# CIN September Town Hall Gathering

September 29, 2021 6:00 PM - 7:30 PM



## **Tonight's Agenda:**

- Mount Sinai Health System and Market Updates
- ► COVID-19 Updates and Q&A with Dr. Waleed Javaid including Boosters, Pediatrics, Vaccines, and Masking
- Payer Updates and State and Federal Policy Updates
- ▶ Review of MSHP's PCP Performance Reports and Action Needed
- Practice Demographic Profile Site- Review and Usage Data
- ▶ Reminders

### **COVID-19 Mount Sinai Health System (MSHS) Updates**

- ► As of 09/29, MSHS only has 98 COVID-19 positive inpatients across the system,13 in critical care.
  - 05/19/21: 72 COVID-19 positive inpatients, 15 in critical care.
  - 03/24/21: 366 COVID-19 positive inpatients, 64 in critical care
  - 12/3/20: 178 COVID-19 positive inpatients, 36 in critical care
  - 10/28/20: 102 COVID-19 positive inpatients, 20 in critical care
- ▶ New York State 7-day average test positivity rates as of yesterday were (<<5%):
  - 1.6 % for New York City
  - 3.3 % for Long Island
  - 2.8 % for the mid-Hudson region.

## **COVID-19 Mount Sinai Health System Updates**

Across NYC, One Dose: 82%! Fully Vaccinated 75%!

Manhattan*	Queens*	Brooklyn*	Bronx*		Nassau County**		West- chester **
One Dose: 88%	One: 89%	One: 76%	One: 78%	One: 78%	One: 92.5%	One: 84.6%	One: 88.6%
Fully Vaccinated (18+): 80%	Fully: 82%	Fully: 68%	Fully: 68%	Fully: 71%	Fully: 78.1%	Fully: 71.1%	Fully: 75.5%

Numbers drop ~ 10% when accounting for age <18

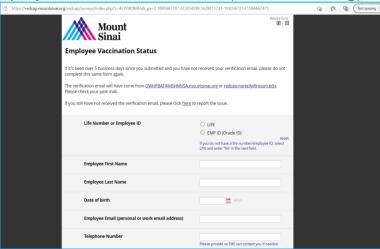
#### Source:

<sup>\*</sup> NYC.gov

<sup>\*\*</sup> NYState.gov

## **COVID-19 Mount Sinai Health System Updates**

- ▶ NY State All Healthcare Workers Vaccine Mandate
  - As of today, fewer than 1% of Mount Sinai employees have chosen to leave/been terminated due to vaccine mandate
  - 65 CIN providers and 68 messenger model providers have not provided proof of vaccination as of yesterday
  - Please upload proof to Mount Sinai Employee Health Services (EHS) ASAP
  - Will provide link (<u>Employee Vaccination Status (mountsinal.org)</u> in post Town Hall email



# MSHS: COVID-19 infection is a risk factor for Prostate Cancer

- ► ~34,000 men die of Prostate Cancer every year, September is Prostate Cancer Awareness month
- ► From Dr. Ash Tewari (Chair of Urology, MSHS) lab:
  - COVID-19 increase risk of prostate cancer
    - COVID-19 Spike Protein attaches to ACE2, but it also enters the cell through another enzyme known as TMPRSS2.
    - TMPRSS2 enzymatic activity linked to prostate cancer
    - Delay in Screening and PSAs
- ► Takeaways: Consider Prostate Cancer Screening, especially in the era of COVID-19
  - Start with Patient Discussion
  - PSA testing and consider DRE
  - MRI, and recent FDA approval for molecular scan- PSMA (prostate specific membrane antigen scan)
    - Allow for better determination of whether invasive evaluation or surgery is necessary

# COVID-19 Updates and Q & A

Waleed Javaid, MD, FACP, FIDSA, FSHEA Professor of Medicine Hospital Epidemiologist Director, Infection Prevention and Control Mount Sinai Downtown

September 29, 2021



# Disclosures

NONE

## **TOPICS**

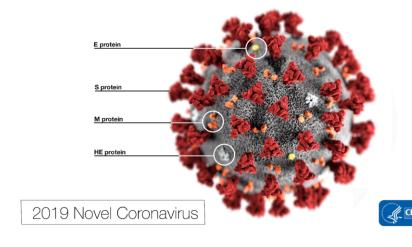
- 1. SARS-COV2
- 2. Disease
- 3. Treatment
- 4. Vaccines
- 5. Variants

# Background

THE VIRUS

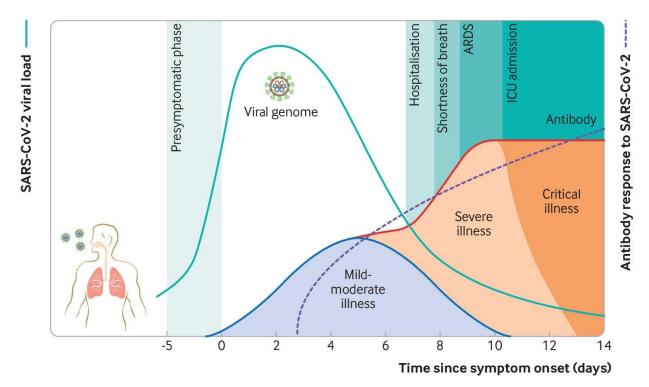


## Coronavirus



- Structural Proteins:
- Spike (S)
- Envelope (E)
- Membrane (M)
- Nucleocapsid (N)
- Hemagglutinin esterase (HE)

## After the initial exposure, patients typically develop symptoms within 5-6 days (incubation period).



Muge Cevik et al. BMJ 2020;371:bmj.m3862



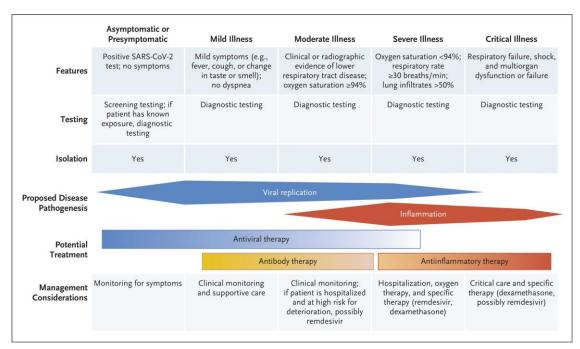
# Spectrum of Illness

- Asymptomatic Infections
- Symptomatic Infections
  - Mild
    - Outpatient
  - Moderate
    - Lower Respiratory disease + SpO2 > 94% on RA
  - Severe
    - Infiltrates > 50%, SpO2 < 94% on RA or RR > 30 or PaO2/FiO2 < 300
  - Critical
    - ARDS, Septic Shock, Cardiac dysfunction, Multiorgan

# Treatments



# Characteristics, Diagnosis, and Management of COVID-19 According to Disease Stage or Severity.



# Asymptomatic Infections

- 20-60% during outbreaks
- Even higher in younger populations
- May still have abnormal imaging
- Some may eventually develop illness
- Can be infectious for 10 days or more.

# Risk Factors for Severe COVID-19.

#### Table 1. Risk Factors for Severe Covid-19.\*

Older age

Chronic obstructive pulmonary disease

Cardiovascular disease (e.g., heart failure, coronary artery disease, or cardiomyopathy)

Type 2 diabetes mellitus

Obesity (body-mass index, ≥30)

Sickle cell disease

Chronic kidney disease

Immunocompromised state from solid-organ transplantation

Cancer

Data are adapted from the Centers for Disease Control and Prevention (CDC).<sup>3</sup> Of note, there has been a disproportionate burden of Cowd-19 on racial and ethnic minorities and the poor. Studies indicate that the risk of severe disease increases with age. Male sex is not currently included on the CDC list of risk factors but has been noted in some reports to be associated with severe disease. Additional conditions that may confer an increased risk but for which the data are unclear include asthma (moderate to severe), cerebrovascular diseases, cystic fibrosis, hypertension, other immunocompromised states or use of immunosuppressive therapy, neurologic conditions such as dementia, liver disease, pregnancy, pulmonary fibrosis, smoking, thalassemia, and type 1 diabetes mellitus. The body-mass index is the weight in kilograms divided by the square of the height in meters.



# Management of Non-Hospitalized Adults with COVID-19

- Mild to Moderate illness
- High risk for severe illness
- Monoclonal Therapy
  - Casirivimab/Imdevimab
  - Bamlanivimab/Etesevimab
    - (no for gamma but yes for delta)

#### PATIENT DISPOSITION

Not Requiring Hospitalization or

Supplemental Oxygen, As
Determined by a Health Care
Provider in ED or an In-Person or
Telehealth Visit

#### PANEL'S RECOMMENDATIONS

Anti-SARS-CoV-2 monoclonal antibody products are recommended for outpatients with mild to moderate COVID-19 who are at high risk of disease progression, as defined by the EUA criteria (treatments are listed in alphabetical order).<sup>28</sup>

- · Casirivimab plus imdevimab; or
- Sotrovimab

At this time, the Panel recommends against the use of bamlanivimab plus etesevimab in these patients due to an increase in the proportion of potentially resistant variants (AIII). See text for details.

The Panel recommends against the use of dexamethasone or other systemic glucocorticoids in the absence of another indication (AIII).<sup>b</sup>

Discharged From Hospital Inpatient Setting in Stable Condition and Does Not Require Supplemental Oxygen

The Panel recommends against continuing the use of remdesivir (Alla), dexamethasone (Alla), or baricitinib (Alla) after hospital discharge.

Discharged From Hospital Inpatient Setting and Requires Supplemental Oxygen

For those who are stable enough for discharge but who still require oxygen°

There is insufficient evidence to recommend either for or against the continued use of remdesivir, dexamethasone, and/or baricitinib. Review the text below when considering the use of any of these agents after hospital discharge.

Discharged From ED Despite New or Increasing Need for Supplemental Oxygen

When hospital resources are limited, inpatient admission is not possible, and close follow-up is ensured<sup>d</sup>

The Panel recommends using **dexamethasone** 6 mg PO once daily for the duration of supplemental oxygen (dexamethasone use should not exceed 10 days) with careful monitoring for adverse events (BIII).

There is insufficient evidence to recommend either for or against the use of remdesivir. When considering the use of remdesivir, review the text below for further discussion.

The Panel recommends against the use of baricitinib in this setting, except in a clinical trial (AIII).

U.S. Department of Health and Human Services. (n.d.). Clinical management summary. National Institutes of Health. Retrieved September 22, 2021, from https://www.covid19treatmentguidelines.nih.gov/management/clinical-management/clinical-management-summary/.

# Management of Hospitalized Patient

- Does Not require O2
  - + High risk of disease progression > Remdesiver may be considered
- Requires O2
  - Remdesivir
  - Dexa + Rem
  - Dexamethasone
- O2 + HF or NIV
  - Dexa
  - Dexa + Rem
  - + Worsening condition
    - Baricitinab or Toci
- MV or ECMO
  - Dexa + Toci
- SARS-CoV-2 antibody therapy\*

#### DISEASE SEVERITY

#### PANEL'S RECOMMENDATIONS

Hospitalized but Does Not Require Supplemental Oxygen The Panel recommends against the use of dexamethasone (Alla) or other corticosteroids (AllI).<sup>a</sup>

There is insufficient evidence to recommend either for or against the routine use of remdesivir. For patients at high risk of disease progression, remdesivir may be appropriate.

Hospitalized and Requires Supplemental Oxygen Use one of the following options:

- Remdesivir<sup>b</sup> (e.g., for patients who require minimal supplemental oxygen) (Blla)
- Dexamethasone plus remdesivir<sup>b</sup> (e.g., for patients who require increasing amounts of supplemental oxygen) (BIII)
- Dexamethasone (when combination with remdesivir cannot be used or is not available) (BI)

Hospitalized and Requires Oxygen Delivery Through a High-Flow Device or Noninvasive Ventilation Use one of the following options:

- Dexamethasone (Al)
- Dexamethasone plus remdesivir<sup>b</sup> (BIII)

For recently hospitalized<sup>c</sup> patients with rapidly increasing oxygen needs and systemic inflammation:

- Add either baricitinib (Bila) or IV tocilizumab (Bila) to one of the two options above<sup>d</sup>
  - If neither baricitinib nor IV tocilizumab is available or feasible to use, tofacitinib can be used instead of baricitinib (Blla) or IV sarilumab can be used instead of IV tocilizumab (Blla).

Hospitalized and Requires IMV or ECMO

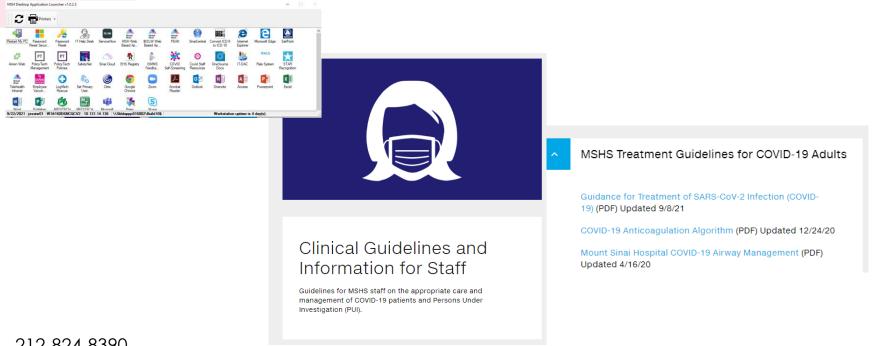
. Dexamethasone (Al)

For patients who are within 24 hours of admission to the ICU:

- Dexamethasone plus IV tocilizumab (Blla)
- If IV tocilizumab is not available or not feasible to use, IV sarilumab can be used (BIIa).

U.S. Department of Health and Human Services. (n.d.). Clinical management summary. National Institutes of Health. Retrieved September 22, 2021, from https://www.covid19treatmentquidelines.nih.gov/management/clinical-management/clinical-management-summary/.

# COVID-19 Staff Resources



212-824-8390

covidtherapeuticreferrals@mountsinai.org

https://www.mountsinai.org/about/covid19/staff-resources/staff-clinical-guidelines-information

### SARS-CoV-2 specific Monoclonal Antibodies

 Casirivimab/imdevimab and bamlanivimab/etesevimab are a combination of two monoclonal antibodies directed toward SARS-CoV-2 available under a EUA

### Treatment of outpatient mild to moderate COVID-19

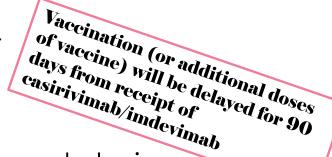
 Outpatients ages 12 and above (> 40 kg) who are at high risk of progression to severe disease

### Post-Exposure Prophylaxis

- Patients ages 12 and above who were exposed\* to COVID-19 who are at high risk of progression to severe disease
  - Includes those who are not fully vaccinated and those who are unlikely to have an adequate response to the vaccine

Not a substitute for vaccination and not to be used for pre-exposure prophylaxis

# Referrals for Casirivimab/Imdevimab or Bamlanivimab/etesevimab

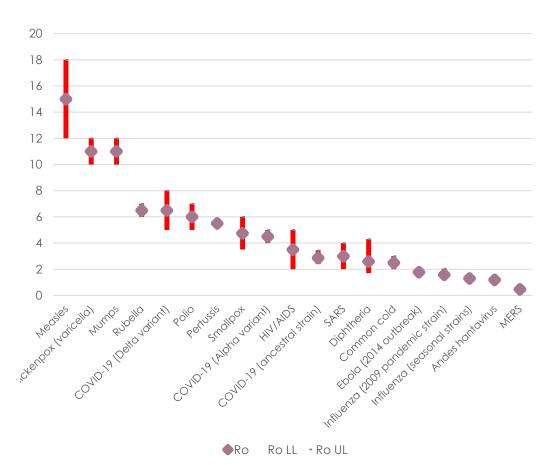


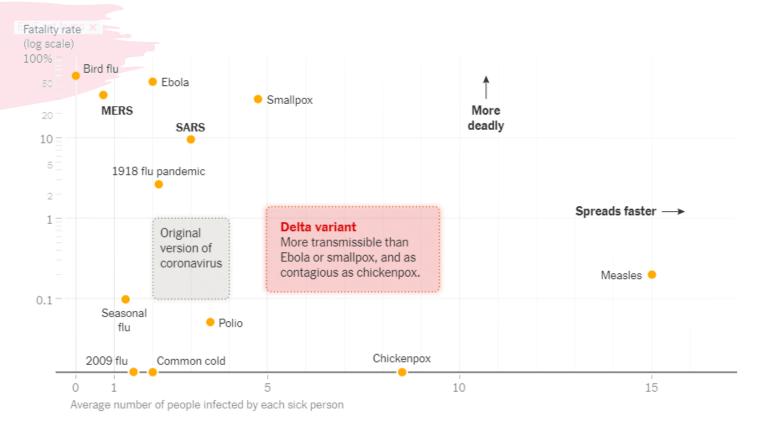
- For both treatment and post-exposure prophylaxis
  - covidtherapeuticreferrals@mountsinai.org
     8390 for New York City based sites including Brooklyn and Queens
  - Mount Sinai South Nassau Outpatient Infusion (516) 632-4998
- For inpatient use discuss with Infectious Diseases

# **Pandemic**

#### **BASIC REPRODUCTIVE NUMBER**

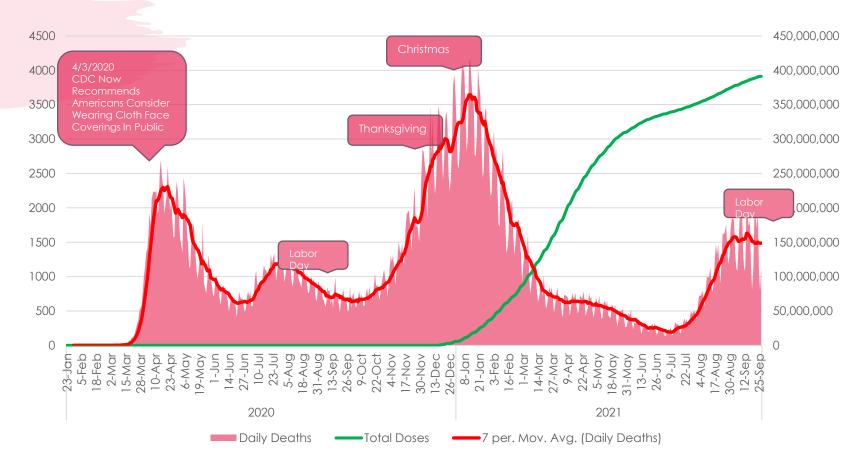
- - 6 \*\*\*\*
- 2.8
- 3.5
- 2.5 And Common cold
- 1.78
- 1.6 hfluenzo (2009)
- 1.3 influenza (seasona)
- 0.48 Å
- 0.47 in





By The New York Times | Note: Average case-fatality rates and transmission numbers are shown. Estimates of case-fatality rates can vary, and numbers for the coronavirus are preliminary estimates.

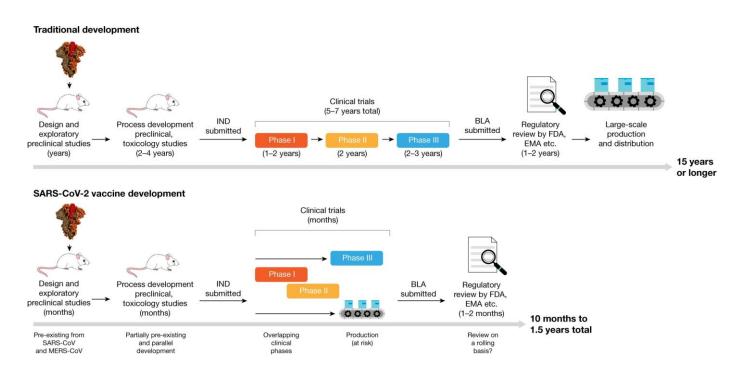
Mandavilli, A. (2021, July 30). C.D.C. internal report calls Delta variant as contagious as chickenpox. The New York Times. Retrieved September 29, 2021, from https://www.nytimes.com/2021/07/30/health/covid-cdc-delta-masks.html.



COVID-19
Pediatric
Vaccine
Update



# Traditional and accelerated vaccinedevelopment pipelines



Krammer, F. SARS-CoV-2 vaccines in development. Nature 586, 516–527 (2020). https://doi.org/10.1038/s41586-020-2798-3

## **Vaccinations**

**Total Vaccine Doses** 

Delivered 467,249,715 Administered 386,780,816

Learn more about the distribution of vaccines.

182.0M
People fully vaccinated

2.24M

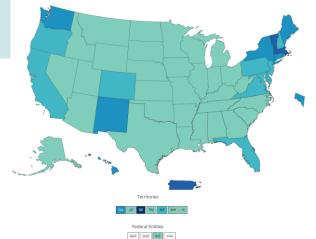
People received an additional dose since August 13th, 2021

About these data

People Vaccinated	At Least One Dose	Fully Vaccinated
Total	212,255,202	182,012,343
% of Total Population	63.9%	54.8%
Population ≥ 12 Years of Age	212,024,583	181,879,375
% of Population ≥ 12 Years of Age	74.8%	64.1%
Population ≥ 18 Years of Age	197,860,013	170,445,634
% of Population ≥ 18 Years of Age	76.6%	66%
Population ≥ 65 Years of Age	50,990,139	45,357,305
% of Population ≥ 65 Years of Age	93.2%	82.9%

CDC | Data as of: September 21, 2021 6:00am ET. Posted: Tuesday, September 21, 2021 4:55 PM ET

Total Doses Administered Reported to the CDC by State/Territory and for Select Federal Entities per 100,000 of the Total Population



## Vaccination Pearls

Issues	Occurrence	Out of Million	Notes
Anaphylaxis	Rare	2-5	
Thrombosis with thrombocytopenia syndrome	Rare	0.000003 with JJ	47 cases
Guillain-Barré Syndrome	Rare	0.000014 with JJ	210 cases
Myocarditis and pericarditis	Rare	0.000002 with mRNA	892 cases
Deaths	None		See below

JJ Doses Given 14.8 mRNA Doses Given 372 million

December 14, 2020, through September 27, 2021

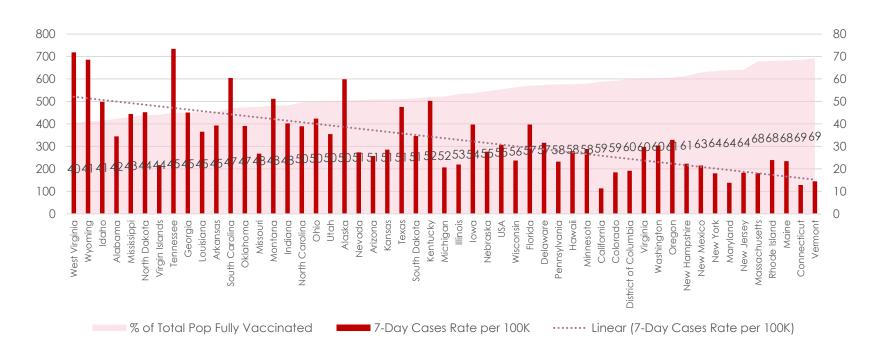
8,164 reports of death (0.0021%) among people who received a COVID-19 vaccine in VAERS. A review of available clinical information, including death certificates, autopsy, and medical records, has not established a causal link to COVID-19 vaccines.

Centers for Disease Control and Prevention. (2021, May 28). COVID-19 Breakthrough Case Investigations and Reporting. Centers for Disease Control and Prevention. https://www.cdc.gov/vaccines/covid-19/health-departments/breakthrough-cases.html.

## Vaccination Pearls

	Totals for USA	Vaccinated Subset	Out of a Million of population	Out of a Million Vaccinated
Population	328,200,000	136,644,618	Per 1,000,000	Per Vaccinated 1,000,000
Infections	33,300,000	10,262	101,463	96
Hospitalizations	2,227,705	2,854	6,788	21
Deaths	592,776	535	1,806	4

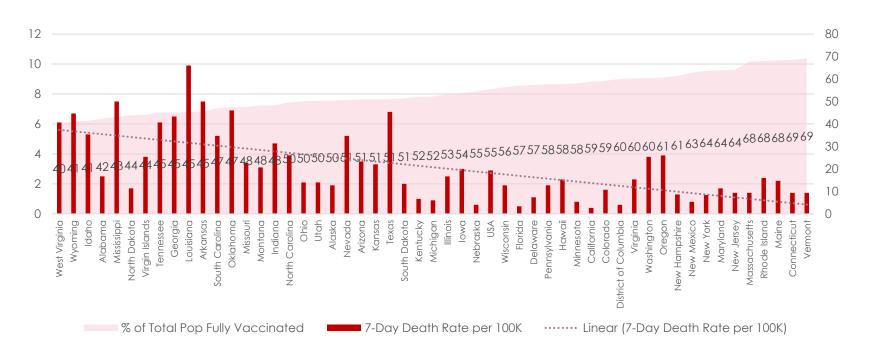
# % Vaccinated vs Cases in last 7 days/100K



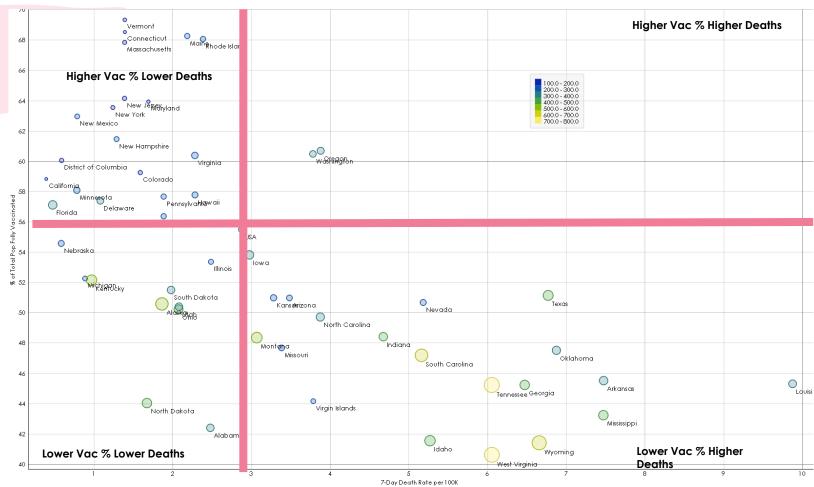
Centers for Disease Control and Prevention. (n.d.). CDC COVID Data Tracker.

Centers for Disease Control and Prevention. https://covid.cdc.gov/covid-data-tracker/#cases\_casesper100klast7days.

# % Vaccinated vs Deaths in last 7 days/100K



Centers for Disease Control and Prevention. (n.d.). CDC COVID Data Tracker. Centers for Disease Control and Prevention. https://covid.cdc.gov/covid-data-tracker/#cases casesper100klast7days.



Centers for Disease Control and Prevention. (n.d.). CDC COVID Data Tracker.

Centers for Disease Control and Prevention. https://covid.cdc.gov/covid-data-tracker/#cases\_casesper100klast7days.

## FDA Fact Sheets

	Pfizer	Moderna	Janssen
Volume	0.3 ml	0.5ml	0.5ml
Doses	2	2	1
Timing of 2 <sup>nd</sup> Dose	3 weeks	1 month	
Storage	-80 to -60 C Until Exp -25 to -15 C for 2 weeks	-50 to -15 C	2 to 8 C
Administered	Intramuscularly	Intramuscularly	Intramuscular
Adverse Reactions in Trials	Injection site - Pain - Swelling - Redness Fatigue Headache Myalgia Chills Arthralgia Fever Nausea Malaise Lymphadenopathy	Injection site - Pain - Swelling - Redness Fatigue Headache Myalgia Arthralgia Chills Fever Nausea / vomiting Lymphadenopathy	Injection site - Pain - Swelling - Redness Fatigue Headache Myalgia Fever Nausea Anaphylaxis
	Anaphylaxis Other hypersensitivity reactions	Anaphylaxis	
Adverse Reactions Post Authorization	Diarrhea Vomiting Myocarditis Pericarditis	Other hypersensitivity reactions Myocarditis Pericarditis	Thrombosis with Thrombocytopenia Guillian-Barre syndrome Capillary leak syndrome
Adverse Reactions Post Authorization  Age	Diarrhea Vomiting Myocarditis	Other hypersensitivity reactions Myocarditis	Guillian-Barre syndrome
	Diarrhea Vomiting Myocarditis Pericarditis	Other hypersensitivity reactions Myocarditis Pericarditis	Guillian-Barre syndrome Capillary leak syndrome
Age	Diarrhea Vomiting Myocarditis Pericarditis > 12 years	Other hypersensitivity reactions Myocarditis Pericarditis > 18 years	Guillian-Barre syndrome Capillary leak syndrome > 18 years

Commissioner, O. of the. (n.d.). COVID-19 vaccines. U.S. Food and Drug Administration. https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines.

#### Pfizer BioNTech COVID-19 Vaccine

Age Group	Status	Date (granted or will apply)
16 and Up	Approval	August 2021
12 to 15	EUA	May 2021
5 to 11	Phase III	Sept 2021
6m to 11	Phase III	Nov 2021

#### Moderna COVID-19 Vaccine

Age Group	Status	Date (granted or will apply)
18 and Up	EUA	Dec 2020
12 to 17	Phase III	Applied for EUA in June 2021
6m to 11	Phase III	Unknown

#### Johnson & Johnson Janssen COVID-19 Vaccine

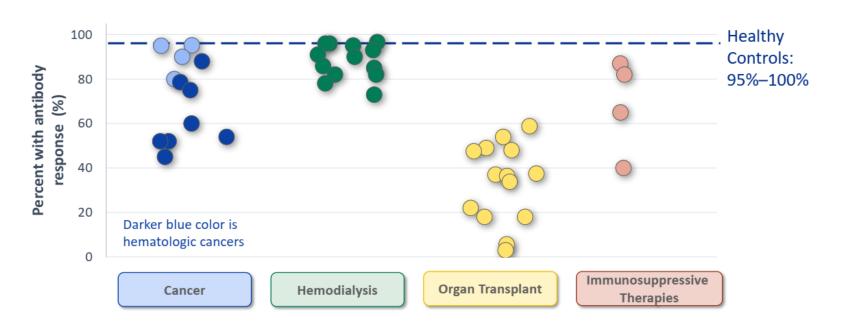
Age Group	Status	Date (granted or will apply)
18 and Up	EUA	Feb 2021
16 to 17	Phase III	Unknown

#### Third Doses and Booster Doses

Third Dose	Booster doses
Initial response to vaccination was not sufficient	Initial response to vaccination sufficient but level of protection wanes over time
Need an altered primary series (3-dose series vs. 2)	May need addition dose to boost the immune system
Identical to first two doses	Identical to first two doses
3 <sup>rd</sup> dose after 28 days of 2 <sup>nd</sup> dose	6 months from 2 <sup>nd</sup> dose
Immunocompromised	Underlying medical conditions or high risk



# Percent antibody response after two m R.N.A vaccine doses by immunocompromised



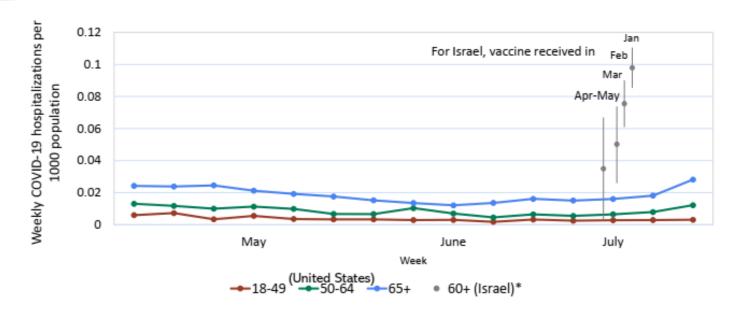
Studies that compared response after 1stand 2<sup>nd</sup> dose demonstrated poor response to dose 1 Antibody measurement and threshold levels vary by study protocol

# Evidence on providing 3<sup>rd</sup> COVID-19 vaccine dose to immunosuppressed people with suboptimal response

- Solid organ transplant recipients (n=30) who had suboptimal response to standard vaccination and subsequently received 3<sup>rd</sup> dose of vaccine
  - 57% received Pfizer series; 43% received Moderna series
  - 24 (80%) had negative antibody titers; 6 (20%) 'low-positive' after primary series
  - Received 3<sup>rd</sup> dose median of 67 days after 2nddose: Janssen (n=15), Moderna (n=9), Pfizer (n=6)
  - After 3<sup>rd</sup> dose:14 (47%) responded, including all low-positives;16 (53%) remained negative
- People on hemodialysis (n=77, no COVID-19 history) vaccinated with up to 3 Pfizer doses
  - 64 (83%) seroconverted after 2<sup>nd</sup> dose
  - Of those negative after 2<sup>nd</sup> dose:
    - 5 (41%) of 12 people given 3<sup>rd</sup> dose seroconverted; 7 (59%) remained negative
- At least one clinical trial pending of 3<sup>rd</sup> dose of Moderna vaccine in transplant recipients

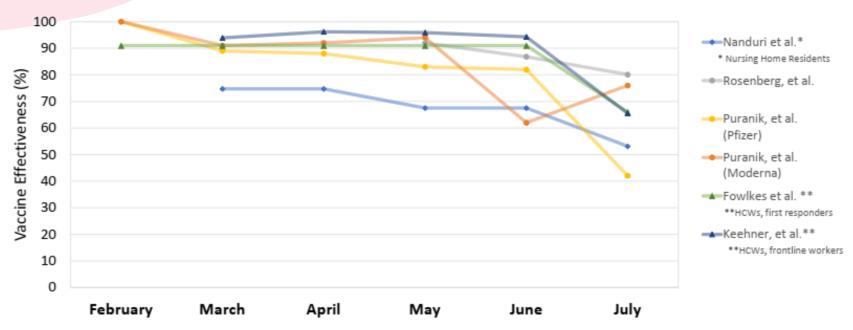


## Incidence among vaccinated people, for hospitalization by month in United States and for severe disease by time since 2nd dose in Israel



<sup>\*</sup>Israel estimates were derived from rate of severe COVID-19 (per 1,000 persons) from July 11, 2021 to July 31, 2021. Each data point represents all person stratified by when second dose of COVID-19 vaccine received.

### Vaccine effectiveness against <u>infection</u> over time Adults ≥18 years of age



Rosenberg ES, Holtgrave DR, Dorabawila V, et al. New COVID-19 Cases and Hospitalizations Among Adults, by Vaccination Status — New York, May 3—July 25, 2021. MMWR Morb Mortal Wkly Rep. ePub: 18 August 2021.

Nanduri S. Effectiveness of Pfizer-BioNTech and Moderna Vaccines in Preventing SARS-CoV-2 Infection Among Nursing Home Residents Before and During Widespread Circulation of the SARS-CoV-2 B.1.617.2 (Delta) Variant

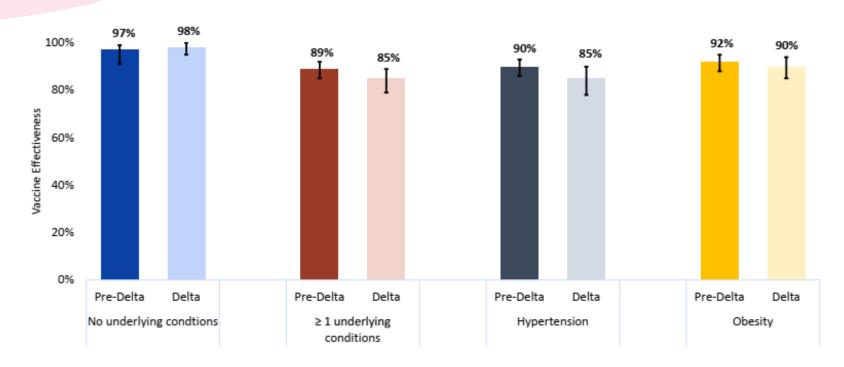
— National Healthcare Safety Network, March 1—August 1, 2021. MMWR Morbidity and Mortality Weekly Report. 2021 2021:70.

Fowlkes A, Gaglani M, Groover K, et al. Effectiveness of COVID-19 Vaccines in Preventing SARS-CoV-2 Infection Among Frontline Workers Before and During B.1.617.2 (Delta) Variant Predominance — Eight U.S. Locations, December 2020—August 2021. MMWR Morb Mortal Wkly Rep. ePub: 24 August 2021.

Puranik A, Lenehan PJ, Silvert E, et al. Comparison of two highly-effective mRNA vaccines for COVID-19 during periods of Alpha and Delta variant prevalence. medRxiv 2021.08.06.21261707.

Keehner J, Horton LE, Binkin NJ et al. Resurgence of SARS-CoV-2 Infection in a Highly Vaccinated Health System Workforce. NEJM, September 1, 2021. DOI: 10.1036/NEJMc2112981

## Vaccine effectiveness against **hospitalization** among adults with underlying medical conditions



## Number of persons eligible (in millions) for a booster dose on September 27th, 2021

	≥6 months after primary series						
Age group	Pfizer-BioNTech	Moderna	Janssen/J&J	Total			
18-29 years old	2.0	1.5	0.3	3.9			
30-49 years old	5.5	4.4	0.9	10.8			
50-64 years old	5.3	4.4	1.2	11.0			
65+ years old	13.6	12.9	0.8	27.4			
Total	26.4	23.4	3.3	53.0			



## At least 28 days after their mRNA vaccine

- Active Tx Malignancies: Solid and Hematologic
- Solid organ Transplant and on Tx
- Hematopoietic stem cell transplant and on Tx
- Moderate or severe primary immunodeficiency
- Advanced or untreated HIV infection
- Active treatment with highdose corticosteroids



At least 6 months after their Pfizer-BioNTech primary series:

- People 65 years and older and residents in long-term care settings
- People aged 50–64 years with underlying medical conditions



### At least 6 months after their Pfizer-BioNTech primary series:

- People aged 18–49 years with underlying medical conditions, based on their individual benefits and risks
- People aged 18-64 years who are at increased risk for COVID-19 exposure and transmission because of occupational or institutional setting

#### Why not use antibodies to decide who gets another dose?

- Helpful for serosurveillance and will tell you about past infection but doesn't tell you about the quality of the entire immune response
  - More than antibodies are involved in the immune response

- Not everyone will have a positive test
  - Depends on test used
  - Do not know "cut-off" to determine protection

## Variants

## NYC Data

Variant	Name	Count	Total	% in NYC	Clasification
B.1.617.2	Delta	4981	5054	98.55	Variant of Concern
B.1.1.7	Alpha	5	5054	0.09	Variant Being Monitored
B.1.351	Beta	0	5054	0	Variant Being Monitored
B.1.427	Epsilon	0	5054	0	Variant Being Monitored
B.1.429	Epsilon	0	5054	0	Variant Being Monitored
B.1.525	Eta	0	5054	0	Variant Being Monitored
B.1.526	lota	0	5054	0	Variant Being Monitored
B.1.621	Mυ	21	5054	0.41	Variant Being Monitored
P.1	Gamma	7	5054	0.13	Variant Being Monitored
P.2	Zeta	0	5054	0	Variant Being Monitored
Other		40	5054	0.79	

 $<sup>&</sup>quot;COVID-19: Data\ on\ Variants."\ 2021.\ Nyc.gov.\ 2021.\ https://www1.nyc.gov/site/doh/covid/covid-19-data-variants.page.$ 

## Mutations of Concern

Туре	Emergence	Location	Effect	Transmissibility	Neutralizing Antibody	Found in
D614G	China	Spike	? Inc Infectious	Increased		Many Variants
N501Y	Independent / Several	Spike	? Tighter fit		•	Alpha, Beta and Gamma
E484K	Independent / Several	Spike	?Evade antibodies		Reduced	Beta and Gamma
L452R	Denmark	Spike	? Help Spread			Delta and Keppa
K417- N/T	South Africa / Brazil	Spike	? Tight Binding	Increased	Reduced	Beta and Gamma, Delta +
Q677- H/P	New Mexico / Louisiana	Spike	? Contagious			Widespread

Corum, J., & Dronavirus variants and mutations. Retrieved June 02, 2021, from https://www.nytimes.com/interactive/2021/health/coronavirus-variant-tracker.html

## Variant Classifications

- Variants being Monitored (VBM)
- Variants of Interest (VOI)
- Variants of Concern (VOC)
- Variants of High Consequence (VOHC)

## Variants Being Monitored (VBM)

Potential or Clear Impact on Medical countermeasures

That has been associated with more severe disease or increased transmission

Are no longer detected or are circulating at very low levels in the United States

Do not pose a significant and imminent risk to public health in the United States.

## Variants being Monitored

Jan 2021

D950N

WHO Label	Name	Protein Substitutions	First Detected	Transmissibility	Virulence	Neutralization by Monoclonal	Neutralization by Convalescent / Post- vaccination sera
Alpha	B.1.1.7	Spike:N501Y, A570D, D614G, P681H, T716I, S982A, D1118H Deletion: 69del, 70del, 144del Some:S494P, E484K, K1191N	United Kingdom Dec 2020	Increased	Increase	No impact	Minimal impact
Beta	B.1.351	Spike:D80A, D215G, K417N, E484K, N501Y, D614G, A701V Deletion: 241del, 242del, 243del	South Africa	Increased		Significantly reduced to m	Reduced
Gamma	P.1	Spike: L18F, T20N, P26S, D138Y, R190S, K417T, E484K, N501Y, D614G, H655Y, T1027I	Japan/ Brazil Nov 2020	Increased	Increased	Significantly reduced	Reduced
Epsilon	B.1.429	Spike: \$13I, W152C, L452R, D614G	United States- (California) Mar 2020			Reduced susceptibility to bamlanivimab and etesevimab	Reduced
Epsilon	B.1.427	Spike: L452R, D614G	United States- (California) Mar 2020	Increased		Reduced susceptibility to bamlanivimab and etesevimab	Reduced
Eta	B.1.525	Spike: A67V, E484K, D614G, Q677H, F888L Deletion: 69del, 70del, 144del,	UK / Nigeria Dec 2020			Potential reduction	Potential reduction
lota	B.1.526	Spike:T95I, D253G, D614G Some: L5F, S477N, E484K A701V	US - New York Nov 2020			Reduced susceptibility to bamlanivimab and etesevimab	Reduced neutralization
Карра	B.1.617.1	Spike: G142D, E154K, L452R, E484Q, D614G, P681R, Q1071H Some: T951	India Dec 2020			Potential reduction	Potential reduction
N/A	B.1.617.3	Spike: T19R, G142D, L452R, E484Q, D614G, P681R, D950N	India Oct 2020			Potential reduction	Potential reduction
Zeta	P.2	Spike: E484K, D614G, V1176F Some: F565L	Brazil Apr 2020			Potential reduction	Reduced neutralization
Mu	B.1.621	Spike: T951, Y144S, Y145N, R346K, E484K, N501Y, D614G, P681H, and	Colombia				

## Variants of Interest (VOI)

Reduced neutralization by antibodies generated against previous infection or vaccination Reduced efficacy of treatments Predicted increase in

## Variants of Interest (VOI)



## Variants of Concern

Increase in transmissibility

More severe disease

Significant reduction in neutralization by antibodies generated during previous infection or vaccination

Reduced effectiveness of treatments or vaccines, or diagnostic detection failures

## Variant of Concern

WHO	Label	Name	Protein Substitutions	First Detected	Transmissibility	Virulence	Neutralization by Monoclonal	Neutralization by Convalescent / Post- vaccination sera
Delta	1	B.1.617.2	Spike: T19R., R158G, L452R, T478K, D614G, P681R, D950N Deletion: 156del, 157del Some: G142D	India Dec 2020	Increased	Increased	Reduced	Potential reduction

## Variant of High Consequence

 A variant of high consequence has clear evidence that prevention measures or medical countermeasures (MCMs) have significantly reduced effectiveness relative to previously circulating variants.



## **Q&A Session with Dr. Waleed Javaid**

# Payer Updates and State and Federal Policy Updates

Maria Alexander
Senior Director of Clinical Operations and
Government Channels
Mount Sinai Health Partners



#### **COVID-19 Vaccine Booster Shot Coverage**

- ▶ Medicare covers Pfizer COVID-19 booster shots for populations specified in EUA
  - \$40 for vaccine administration
- Medicare FFS covers vaccine administration for Medicare FFS and Medicare Advantage patients
  - For Medicare Advantage patients, vaccine claim should be submitted to Part B
     Medicare Administrative Contractor (not the MA plan)
- ► For more information on billing Medicare for vaccines, visit: https://www.cms.gov/covidvax-provider
- ► As we receive payer-specific updates, they will be posted on the COVID-19 Hub: <a href="https://mshp.mountsinai.org/web/mshp/covid-19-payer-updates">https://mshp.mountsinai.org/web/mshp/covid-19-payer-updates</a>

#### **Monoclonal Antibody Treatment – Medicare Coverage**

- ▶ During the COVID-19 public health emergency (PHE), Medicare will cover and pay for these infusions when furnished consistent with their respective EUAs.
- Can be administered by:
  - Freestanding and hospital-based infusion centers
  - Home health agencies
  - Nursing homes
  - Entities with whom nursing homes contract to administer treatment
- ► Health care providers administering the infusions of monoclonal antibody products to treat COVID-19 will follow the same enrollment process as those administering the COVID-19 vaccines.
- ▶ As with COVID-19 vaccines, claims for these services delivered to Medicare Advantage patients should be submitted to original Medicare.
- ► For additional information: <a href="https://www.cms.gov/medicare/covid-19/monoclonal-antibody-covid-19-infusion">https://www.cms.gov/medicare/covid-19/monoclonal-antibody-covid-19-infusion</a>

## Reimbursement for Counseling Unvaccinated NYC Medicaid and MA Patients

- ▶ NYC Health Department Program running from September 1 October 31, 2021
- Providers can receive reimbursement for providing COVID-19 vaccine counseling services:
  - \$50 clinical outreach by licensed health provider
  - \$25 nonclinical outreach by health provider's designee
- Participating Medicaid and MA plans will provide list of patients to provider for outreach
- ▶ Participating plans as of 9/17/21: Amida Care, Empire BCBC/HealthPlus, HealthFirst, Health Insurance Plan of Greater New York/EmblemHealth, MetroPlus Health and United Healthcare Community Plan
- ► Additional information including toolkit with guidance on billing requirements can be found here: <a href="https://www1.nyc.gov/site/doh/covid/covid-19-providers-vaccines.page">https://www1.nyc.gov/site/doh/covid/covid-19-providers-vaccines.page</a>

#### **Provider Relief Funds Updates**

#### **Round 4 Funding**

- ▶ HHS to distribute additional \$17 billion in Provider Relief Funds to providers
- ▶ Intended to cover financial losses from July 1, 2020 March 31, 2021
- ▶ Application period: September 29 October 26, 2021
- Changes for this round:
  - Will reimburse smaller providers at a higher percentage compared to larger providers
  - Bonus payments awarded based on the amount of services provided to Medicaid, CHIP, and Medicare patients
- Application requires information such as internally generated financial statements and federal income tax return
- ► HRSA/HHS hosting technical assistance webinars: 9/30; 10/5; TBD week of 10/11 and 10/18
- Additional information available here: <a href="https://www.hrsa.gov/provider-relief/future-payments">https://www.hrsa.gov/provider-relief/future-payments</a>

#### **Provider Relief Funds Updates Continued ...**

#### **Reporting Deadline Grace Period**

- ► For Recipients who received more than \$10,000 during Payment Received Period 1 (April 10, 2020 to June 30, 2020), reporting Period 1 deadline is September 30, 2021
- ▶ Due to HHS is providing a 60-day grace period to allow providers to come into reporting compliance by November 30, 2021
- ▶ Funds must still be used by September 30, 2021 or returned
- More information on reporting can be found here: https://www.hrsa.gov/provider-relief/reporting-auditing

## Review of Value Based Care Performance Profiles and Action Needed

Loredana Ladogana, MD, FAAFP Medical Director, Provider Engagement

Alexandra Ingber, MPH
Director of Clinical Integration



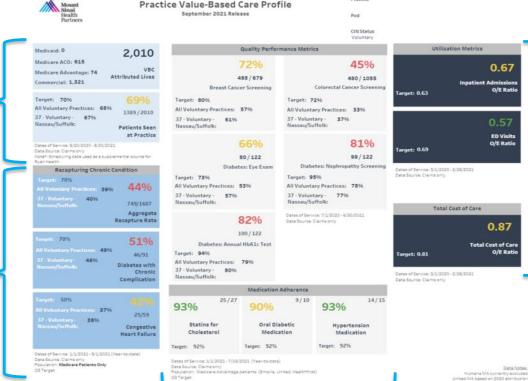
#### **Practice VBC Performance Profile**

#### VBC attribution and **Patients Seen**

- All attributed patients
- Rolling 12 months
- Any Primary Care visit
- Claims based

#### **HCC** chronic condition recapture rate for **Medicare patients**

- Year to date rates
- MSSP/ MA patients
- Diagnoses captured on claims:
  - Aggregate recapture (overall chronic conditions)
  - Heart Failure
  - Diabetes w/ chronic complications



Practice

#### Utilization

- All attributed patients
- Rolling 12 months
- Accompanying high utilizer list
- Observed to Expected (O:E) Ratio
- 1.0 ratio means Observed (actual used services) = Expected (budgeted utilization or cost)

#### **KEY Levers:**

Date Notes

- Capturing condition complexity (E)
- Following up on ED & Inpatient Events (O)

#### **Medication Adherence**

- Year to Date
- Medicare Advantage Patients

### Value Based Contract Practice Profiles: Quality Performance

**Metrics** 

#### **Claims Based**

- Rolling 12 months
- Denominator all VBL meeting the criteria for inclusion
- Numerator patients with a claim that has closed the gap
- Reminder: CPT II Codes on a claim will capture RESULTS (BP & A1c)

### Two Categories Screening & Prevention

- Breast Cancer Screening
- Colorectal Cancer Screening

#### Chronic Condition Management

- Diabetes Mellitus
- A1c Performed
- Nephropathy
- Eye Exam

#### **Ouality Performance Metrics 72**% 488 / 679 Breast Cancer Screening Target: 80% All Voluntary Practices: 57% 37 - Voluntary - 61% Nassau/Suffolk: 66% 80 / 122 Diabetes: Eye Exam Target: 73% All Voluntary Practices: 53% 37 - Voluntary -Nassau/Suffolk: **82**% Data Source: Claims only 100/122 Diabetes: Annual HbA1c Test Target: 94% All Voluntary Practices: 79% 37 - Voluntary -80%

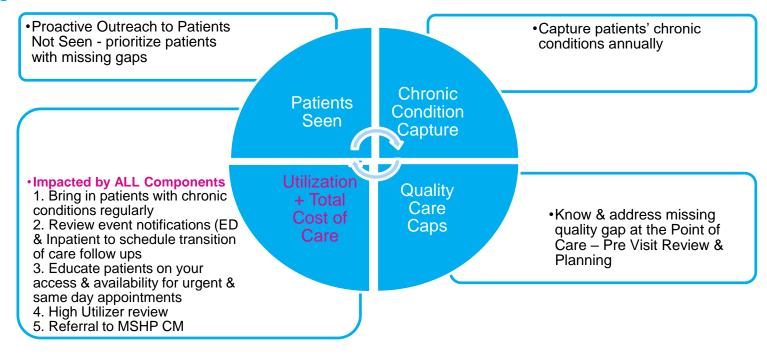
Nassau/Suffolk:

#### 45% 480 / 1055 Colorectal Cancer Screening Target: 72% All Voluntary Practices: 33% 37 - Voluntary -Nassau/Suffolk: **81**% 99/122 Diabetes: Nephropathy Screening Target: 95% All Voluntary Practices: 78% 37 - Voluntary - 77% Nassau/Suffolk: Dates of Service: 7/1/2020 - 6/30/2021

#### **Opportunity for Action**

- Patient Opportunity Report (POR) identifies patients with open gaps - prioritize for outreach to close the gap
- Review your process for knowing what the patient is missing at the time of the visit (i.e. Pre-Visit Planning)

# **Key Intervention Strategy: Use Patient Opportunity Reports Identify Patients to Bring in and Know the Gaps at the Point of Care**



## Practice Demographic Profile Site-Review and Usage Data

Sabrina Raghunandan, MHA Senior Director, Clinical Integrated Network Operations



### **Practice Communication, CI Requirement - Update**

# Practice

#### Practice Profile Web Tool

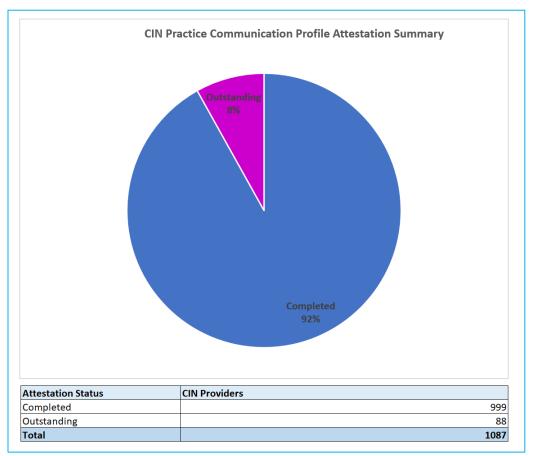
Launched in early June on the MSHP Provider Portal

- Providers and Office Managers are able to make updates to your practice
- Saves manual work and creates a more efficient CIN

#### Advantages in utilizing the tool...

- Update or confirm your practice demographic information online
- Complete the "Practice Communication" requirement of the MSHP Clinical Integration Program
- Ensure your practice is accurately represented in MSHP and health plans' provider directories
- This space can be revisited throughout the year

### **CIN Practice Communications Profile Attestation Summary**



## **Q&A Session**

#### **Board of Managers Election Reminder**

#### Nominate yourself or a colleague!

- ▶ MSHP providers have the opportunity to nominate themselves or a colleague to fill open seats for MSHP's Board of Managers.
- Nominations close on Wednesday, October 6
- ► Submit your nominations here: https://bit.ly/MSHPBoardofManagers

#### **5 Open Seats**

#### **Voluntary Seats:**

- One Manhattan PCP
- One Non-Manhattan PCP
- One Non-Manhattan Specialist

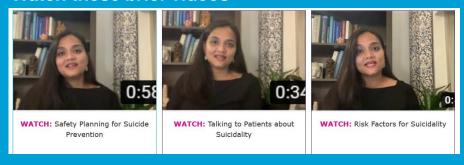
#### **Employed, Any Specialty:**

- One West Side, Manhattan
- One Non-Manhattan



#### **Behavioral Health Reminders**

1. September is Suicide Prevention Month Hear from Dr. Anitha Iyer Watch these brief videos



Visit: https://mshp.mountsinai.org/web/mshp/suicide-prevention-month

#### 2. Depression Screening Improves and Saves Lives

Note: October 7, 2021,

National Depression Screening Day

3. Hear from Dr. Fields and Dr. DePierro (Mount Sinai Clinical Director, Center for Stress Resilience, and Personal Growth)

#### **Stream the MSHP Podcast**





Episode 37: Suicide Prevention Programs In The Healthcare Workforce

Listen on iTunes or SoundCloud

## Thank You for Attending and Participating!

# The next Town Hall will be on November 16, 2021!