COVID-19 Update: Grand Rounds

Sherrill Brown, MD
Medical Director, Infection Prevention

07/20/2021

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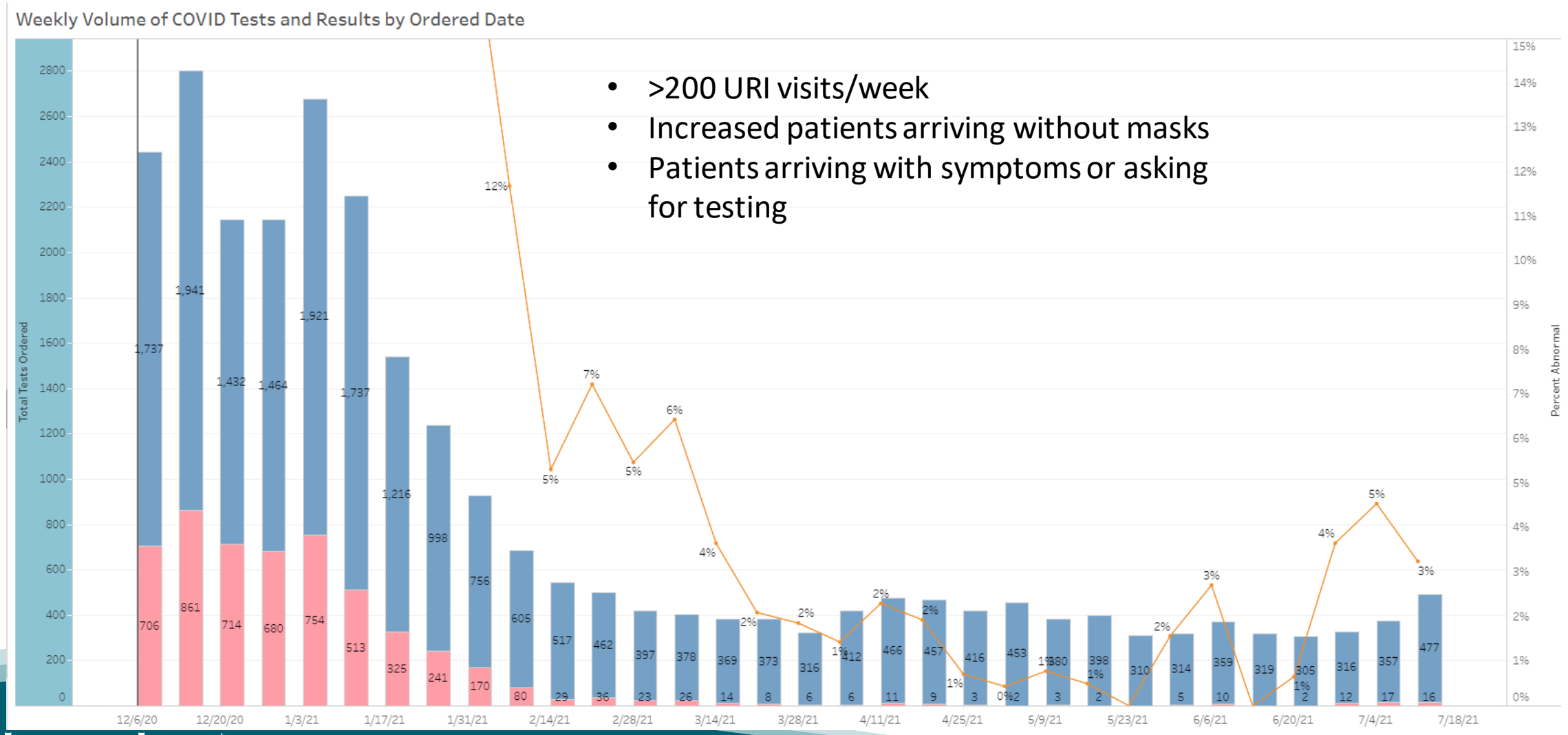
Main Points of Discussion

- **Response to Increased Cases**
- **Refresher on PPE Recs**
- **Updates on Testing Recommendations**
- **Refresher on Treatment with Monoclonal Ab**
- **Vaccine Dos and Don’ts**
- **Questions**

Main Points of Discussion

- **Response to Increased Cases**
  - Following safe environment practices is still critical!
  - Screening is vital to holding the line and treating patients in the most appropriate location for safety (In an isolation room).

AltaMed: Increased URI visit, testing and positivity rate



- >200 URI visits/week
- Increased patients arriving without masks
- Patients arriving with symptoms or asking for testing

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How is COVID-19 Spread?

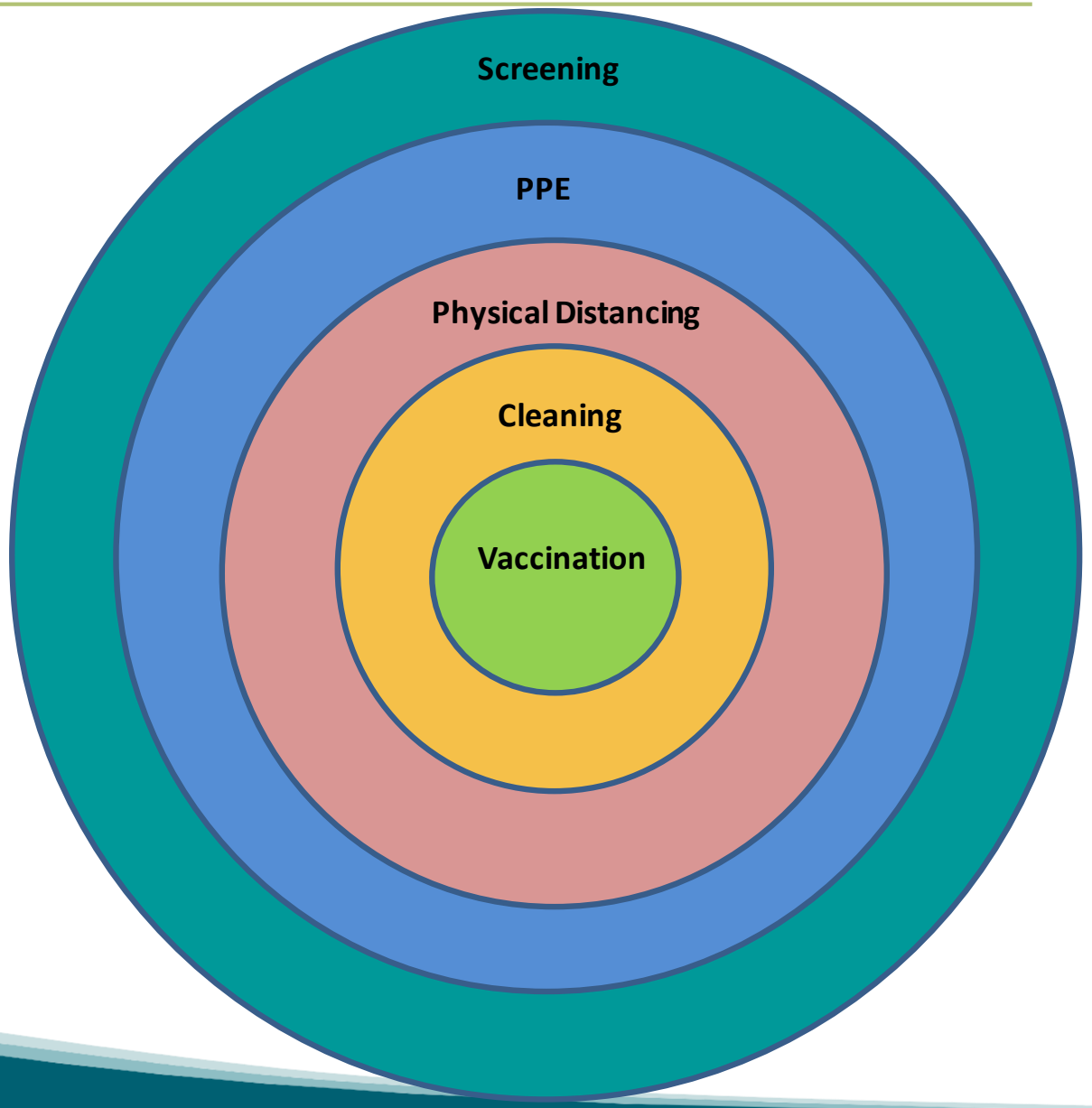
- Aerosol Transmission

- Isolation Precautions include:
  - ✓ Standard Precautions
  - ✓ Contact Precautions
  - ✓ Airborne Precautions
  - ✓ Droplet Precautions

AltaMed COVID19 Safe Environment

5 Elements of Prevention for COVID-19

1. Screening all patients and staff for COVID-19 sx or exposure prior to entry
2. Universal Mask Wearing/Appropriate PPE at all times by all staff and patients
3. Physical Distancing 6ft
4. Cleaning (Air, surfaces, hands)
5. Vaccination!



How do we identify patients at risk?

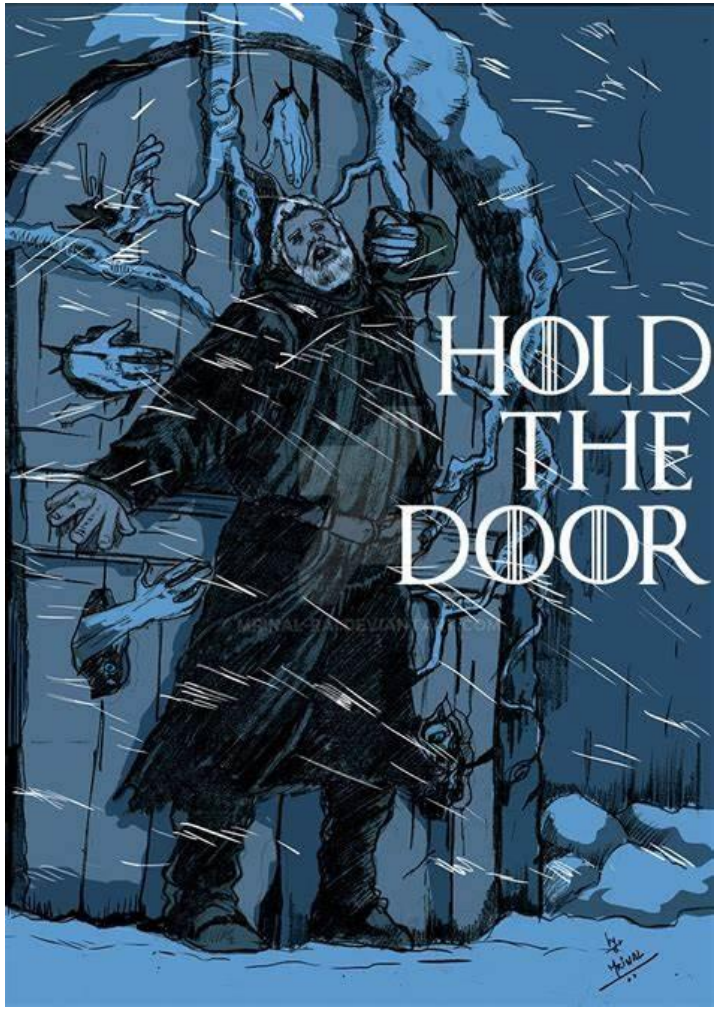
1. **Screen patients when calling into the PSC for symptoms of COVID or exposure to COVID.**
2. **Screen patients when arriving to the clinic prior to entry.**
3. **Screening patients when checking into the electronic health record upon arrival.**

What if a patient is at risk for COVID?

1. **Offer telehealth visit prior to F2F visit.**
2. **Upon identifying the patient is at risk for COVID at the clinic, they should be immediately taken to an isolation room with a HEPA unit turned on.**
3. **All staff that interact with a patient at risk for COVID should be wearing full PPE including: eye protection, gown, gloves, N95 respirator.**
4. **Gown, Gloves can be disposed of after the patient encounter.**
5. **N95 mask can be disposed of after that patient or shift if wearing as extended use.**
6. **Eye protection should be cleaned with disinfectant wipes after use and stored in a dry clean paper bag labeled with the staff member's name or be hung on a hook with name on eye protection.**
7. **Wash hands before and after donning, doffing and cleaning PPE.**

What if a patient is at risk for COVID?

1. **“Hold the door!”**
2. **Discuss with screeners and front office the importance of communicable disease screening.**
    1. They are the last line of defense for our clinic.
    2. Encourage patients to be honest and truthful.
    3. Ask for genuine responses from patients.
3. **Remind patients and visitors that they cannot enter without a mask.**
    1. This is a CDC and Department of Health Requirement for healthcare facilities regardless of vaccine status.



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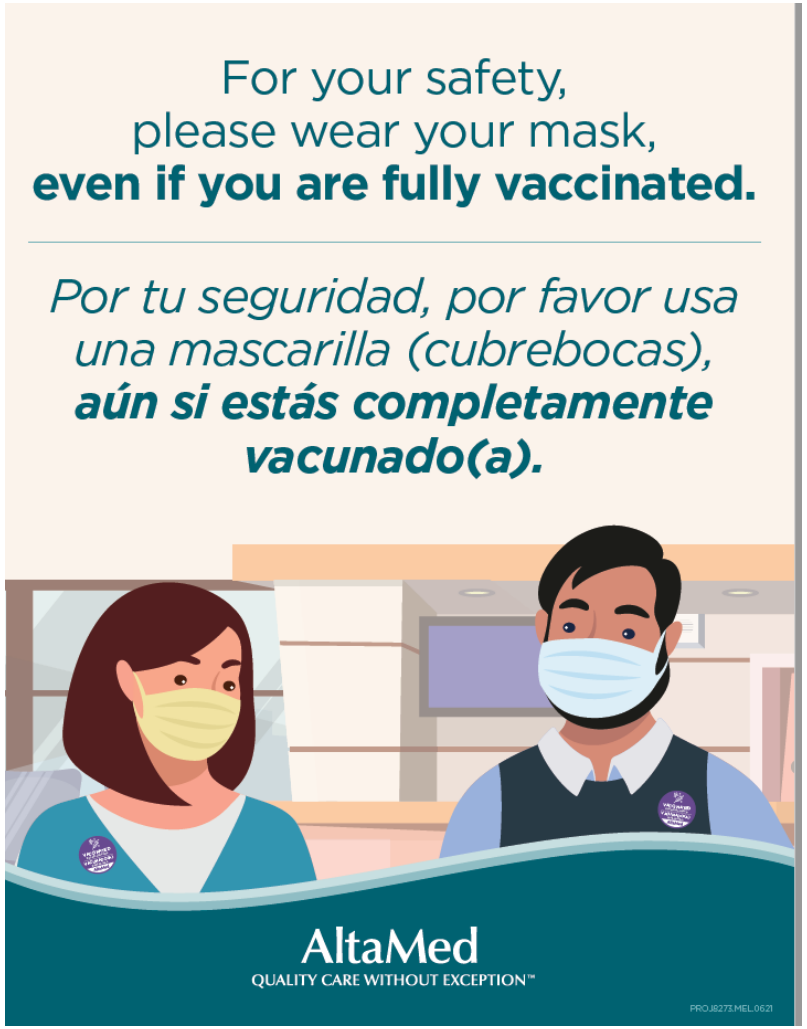

What if there is no isolation room ready?

Last resort is for a patient to wait in the car prior to being roomed. Have a method to keep track of patients waiting in alternative spaces so they are not forgotten or delayed.

What if a patient slips through?
COVID-19 Pandemic: Appropriate PPE

Non-Patient Facing Employee or Patient	Sitting closer than 6ft with staff for >15min	Patient Contact <15min	Patient Contact >15min	Symptomatic Patient or COVID Risk Factors	Swabbing or Neb treatment for Any Patient
Surgical Face Mask (at all times)	Face Shield or Eye protection	Face Shield or Eye protection	Face Shield or Eye Protection	Face Shield or Eye Protection	Face Shield or Eye Protection
	Surgical Face Mask*	Surgical Face Mask*	N95 Mask	N95 Mask	N95 Mask
		Gloves	Gloves	Gown	Gown
				Gloves	Gloves

*Respirators are available for all staff at all times.

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Main Points of Discussion

- **Updates on COVID-19 Testing**
  - Make room on nursing schedule for testing.
  - New policy COVID-19 Rapid Testing-Curbside

AltaMed COVID19 Who to Test?

Individuals appropriate to test through AltaMed would be:

- Patients that have symptoms of COVID-19,
- A high risk close exposure to COVID-19
- Screening test prior to a procedure or surgery,
- Patients residing in a congregate living facility.
- Returning back to school if needed.

- What about travel?
  - Proceed with extreme caution.
  - We cannot guarantee the timeliness of the test.
  - Best to test at a site with guaranteed timing for travel.

Monoclonal Antibody Treatment for COVID-19 High Risk Patients

July 6th, 2021

Ursula Baffigo MD MPH Medical Director, Medical Management

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Inclusion Criteria

- Inclusion criteria:
  - 12 or older age group
  - Weigh at least 40 kg
  - Positive COVID-19
  - Within 10 days of symptom onset
  - Meets **high risk criteria**

High Risk Conditions

- Obesity or being overweight (BMI >25 or if age 12-17, have BMI ≥85th percentile for their age and gender)
- Pregnancy
- Chronic kidney disease
- Diabetes
- Immunosuppressive disease or immunosuppressive treatment
- Cardiovascular disease (including congenital heart disease) or hypertension
- Chronic lung diseases (for example, chronic obstructive pulmonary disease, asthma [moderate-to-severe], interstitial lung disease, cystic fibrosis and pulmonary hypertension)
- Sickle cell disease
- Neurodevelopmental disorders (for example, cerebral palsy) or other conditions that confer medical complexity (for example, genetic or metabolic syndromes and severe congenital anomalies)
- Having a medical-related technological dependence (for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID 19)

MONOCLONAL ANTIBODY INFUSION ORDER FOR COVID-19 POSITIVE PATIENTS

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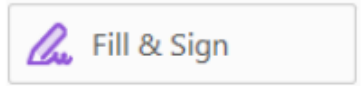
INSTRUCTIONS: REQUIRED STEPS

* Print & fill out manually OR download & fill out electronically:

* Use Adobe Acrobat  and select 

* *Instructions for changing default program for PDFs to Acrobat*

☐ PROVIDER: Place Epic order "Referral to Home Health > IV Infusion" + mark order as **Urgent**

☐ Under order comments enter "*MONOCLONAL ANTIBODY THERAPY*"

☐ Fill out the attached **Infusion Order Form**

** Team member may complete form based on documentation in Epic, but PROVIDER must sign*

☐ **Completed AND signed form** must be RETURNED to AltaMed Centralized Referral Team for urgent processing:

Provider or Clinic CGC's can return form via
Email: DL_Referral_Coordinators@altamed.org
or Fax: (323) 596-2166

☐ **Send message** to *Justin Maldonado* on WebEx Teams to confirm that ORDER is placed & form emailed/faxed

MONOCLONAL ANTIBODY INFUSION ORDER FOR COVID-19 POSITIVE PATIENTS (Adult and Pediatric Patients)

☐ The patient or his/her guardian have provided their informed consent for the administration of **REGEN-COV (Casirivimab + Imdevimab)**

☐ I have notified the patient that this therapy is approved for emergency use by the FDA.

Home Infusion Provider Order Form for Casirivimab + Imdevimab
Patient Name: _____ DOB: _____
Patient Phone #: _____
Allergies: _____
Patient's Height (in) or (cm): _____ Patient's Weight (lb) or (kg):_____
Is Patient Pregnant? ☐ Yes ☐ No
Date of First COVID related Symptom Onset: _____
COVID Positive test Date: _____

DIAGNOSIS:
☒ Covid-19 Infection (U07.1)
☐ Other: _____

Administer Monoclonal Antibody Drug Therapy within 10 days of symptom onset.

***Patient Eligibility* Exclusion Criteria:** (Patients meeting any of the following criteria are NOT ELIGIBLE for either therapy)

a) who are hospitalized due to COVID-19
b) who require oxygen therapy due to COVID-19
c) who require an increase in baseline oxygen flow rate due to COVID-19 in those on chronic oxygen therapy due to underlying non-COVID-19 related comorbidity

By signing this order, physician verifies that none of the above criteria apply.

Inclusion Criteria:

- Patient is 12 years of age or older weighting at least 40 kg (88.2lbs)

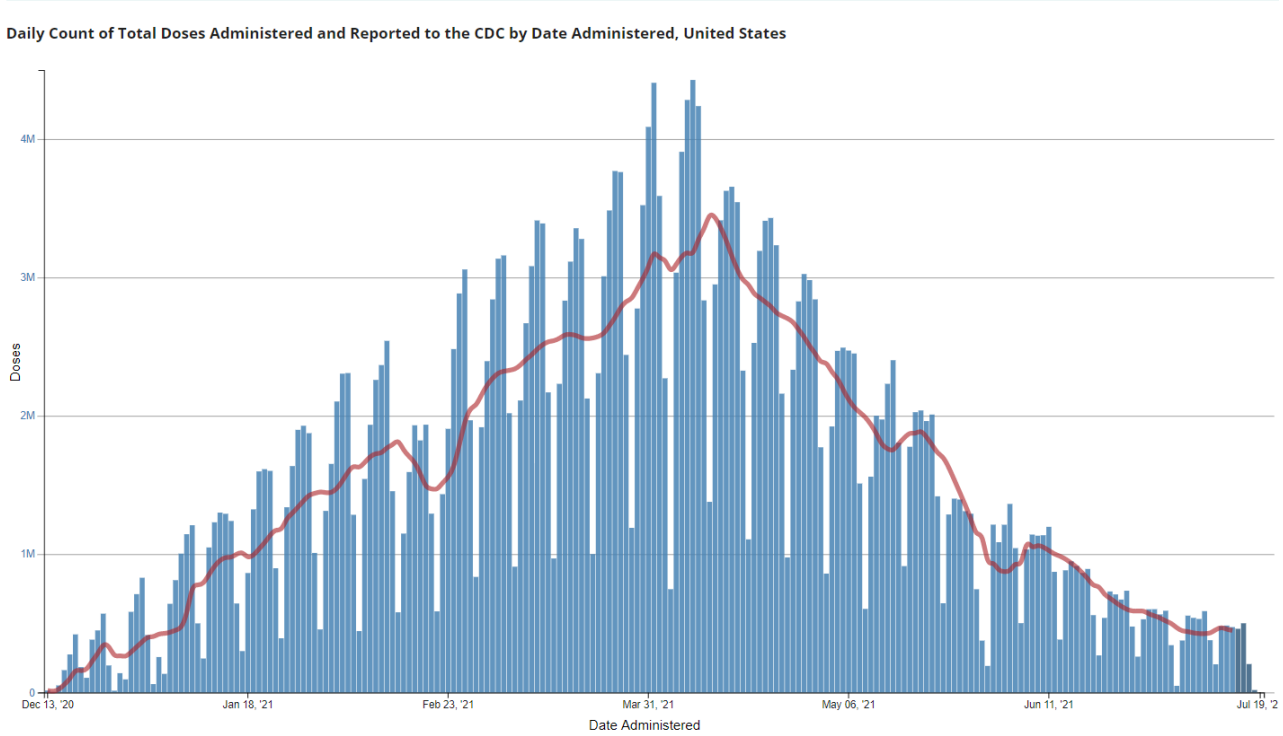
At least one of the following criteria must be met to qualify for therapy (*Select all that apply*):

☐ **Older age** (for example, age ≥65 years of age)

☐ Obesity or being overweight (for example, BMI >25 kg/m^2, or if **age 12-17**, have BMI ≥85th percentile for their age and gender based on CDC growth charts, https://www.cdc.gov/growthcharts/clinical_charts.htm

Vaccine Do's

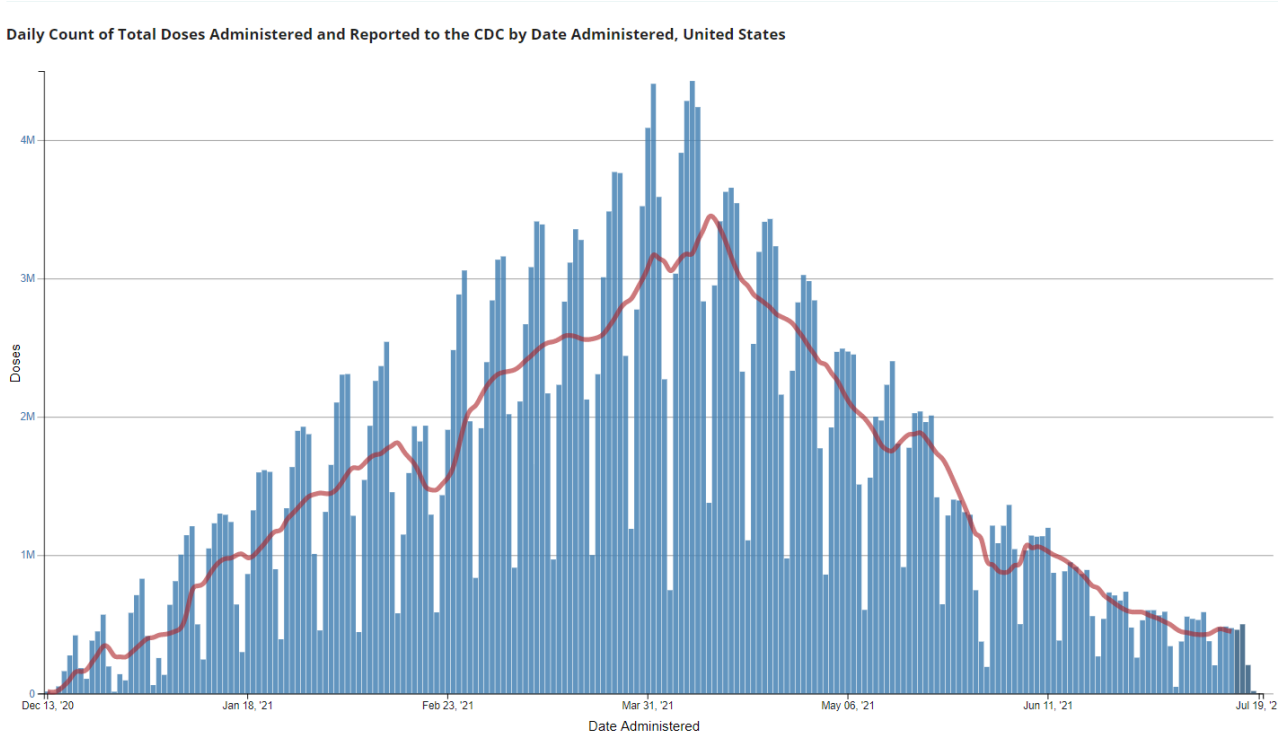
- DO:
- Talk with your staff about vaccine questions both personal and patient/community.
- Take the time and make a safe space to discuss the vaccine.
- Encourage themes persuading people to get vaccinated:
    1. Millions of Americans have been safely vaccinated.
    2. Close friends, relatives, community members and doctors giving pro-vaccine messages.
    3. Being vaccinated will help people to do some things like travel.



COVID-19 Vaccine Don’ts

- DON’T

- Non providers cannot give medical advice while at work. They can only give legitimate and proven information which has been provided as a reference by AltaMed.
- If someone is not “pro vaccine”, they should not discuss this stance while at work to patients or their co-workers.



Questions?

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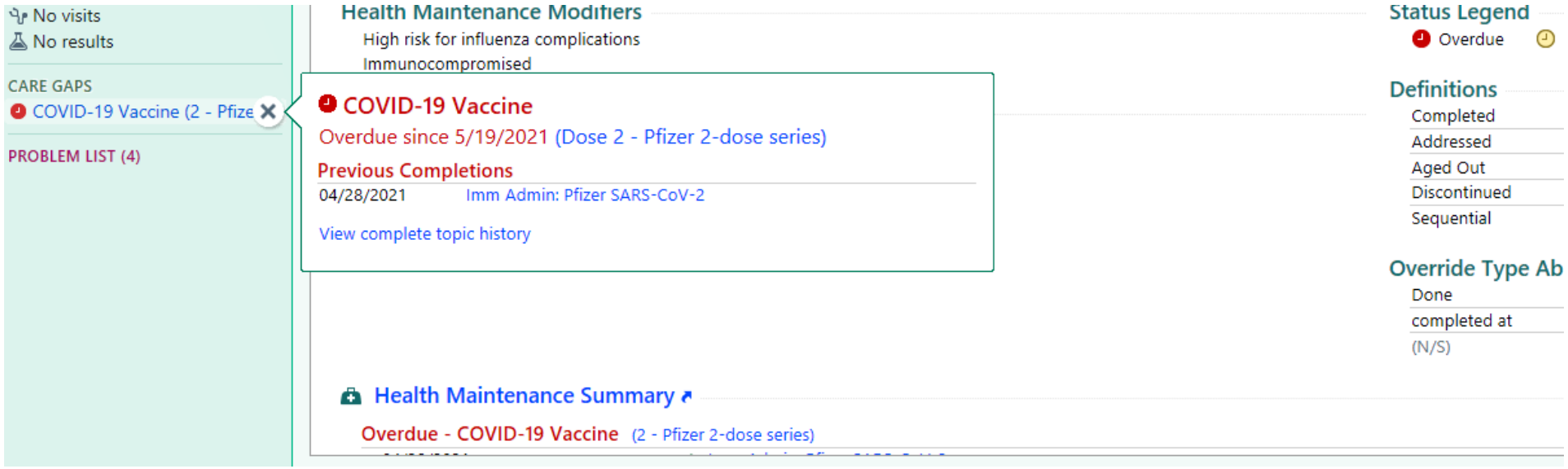
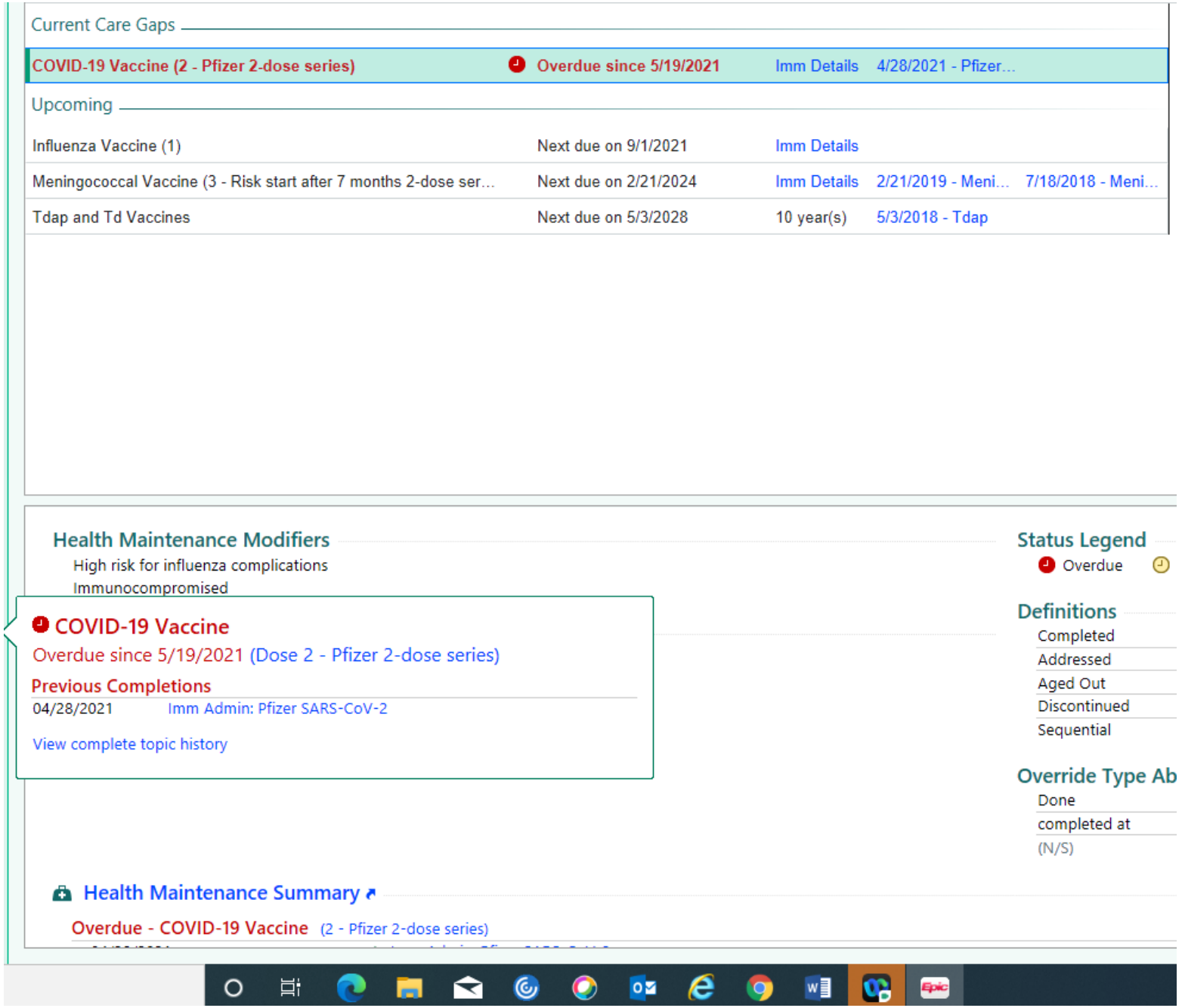
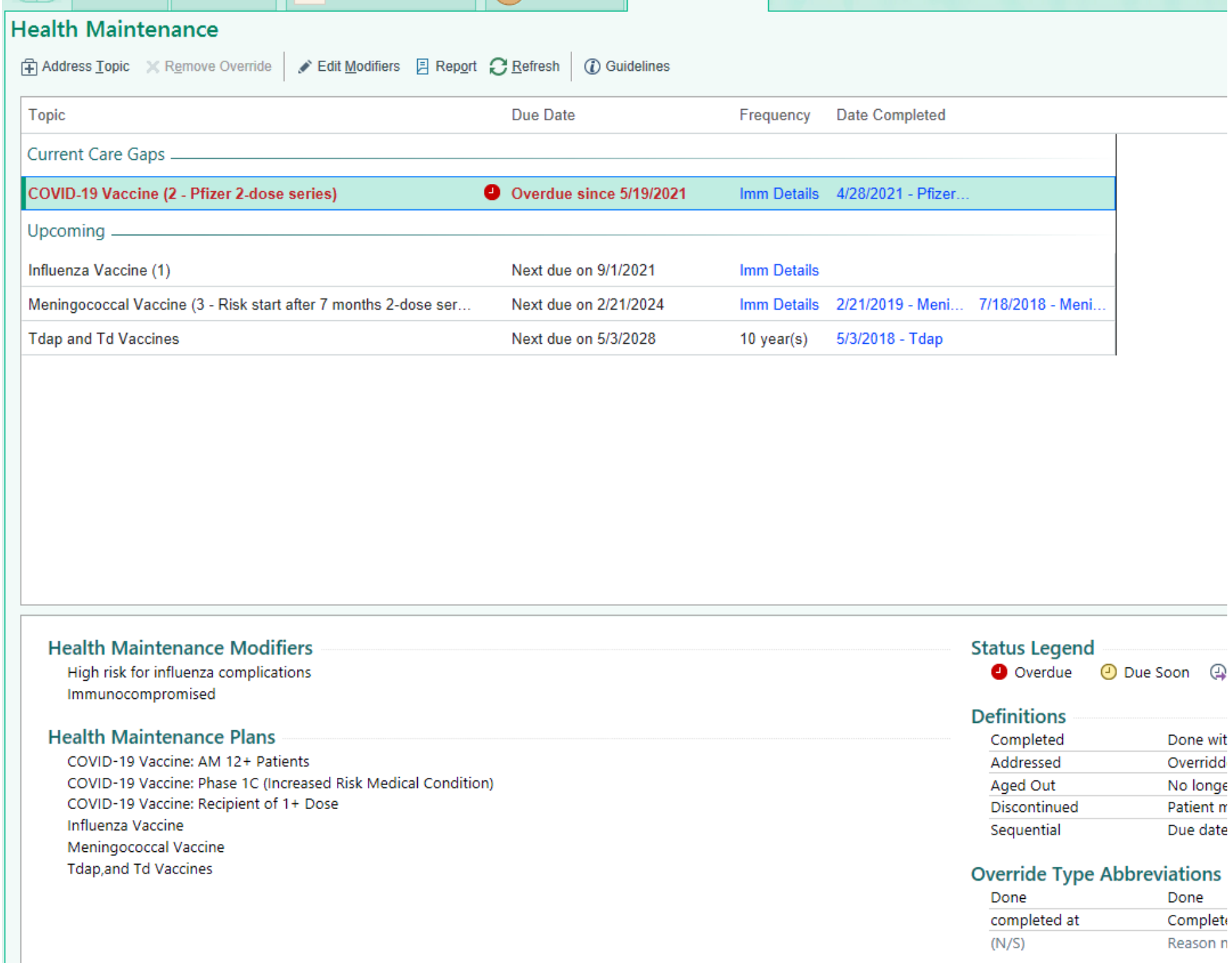


- Take 2 min to look at care gaps
- Hover over the care gaps to show all care gaps due.
- “In reviewing your history I see that…”

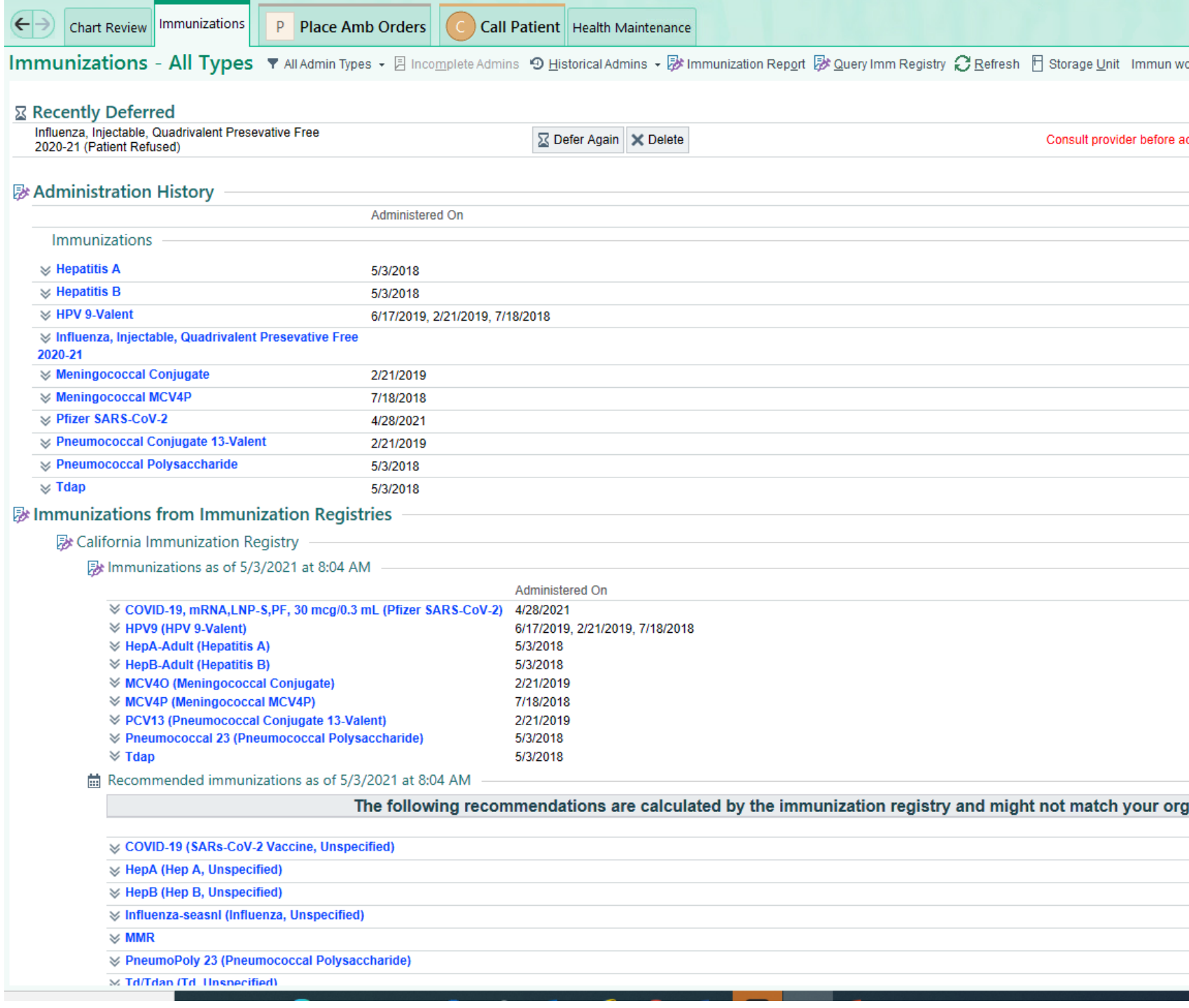
- Click on Care Gaps to address care gap.



- Click address topic



- If no care gaps due, click on Immunizations to see what the patient has had and what is due.
- Sometimes a vaccine has been given but under a different name.
- Go down the line.
- Watch for deferred vaccine to address vaccine confidence.



CDC/IDSA COVID-19 Clinician Call

June 26, 2021

Welcome & Introduction

Dana Wollins, DrPH, MGC
Vice President, Clinical Affairs & Guidelines
IDSA

- 69th in a series of weekly calls, initiated by CDC as a forum for information sharing among frontline clinicians caring for patients with COVID-19
- The views and opinions expressed here are those of the presenters and do not necessarily reflect the official policy or position of the CDC or IDSA. Involvement of CDC and IDSA should not be viewed as endorsement of any entity or individual involved.
- This webinar is being recorded and can be found online at www.idsociety.org/cliniciancalls.

Pericarditis diagnosis

- Must have 2 of:
  - Chest pain
  - Pericardial rub audible by stethoscope
  - Abnormal ECG findings (New ST-elevation or PR-depression)
  - Pericardial effusion on echocardiogram or MRI

Adler et al. *Eur Heart J*. 2015.

Causes of traditional myocarditis

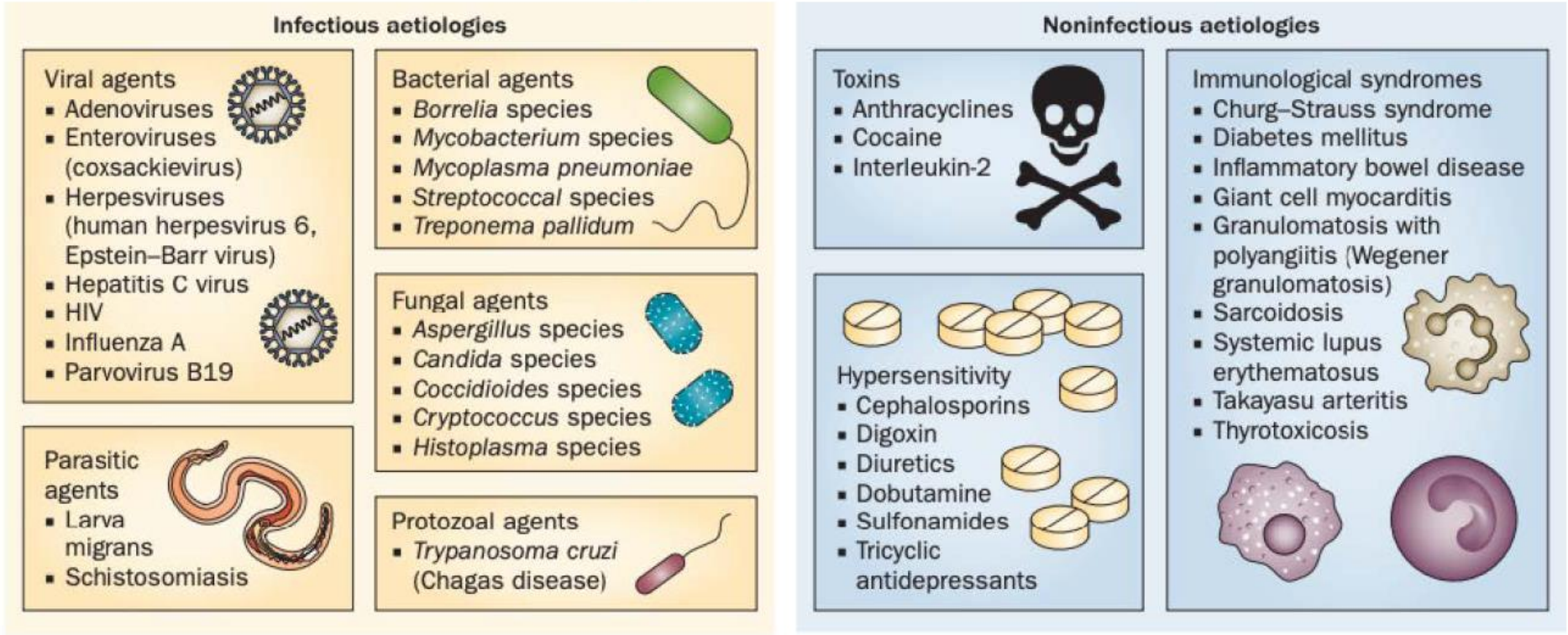


Figure 1 | Common causes of myocarditis. Viral infection is the most common aetiology, but several other aetiologies of myocarditis have also been implicated.

Treatment: Supportive Care

Oxygen supplementation, even if for comfort

- Intubation in severe cases

Fluid resuscitation

Heart Failure management

- Diuretics
- Afterload reduction
- Beta blockers (use in acute setting controversial)
- Inotropes
- Anti-arrhymic medications

Mechanical circulatory support

- Extracorporeal Membrane Oxygenation (ECMO)
- Ventricular Assist Device (VAD)

Transplant

Treatment: Anti-inflammatory

- Non-steroidal Anti-inflammatory Drugs (NSAIDs)
  - Mice studies shown to worsen myocardial injury in myocarditis due to coxsackievirus
  - Still often used for mild cases, particularly when concern for pericarditis
- Intravenous Immunoglobulin (IVIG)
  - Also controversial, as studies have failed to show benefit, particularly in children
  - Still, often used in many hospitals
- Glucocorticoids
  - No good data to support their use, yet still commonly used
  - Exception is in giant cell myocarditis (rare)

Activity Restrictions

- Risk of sudden death
  - 5-10% of sudden death in adolescents and young adults attributable to myocarditis (typically not previously diagnosed)
- Guidelines from American Heart Association and American College of Cardiology

1. Before returning to competitive sports, athletes who initially present with an acute clinical syndrome consistent with myocarditis should undergo a resting echocardiogram, 24-hour Holter monitoring, and an exercise ECG no less than 3 to 6 months after the initial illness *(Class I; Level of Evidence C)*.
2. It is reasonable that athletes resume training and competition if all of the following criteria are met *(Class IIa; Level of Evidence C)*:
   a. Ventricular systolic function has returned to the normal range.
   b. Serum markers of myocardial injury, inflammation, and heart failure have normalized.
   c. Clinically relevant arrhythmias such as frequent or complex repetitive forms of ventricular or supraventricular ectopic activity are absent on Holter monitor and graded exercise ECGs.

   At present, it is unresolved whether resolution of myocarditis-related LGE should be required to permit return to competitive sports.
3. Athletes with probable or definite myocarditis should not participate in competitive sports while active inflammation is present. This recommendation is independent of age, gender, and LV function *(Class III; Level of Evidence C)*.

Maron et al. *JACC*. 2015
Burns et al. *J Peds X*. 2020.

Prepublication Release

PEDIATRICS

OFFICIAL JOURNAL OF THE AMERICAN ACADEMY OF PEDIATRICS

Symptomatic Acute Myocarditis in Seven Adolescents Following Pfizer-BioNTech COVID-19 Vaccination

Mayme Marshall, MD, Ian D. Ferguson, MD, Paul Lewis, MD, MPH, Preeti Jaggi, MD, Christina Gagliardo, MD, James Steward Collins, MD, Robin Shaughnessy, MD, Rachel Caron, BA, Cristina Fuss, MD, Kathleen Jo E. Corbin, MD, MHS, Leonard Emuren, MBBS, PhD, Erin Faherty, MD, E. Kevin Hall, MD, Cecilia Di Pentima, MD, MPH, Matthew E. Oste, MD, MPH, Elijah Paintsil, MD, Saira Siddiqui, MD, Donna M. Timchak, MD, Judith A. Guzman-Cottrill, DO

Released online, ahead of print June 4, 2021

Introduction

- The FDA EUA for Pfizer-BioNTech COVID-19 mRNA vaccine was revised to include children 12 years of age and older on 5/10/2021
- Around that same time, media and case reports suggested a possible correlation of COVID-19 mRNA vaccination and myocarditis:
  - United States military
  - Israeli cohort, identified a male predominance
  - 56-year-old man with previous COVID-19
  - 39-year-old man with no history of COVID-19
- Our case series includes 7 healthy male adolescents with acute symptomatic myocarditis, all within four days after the second dose of Pfizer-BioNTech COVID-19 vaccine in April or May, 2021

Our Discussion

- Temporal relationship of clinical myocarditis following second Pfizer-BioNTech COVID-19 vaccine in adolescent males aged 14-19 years of age
- No patient had acute COVID-19 infection
- 4 patients had detectable SARS-CoV-2 spike antibodies (component of vaccine)
- 6/6 patients had negative SARS-CoV-2 nucleocapsid antibody (suggesting no prior SARS-CoV-2 infection)
- None of our patients were critically ill, and all responded quickly to treatment; however, all patients required hospitalization for cardiac monitoring
- Findings consistent with a known male preponderance of myocarditis

Characteristics of preliminary* myocarditis/pericarditis reports to VAERS following mRNA COVID-19 vaccination (data thru Jun 11, 2021)

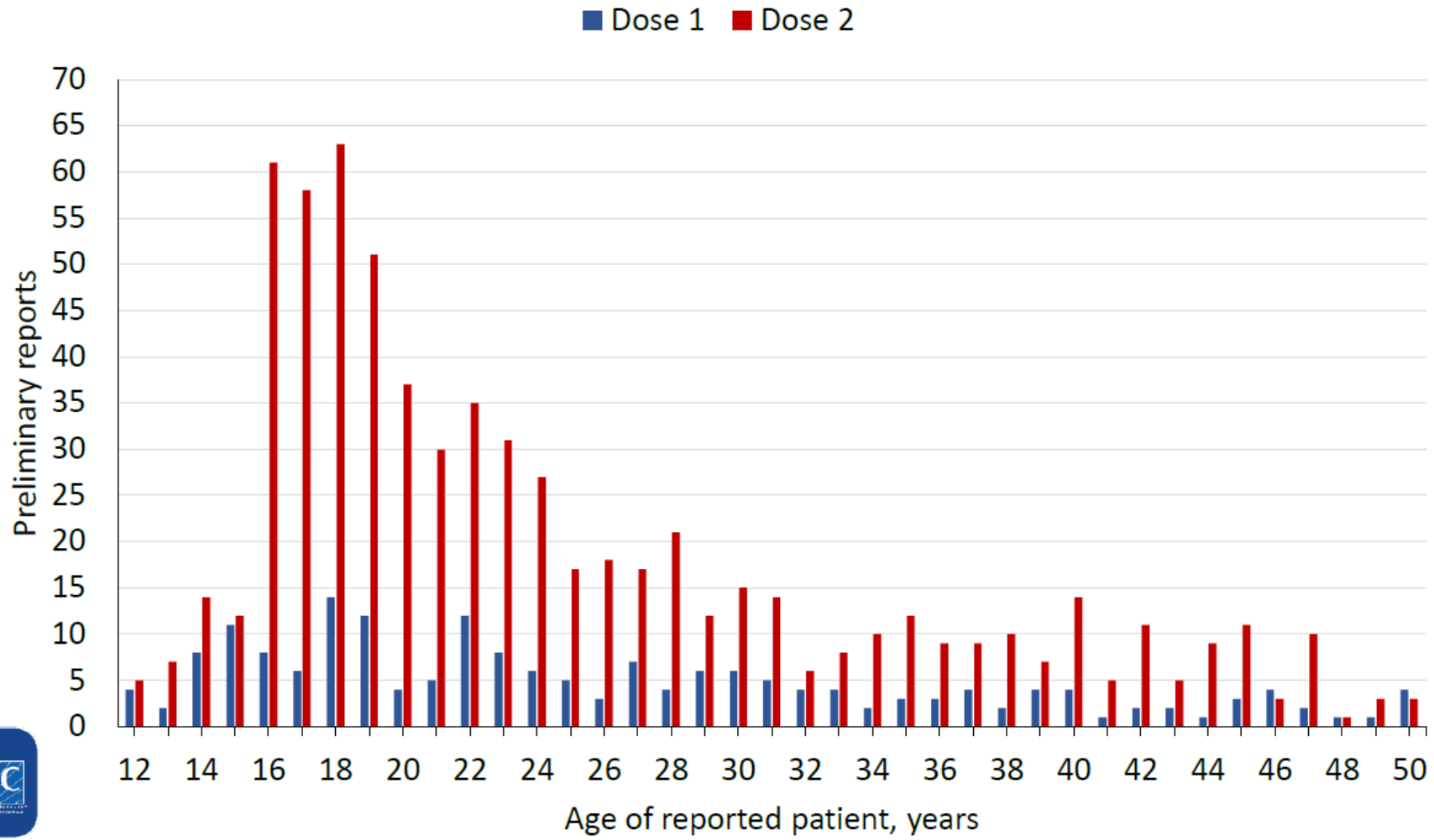
Characteristics	Dose 1 (n=267)	Dose 2 (n=827)
Median age, years (range)	30 (12–94)	24 (12–87)
Median time to symptom onset, days (range)	4 (0–61)†	3 (0–98)†
Sex (%)		
Male	176 (66%)	655 (79%)
Female	88 (33%)	165 (20%)
Not reported/not available	3 (1%)	7 (1%)

* Includes total reports identified through VAERS database searches for reports with myocarditis/pericarditis MedDRA codes and pre-screened VAERS reports with signs and symptoms consistent with myocarditis/pericarditis (and with dose number documented); Follow-up, medical record review, application of CDC working case definition, and adjudication is ongoing or pending

† One report of 179-day onset after dose 1; one report of 1 range

Preliminary reports of myocarditis/pericarditis to VAERS after mRNA COVID-19 vaccination by age and dose number*

(as of Jun 11, 2021)

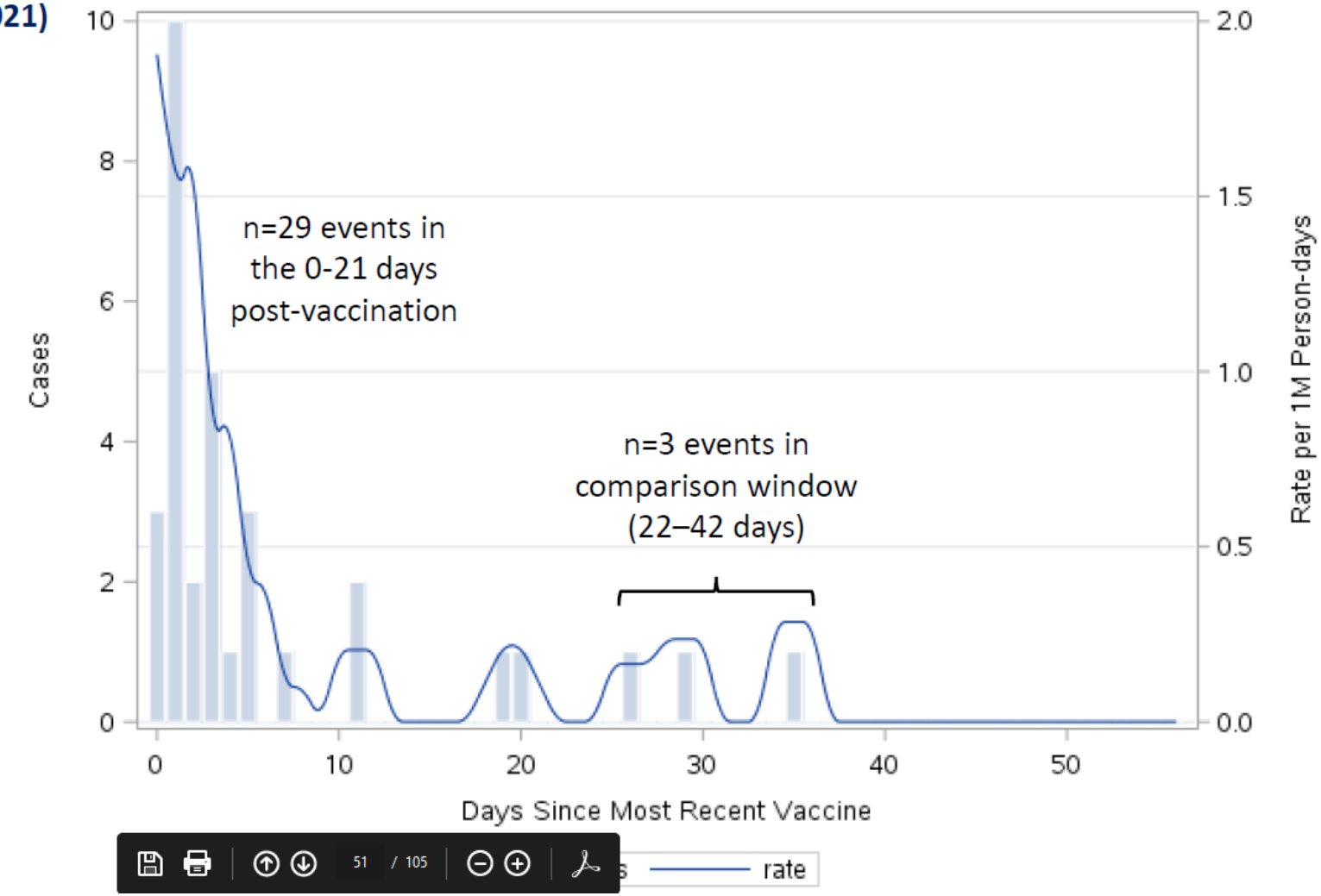


* Age truncated at >50yr: Reports of persons >50yr of age include 70 after Dose 1, 119 after Dose 2

Chart confirmed myocarditis/pericarditis cases in VSD by day of symptom onset since most recent mRNA COVID-19 vaccination, 12–39-year-olds

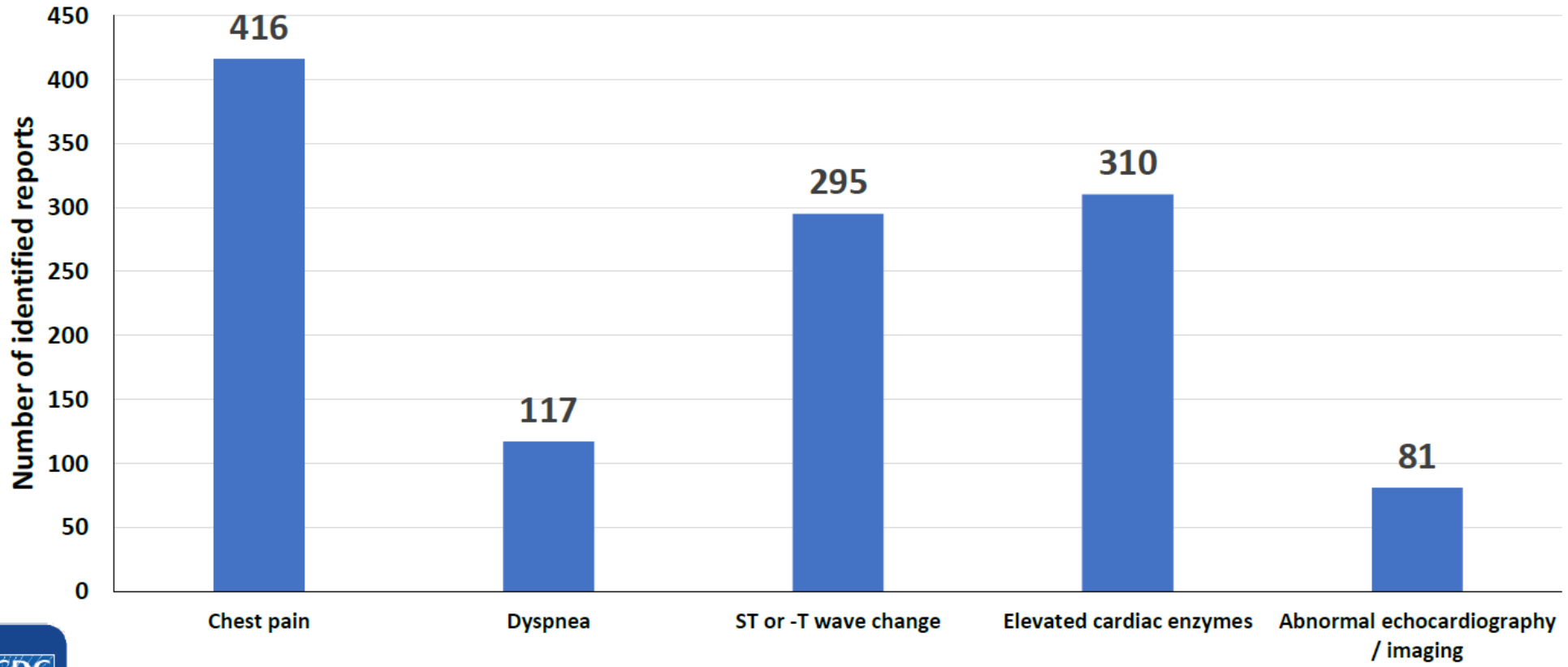
(thru Jun 5, 2021)

- Most likely clusters
  - Days 0–5
  - Days 0–3
  - Days 0–6
- All have a p-value <0.000001
- Parameters for the scan
  - Includes days 0–56
  - Scans all possible windows of length 1–28 days



Symptoms and diagnostic findings of preliminary myocarditis/pericarditis reports after mRNA COVID-19 vaccination under review, limited to ≤29 years old (N=484)

(data thru Jun 11, 2021)



Myocarditis/pericarditis chart confirmed rates in VSD in 21-day risk interval, 12–39-year-olds

(thru Jun 5, 2021)

Vaccine(s) (dose #)	Cases	Doses admin	Rate per million doses (95% CI)
mRNA (both doses)	26	3,418,443	8 (5.3–11.8)
mRNA (dose 1)	8	1,879,585	4.4 (1.9–8.8)
mRNA (dose 2)	18	1,538,858	12.6 (7.5–19.9)
Pfizer-BioNTech (dose 1)	3	1,211,080	2.6 (0.5–7.7)
Pfizer-BioNTech (dose 2)	7	958,721	8.0 (3.2–16.5)
Moderna (dose 1)	5	668,505	7.5 (2.4–17.6)
Moderna (dose 2)	11	580,137	19.8 (9.9–35.5)

Summary

- Analysis of VAERS preliminary reports of myocarditis/pericarditis is in progress, including follow-up to obtain medical records, complete reviews, apply CDC working case definition, and adjudicate cases
- Preliminary VAERS findings suggest:
  - Median age of reported patients is younger for reports after dose 2 vs. dose 1
  - Symptom onset clusters within the week following vaccination (mostly within 4 days)
  - Predominance of male patients in younger age groups, especially after dose 2
  - Observed reports > expected cases, especially after dose 2 in younger age groups
- Early VSD data for myocarditis/pericarditis in 12–39-year-olds also suggest:
  - More cases after mRNA COVID-19 vaccination with dose 2 vs. dose 1
  - Rate of 12.6 cases per million 2nd doses of any mRNA vaccine in the 21 days following vaccination
    - Rates appear higher in males vs. females
  - Clustering of myocarditis/pericarditis within the week following vaccination (most likely 0–5 days)
- Available outcome data indicate that patients generally recover from symptoms and do well

Early reports of myocarditis after mRNA COVID-19 vaccine: United States

- Marshall et al – 7 healthy males 14-19yo within 4 days of 2nd mRNA vaccine
  - All with abnormal troponin, ECG, and MRI
  - Treatment with NSAIDs alone in 3, IVIG/steroids in 4
  - All discharged to home after 2-6 days in the hospital (median 4)

- Rosner et al* – 5 males 19-39yo within 4 days of 2nd dose of vaccine, 1 24yo male 7 days after 1st dose
  - All with abnormal troponin and MRI findings, varying ECG findings
  - Treatment with NSAIDs or colchicine in 4, beta-blockers in 2, steroids in 1
  - All discharged to home after 2-4 days in the hospital (median 3)
  - Note: Spike protein antibodies **negative** in patient who presented after 1st dose

Marshall et al. *Pediatrics.* 2021.
Rosner et al. *Circulation 2021*
**Rosner et al. also reported a 28yo with myocarditis after Johnson & Johnson's Janssen COVID-19 vaccine*

Early reports of myocarditis after mRNA COVID-19 vaccine: International

- Larson et al – 8 males 22-56yo (4 in U.S., 4 in Italy); 7 within 4 days of dose 2, 1 with onset 2 days after dose 1 (had hx of prior SARS-CoV-2 infection)
  - All with abnormal troponin, echo, and MRI; 7/8 with abnormal ECG
  - Treatment with NSAIDs or colchicine in 4, steroids in 2, no treatment in 3
  - All discharged home with resolution of symptoms and preserved ejection fraction

- Israeli Ministry of Health - 148 myocarditis cases occurring within 30 days of mRNA vaccine
  - 27 cases out of ~5.4 million first doses
  - 121 cases out of ~5 million second doses
  - Mostly in men aged 16-30 (particularly 16-19)
  - Most were in the hospital up to 4 days
  - 95% of cases considered mild

Larson et al. *Circulation*. 2021
https://www.gov.il/en/departments/news/01062021-03

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- Available outcome data indicate that patients generally recover from symptoms and do well

Next steps for assessing myocarditis/pericarditis following mRNA COVID-19 vaccination

- Continue monitoring in VAERS
  - Follow-up to obtain medical records, conduct case reviews, apply CDC working case definition, and adjudicate case reports
  - Surveillance review focusing on myocarditis and myopericarditis to describe epidemiology and characterize clinical features of cases is in progress
- Continue monitoring and assessment in VSD
  - Quantify risk and characterize clinical features of cases
- Conduct follow-up on vaccine-associated cases to assess longer-term outcomes (i.e., at 3–6 months)

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

- Please send records to VAERS ASAP if contacted and asked
  - HIPAA permits reporting of protected health information to public health authorities including CDC and FDA