COVID-19 – Where We are and the Path Ahead for Staff and Patients
October 13, 2021

Objectives

- Learn how the Delta Variant has affected SOT clinics and projects and thus, be able to plan for more in-person encounters with patients/clients in a safe manner.
- Gain a fuller understanding as to how the dynamics of the health care worker – patient/client relationship shifted due to the lack of face-to-face encounters and how to best address this issue.
- Identify the importance of the principles of self-care.

Presenters

Rajeev Bais, MD, MPH
COVID Pandemic

Where are we now?
Where are we headed?
Rajeev Bals and Edwin Hayes
10/13/2021
<table>
<thead>
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New COVID-19 cases plummet to lowest levels since last June

New reported cases

Delta variant now dominant in England
Rolling 7 day average of daily cases in England

Variant cases estimated using proportion found in sequences analysed by COG-UK
Source: BBC analyses of COG-UK and geno.uk data
The number of people that one sick person will infect (on average) is called $R_0$. Here are the maximum $R_0$ values for a few viruses.

- COVID-19 (original strain): 3 people
- COVID-19 (Delta strain): 7 people
- Chickenpox: 10 people
- Measles: 12 people
- Mumps: 12 people
- 1918 flu: 2 people
- SARS: 4 people

More contagious

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Outbreak of SARS-CoV-2 Infections, Including COVID-19 Vaccine Breakthrough Infections, Associated with Large Public Gatherings — Barnstable County, Massachusetts, July 2021

Weekly, August 6, 2021 / 75(3):338-339

On July 30, 2021, the report was posted online as an MMWR Early Release.

Centers for Disease Control and Prevention

Morbidity and Mortality Weekly Report (MMWR)

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FIGURE 1. SARS-CoV-2 infections (N = 46) associated with large public gatherings, by date of specimen collection and vaccination status — Barnstable County, Massachusetts, July 2021

- Fully vaccinated
- Partially vaccinated or fully vaccinated, or vaccination status unknown

Multiple events and large public gatherings

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10/14/2021
CDC Reverses Guidance, Says Fully Vaccinated People Should Wear Masks Inside in Certain Areas

Citing "preliminary data on the highly transmissible delta coronavirus variant, the agency also changed its masking guidance for schools.

By Canalia Behbahani | July 27, 2021, 5:05 p.m.

FDA Approves First COVID-19 Vaccine

Approval Signifies Key Achievement for Public Health

For immediate release: August 23, 2021

Today, the U.S. Food and Drug Administration approved the first COVID-19 vaccine. The vaccine has been licensed as the Pfizer-BioNTech COVID-19 Vaccine, and is now authorized for use in individuals 16 and older. The vaccine also continues to be under study in adolescents, children, and adults.
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After Delta became the most common variant, fully vaccinated people had reduced risk of...

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<tr>
<th>INFECTION</th>
<th>HOSPITALIZATION</th>
<th>DEATH</th>
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<tr>
<td>5X</td>
<td>&gt;10X</td>
<td>&gt;10X</td>
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Vaccination offers strong protection against COVID-19

COVID-19 Vaccine Breakthrough Infections Reported to CDC — United States, January 1—April 30, 2021

Mortality and Morbidity Weekly Report (MMWR)

Increasing percentage of vaccinated persons among those hospitalized in COVID-NET

- Reflects increases in vaccine coverage, higher coverage in older adults
- Higher risk among older age groups for hospitalization and death relative to younger people (regardless of vaccination status)
Common Comorbidities in hospitalized COVID-19 patients

**Coronavirus Disease 2019 (COVID-19)-
Associated Hospitalization Surveillance Network: March 2020-March 2021**

**Adults:**
- Obesity: 48.6%
- Diabetes: 43.9%
- Cardiovascular disease: 36.5%

**Children:** <17
- Obesity: 34.2%
- Asthma: 12.2%

- Preeclampsia/eclampsia (relative risk [RR], 1.76; 95% CI, 1.27-2.43)
- Severe infections (RR, 3.38; 95% CI, 1.63-7.01)
- Intensive care unit admission (RR, 5.04; 95% CI, 3.13-8.10)
- Maternal mortality (RR, 22.3; 95% CI, 2.88-172)
- Preterm birth (RR, 1.59; 95% CI, 1.30-1.94)
- Medically indicated preterm birth (RR, 1.97; 95% CI, 1.56-2.51)
- Severe neonatal morbidity index (RR, 2.66; 95% CI, 1.69-4.18)
- Severe perinatal morbidity and mortality index (RR, 2.14; 95% CI, 1.66-2.75)
Refugees to the United States, especially those who are recently resettled, may experience living arrangements or working conditions that put them at greater risk of getting COVID-19. Some refugees also have limited access to health care, as well as certain underlying medical conditions that put them at increased risk of severe illness from COVID-19, compared to the rest of the U.S. population.

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Mild Covid
Severe Covid (hospitalized)
Vaccinated
examined serum effect on various SARAS-CoV2 variants
- Spike protein binding
- Neutralization Potential
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Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine through 6 Months

• 44,165 >16 yrs
• 2,264 12-15 yrs
• Overall vaccine efficacy at 6 mo was 91.3%
• Vaccine efficacy against severe disease was 96.7%
• Gradual decline in efficacy over time
• Not powered to give assess efficacy according to subgroup, however VE was consistently high in all groups
6 mo, prospective study on 4868 healthcare workers in Israel who were tested monthly for the presence of anti-spike IgG and neutralizing Ab

- Level of IgG decreased at a consistent rate
- Neutralizing ab decreased rapidly for the 1st 3 mo with a slow decrease after
- Neutralizing ab at 6mo was substantially lower in men, persons over 65yrs, and in those with immunosuppression
Dec 21, 2020 - Sept 5, 2021

- 947,035 received 1 dose; 907,763 received 2
- 18,746 breakthrough case; 10,543 with 2 doses
- 35% received a dx of COVID-19 based on symptoms
- 377 (1 dose) and 106 (2 dose) hospitalizations
- 34 (1 dose) and 15 (2 dose) fatalities

Vaccine effectiveness against any SARS-CoV-2 infection

- negligible for the 1st 2 weeks after the 1st dose
- 36.8% in the 3rd week after the 1st dose
- 77.5% in the 1st month after the 2nd dose
- effectiveness gradually declined afterward
- patterns of decline effectiveness were similar in all strains
Waning of BNT162b2 Vaccine Protection against SARS-CoV-2 Infection in Qatar

• no significant difference between age groups above/below 60
• peak effectiveness against symptomatic disease was 81.5%
  • 73% against asymptomatic disease
• effectiveness against severe disease
  • negligible in 1st 2 weeks after 1st dose
  • 66% in 3rd weeks after 1st dose
  • >96% in 1st 2 months after 2nd dose

Assessed ‘real-world’ effectiveness of mRNA vaccines against the delta variant
• Qatar: As of August 2021: 73.8% 2 doses, 87.8% 1 dose
• Pfizer: 906,078 (1 dose), 877,354 (2 doses)
• Moderna: 490,828 (1 dose), 409,041 (2 doses)
• Median date of second dose was May 7, 2021 (Pfizer) and May 12, 2021 (Moderna)
• Median age 31-32 yrs; co-morbidities not assessed

As of July 21, 2021
• Breakthrough Infections of the Delta Strain
  • Pfizer: 54 (1 doses) and 249 (2 dose)
  • Moderna: 27 (1 doses) and 26 (2 doses)
• Severe Infections (hospitalizations) from the Delta Strain
  • Pfizer: 3 (1 dose) and 4 (2 doses) [1 ICU admission]
  • Moderna: 3 (1 dose) and 0 (2 doses)
• Zero fatalities
• Estimated Vaccine Effectiveness (+PCR regardless of reason for test)
  • >14 days after 1\textsuperscript{st} dose: 64.2\% (Pfizer), 79\% (Moderna)
  • Severe dx effectiveness: 100\% (Pfizer and Moderna)
  • >14 days after the 2\textsuperscript{nd} dose: 53.5\% (Pfizer), 84.8\% (Moderna)
    • Severe dx effectiveness: 89.7\% (Pfizer), 100\% (Moderna)

\begin{figure}
\centering
\includegraphics[width=\textwidth]{figure1}
\caption{BNT162b2 and mRNA-1273 COVID-19 vaccine effectiveness against the Delta (B.1.617.2) variant in Qatar}
\end{figure}

\begin{figure}
\centering
\includegraphics[width=\textwidth]{figure2}
\caption{Effectiveness of Covid-19 Vaccines in Ambulatory and Inpatient Care Settings}
\end{figure}

21,544 ED or UC visits
41,552 hospitalizations
Adults >50 yrs with COVID-like symptoms
Jan-June 2021 (not yet delta)
Tested for SARS-CoV-2
Vaccination status determined
Vaccine effectiveness estimated
Effectiveness of Covid-19 Vaccines in Ambulatory and Inpatient Care Settings

- Vaccine effectiveness against hospitalization relating to:
  - African Americans - 86%
  - Hispanics - 90%
  - Patients > 85yrs - 83%

LACDPH/California Immunizations Registry 2 (CAIR2) data
- Delta predominant strain
- 43,127 reported COVID infections in people >16 years old
- Fully Vaccinated: 10,895 (25.3%)
- Partially Vaccinated: 1,431 (3.3%)
- Unvaccinated: 30,801 (71.4%)
- Fully Vaccinated: 3.2% hospitalized, 0.5% ICU, 0.2% mech vent
- Unvaccinated: 7.6% hospitalized, 1.5% ICU, 0.5% mech vent
- Unvaccinated had 4.9x the rate of infection and 29.2x the rate of hospitalization
• 60+ yr olds who received their vax in March 21 were 1.6x more protected against infection and 1.7x more protected against severe disease than those who received their vax in Jan 21

• Similar results were found in all age groups after 6 mo

Protection of BNT162b2 Vaccine Booster against Covid-19 in Israel

Tamar Ben-On et al.

Table 1. Primary Outcomes of Confirmed Infection and Severe Illness

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Booster Group</th>
<th>Confirmed Infection</th>
<th>Adjusted Rate Ratio (95% CI)</th>
</tr>
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<tbody>
<tr>
<td>Confirmed infection</td>
<td>534</td>
<td>395</td>
<td>11.5 (10.4–12.5)</td>
</tr>
<tr>
<td>Severe cases</td>
<td>29</td>
<td>6</td>
<td>19.5 (13.9–25.3)</td>
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Considerations in boosting COVID-19 vaccine immune responses
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Reduced Risk of Reinfection with SARS-CoV-2 After COVID-19 Vaccination — Kentucky, May–June 2021

• case (1): control (2)
  • matched by age, sex, and date of initial + SARS-CoV-2 PCR test (March–December 2020)
  • 246 cases: 492 controls
  • 60.6% female
  • Fully Vaccinated: 20.3% cases, 34.3% controls
  • Ky residents with previous infections who were unvaccinated had 2.34 times the odds of reinfection compared to those fully vaccinated

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Comparing January to August 2021
By age groups

- Age <12: 0.6% vs. 2.9%
- Age 12-19: 0.0% vs. 1.8%
- Age 20-39: 6.7% vs. 15.3%
- Age 40-59: 24% vs. 37.6%
- Age 60-79: 52% vs. 34.1%
- Age 80+: 17.3% vs. 8.2%
### Why are vaccination rates so low in 12-24? Myocarditis Fears

- VAERS data
- Kaiser Permanente Southern California analysis
- Incidence myocarditis post mRNA vaccine aged 18 and older
- Compared with myocarditis incidence in unvaccinated 12/14/2020-07/20/2021, and with vaccinated individuals during a 10-day period 1 year prior to vaccination

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#### Acute Myocarditis Following COVID-19 mRNA Vaccination in Adults Aged 18 Years or Older


[https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/27848](https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/27848)
• 15 cases of myocarditis among the 2,392,924 Kaiser Permanente Southern California members who received at least 1 dose of the mRNA vaccines within 6 months of follow up
• 1 case per 172,414 fully vaccinated individuals
• Relative ratio of 2.7 compared with unvaccinated individuals

https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/27848

All men aged <40 years, no prior cardiac history, discharged within 1-5 days (median 3) of conservative management

https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2784801
Safety of the BNT162b2 mRNA Covid-19 Vaccine in a Nationwide Setting

- Vaccinated and control groups 884,828 persons
- Vaccination associated with an elevated risk of myocarditis (risk ratio, 3.24; 95% confidence interval [CI], 1.55 to 6.84)
- SARS-CoV-2 infection associated with substantially increased risk of myocarditis (risk ratio, 18.28; 95% CI, 3.95 to 25.12) and of additional serious adverse events, including deep-vein thrombosis, pulmonary embolism, myocardial infarction, intracranial hemorrhage, and thrombocytopenia.

DOI: 10.1056/NEJMc2110475

Myocarditis: classic, MIS-C, and vaccine-associated

- Pre-print, retrospective cohort study, all patients hospitalized at Emory aged <21 years with classic viral myocarditis from 2015-2019, MIS-C myocarditis from 3/2020-2/2021 and COVID-19 vaccine-related myocarditis from 5/2021-6/2021
- 201 total, 43 with classic myocarditis, 149 MIS-C myocarditis, and 9 COVID-19 vaccine-related myocarditis
- 93% (139/149) with MIS-C myocarditis and 100% of patients with COVID-19 vaccine-related myocarditis had normal LVEF at the time of discharge compared to 70% (30/43) of classic myocarditis group (p<0.001)

https://www.medrxiv.org/content/10.1101/2021.10.05.21264581v1
Multisystem Inflammatory Syndrome in Children (MIS-C)

- An individual aged <21 years presenting with fever*, laboratory evidence of inflammation**, and evidence of clinically severe illness requiring hospitalization, with multisystem (≥2) organ involvement (cardiac, renal, respiratory, hematologic, gastrointestinal, dermatologic or neurological); AND
- No alternative plausible diagnoses; AND
- Positive for current or recent SARS-CoV-2 infection by RT-PCR, serology, or antigen test; or exposure to a suspected or confirmed COVID-19 case within the 4 weeks prior to the onset of symptoms.

https://www.medrxiv.org/content/10.1101/2021.10.05.21264581v1
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What is new in terms of treatment?

- Monoclonal antibodies
- Dexamethasone
- Remdesivir
- Tocilizumab/Baricitinib
  - Molnupiravir
Molnupiravir

• Oral
• Ribonucleoside analog
• Inhibits the replication of SARS-CoV-2

Molnupiravir – MOVe-OUT

• Randomized, placebo-controlled, double-blind, multisite trial
• End points: Hospitalization and/or Death from time of enrollment through 29 days
• 775 pts, 18 yo or older
• Mild to moderate COVID
• Less than 5day of symptoms
• At least 1 risk factor associated with poor disease outcome
• Excluded HD/eGFR <30ml/min, HIV with VL>50 or AIDS defining illness w/in 6mo; hx of hep b/c with cirrhosis, ESLD, HCC, AST/ALT >3x ULN; plt<100K

Molnupiravir – MOVe-OUT

• Compared 200mg; 400mg; 800mg of molnupiravir BID for 5 days to placebo
• Interim analysis: 775pts (Molnu:385, Placebo:377)
• Hospitalization/Death: 7.5% vs 14.1% (0 deaths vs 8 deaths)
• Delta, Gamma, Mu strains accounted for 80%
• Under FDA EUA evaluation
**Costs**

- Molnupiravir ~$700 for 5-day course
- Monoclonal antibodies ~$1,250-$2,100 per infusion
- Vaccine ~$20/dose

**COVID-19 hospitalizations**

October 6, 2021

- 215 Hospitalized
- 90 Vaccinated (42%)
- 125 Unvaccinated (58%)
- 49 Ventilated
- 2 Vaccinated (6%)
- 46 Unvaccinated (94%)
- 79 ICU
- 9 Vaccinated (11%)
- 70 Unvaccinated (89%)

Combined data from all 21 Prisma Health hospitals treating COVID-19 patients in its Columbia and Greenville, S.C. markets.

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Thank you for attending this webinar!

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The National Capacity Building Project is a project of the Center for Victims of Torture: www.cvt.org

More resources are available at www.healtorture.org.