chills, myalgia, arthralgia) that are consistent with a post-vaccination reaction, SARS-CoV-2 infection, or another infectious etiology.
- Suggested approach
  - HCP who meet the following criteria may be considered for return to work without viral testing for SARS-CoV-2:
    - Feel well enough and are willing to work, and
    - Are afebrile, and
    - Systemic signs and symptoms are limited only to those observed following vaccination.

Monoclonal Antibody

Bamlanivimab (LY-CoV555) –
https://www.phe.gov/emergency/events/COVID19/investigationMCM/Bamlanivimab/Pages/default.aspx

Casirivimab/Imdevimab (Regeneron) –
https://www.phe.gov/emergency/events/COVID19/investigation-MCM/cas_imd/Pages/default.aspx



COVID 19 Risk Score Calculator

Demographic Risk Factors	Points
Male	1
Age	**0.5 for every decade:** 12-20=**1**, 21-30=**1.5**, 31-40=**2**, 41-50=**2.5**, 51-60=**3**, 61-70=**3.5**, 71-80=**4**, 81-90=**4.5**, 91-100=**5**, >100=**5.5**
Non-White Race or Hispanic/Latinx Ethnicity	**2**
Highest-Risk Comorbidities	
Diabetes melitus	**2**
Severely Immunocompromised	**2**
Obesity (BMI>30) calculator	**2**
Other High-Risk Comorbidities	
Hypertension	**1**
Coronary artery disease	**1**
Cardiac Arrhythmia	**1**
Congestive Heart Failure	**1**
Chronic Kidney Disease	**1**
Chronic Pulmonary Disease	**1**
Chronic Liver Disease	**1**
Cerebrovascular disease	**1**
Chronic Neurologic disease	**1**
Symptom Risk Factor	
New Shortness of Breath	**1**
Total	

https://coronavirus.utah.gov/noveltherapeutics

- Score of 5- Average risk
- Score of 6.5-200% greater risk
- Score of 8-300% greater risk
- Score of 9- 400% greater risk

Davis Hospital
Layton IHC

Remote Patient Monitoring for COVID

1. COVID creates hypoxia out of proportion to dyspnea
2. Must be COVID-19 positive by testing or a high probability PUI
3. Does not meet criteria for admission and is safe for outpatient management
4. Has high risk comorbidity-calculate risk score
5. Can track and report (or your office call for daily to twice daily measurements)
6. STRICT ER precautions- LOOK FOR HYPOXIA AT REST and HYPOXIA WITH EXERCISE (1 min)

2020 RPM Codes

CMS Guidelines: For providing RPM services to patients, as well for staff time spent monitoring these patients. These actions are billable through four CPT codes:

- 99453: Initial set up and patient education
- 99454: Supply of devices and collection, transmission, and summary of services
- 99457: First 20 minutes of remote physiologic monitoring by clinical staff/MD/QHCP
- 99458: For an additional 20 minutes of remote physiologic monitoring by clinical staff/MD/QHCP

Outpatient Therapeutics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Aspirin Use is Associated with Decreased Mechanical Ventilation, ICU Admission, and In-Hospital Mortality in Hospitalized Patients with COVID-19

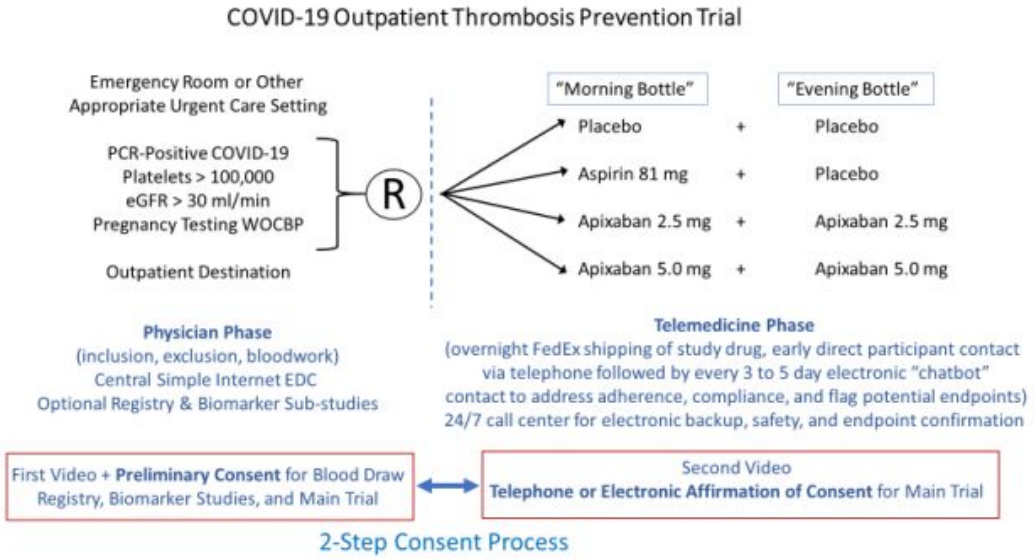
aspirin use was independently associated with

- decreased risk of mechanical ventilation (adjusted HR 0.56, 95% CI 0.37-0.85, p=0.007),
- ICU admission (adjusted HR 0.57, 95% CI 0.38-0.85, p=0.005),
- in-hospital mortality (adjusted HR 0.53, 95% CI 0.31-0.90, p=0.02).

People with COVID-19 are at an increased risk of blood clots, particularly if they are in the ICU.

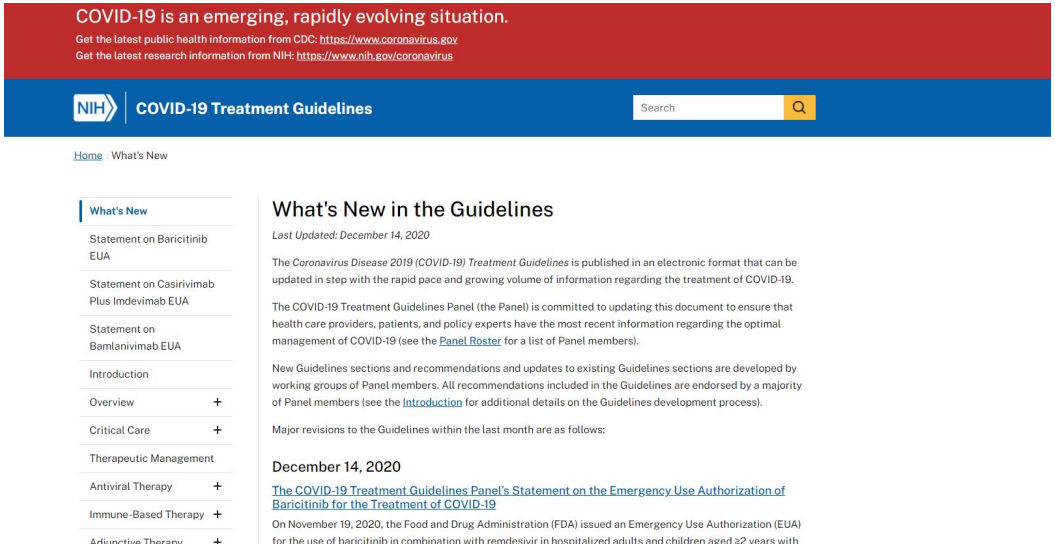
Some studies suggest between 30 percent and 70 percent of people with COVID-19 in the ICU will develop blood clots in the legs or lungs.

Aspirin is being studies in the outpatients with COVID



Study is starting within 14 days of diagnosis and 45 days

https://www.covid19treatmentguidelines.nih.gov/whats-new/



THANKS! CALL ANYTIME, Stay Well!