NCB Webinar

COVID Vaccinations: Practical and Ethical Considerations

February 24, 2021

National Capacity Building Project
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NCB Webinar

COVID Vaccinations: Practical and Ethical Considerations

February 24, 2021
Objectives

1. Have new tools for developing or strengthening their program’s approach to COVID vaccination
2. Be able to recognize current and novel treatment options for COVID-19
3. Be able to identify good practices and ethical considerations for talking with clients about COVID-19 vaccinations
4. Be able to locate resources to help themselves and their clients obtain accurate information on COVID-19
5. Learn/adapt approaches for addressing vaccine hesitancy and equity concerns among underserved clients
Presenters

Rajeev Bais, MD, MPH
Director
The Carolina Survivor Clinic at USC

Edwin Hayes II, MD
Co-director
The Carolina Survivor Clinic at USC

National Capacity Building Project
COVID Vaccinations: Practical and Ethical considerations

Edwin Hayes, MD and Rajeev Bais, MD
The Carolina Survivor Clinic at USC

2/24/21
- Epidemiology
- Tests and Treatments
- Vaccines
- Variants
- Vaccine Hesitancy
- Barriers to Overcome
<table>
<thead>
<tr>
<th>State</th>
<th>Total Cases</th>
<th>Per 100,000</th>
<th>Daily Avg. in Last 7 Days</th>
<th>▼ Per 100,000</th>
</tr>
</thead>
<tbody>
<tr>
<td>South Carolina</td>
<td>505,589</td>
<td>9,820</td>
<td>2,367</td>
<td>46</td>
</tr>
<tr>
<td>New York</td>
<td>1,598,226</td>
<td>8,216</td>
<td>7,366</td>
<td>38</td>
</tr>
<tr>
<td>New Jersey</td>
<td>769,109</td>
<td>8,659</td>
<td>3,097</td>
<td>35</td>
</tr>
<tr>
<td>Rhode Island</td>
<td>123,980</td>
<td>11,703</td>
<td>313</td>
<td>30</td>
</tr>
<tr>
<td>North Carolina</td>
<td>849,325</td>
<td>8,098</td>
<td>2,936</td>
<td>28</td>
</tr>
<tr>
<td>Florida</td>
<td>1,872,915</td>
<td>8,720</td>
<td>5,991</td>
<td>28</td>
</tr>
<tr>
<td>Delaware</td>
<td>85,090</td>
<td>8,738</td>
<td>264</td>
<td>27</td>
</tr>
<tr>
<td>Georgia</td>
<td>962,215</td>
<td>9,063</td>
<td>2,819</td>
<td>27</td>
</tr>
<tr>
<td>Alaska</td>
<td>57,316</td>
<td>7,835</td>
<td>187</td>
<td>26</td>
</tr>
<tr>
<td>Kentucky</td>
<td>401,579</td>
<td>8,989</td>
<td>1,115</td>
<td>25</td>
</tr>
</tbody>
</table>
• Decision analytical model
  • Assessed multiple scenarios for transmission
  • Estimated that over 50% of overall transmission from asymptomatic individuals
  • Pre-symptomatic individuals and asymptomatic
Compared PCR and antigen test results:
In PCR + symptomatic people, antigen test missed 1 in 5
In PCR + asymptomatic people, antigen test missed 3 in 5
<table>
<thead>
<tr>
<th>DISEASE SEVERITY</th>
<th>PANEL'S RECOMMENDATIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Hospitalized, Mild to Moderate COVID-19</td>
<td>There are insufficient data to recommend either for or against any specific antiviral or antibody therapy. SARS-CoV-2 neutralizing antibodies (bamlanivimab or casirivimab plus imdevimab) are available through EUAs for outpatients who are at high risk of disease progression. The Panel recommends against the use of dexamethasone or other corticosteroids (AIi).</td>
</tr>
<tr>
<td>Hospitalized but Does Not Require Supplemental Oxygen</td>
<td>The Panel recommends against the use of dexamethasone (AIi) or other corticosteroids (AIii). There are insufficient data to recommend either for or against the routine use of remdesivir. For patients at high risk of disease progression, the use of remdesivir may be appropriate.</td>
</tr>
</tbody>
</table>
| Hospitalized and Requires Supplemental Oxygen (But Does Not Require Oxygen Delivery Through a High-Flow Device, Noninvasive Ventilation, Invasive Mechanical Ventilation, or ECMO) | Use one of the following options:  
- Remdesivir<sup>1,2</sup> (e.g., for patients who require minimal supplemental oxygen) (BIIa)  
- Dexamethasone<sup>1,2</sup> plus remdesivir<sup>1,2</sup> (e.g., for patients who require increasing amounts of supplemental oxygen) (BIIi)<sup>1,2</sup>  
- Dexamethasone<sup>1</sup> (e.g., when combination therapy with remdesivir cannot be used or is not available) (BII) |
| Hospitalized and Requires Oxygen Delivery Through a High-Flow Device or Noninvasive Ventilation | Use one of the following options:  
- Dexamethasone<sup>1,2</sup> (AI)  
- Dexamethasone<sup>1,2</sup> plus remdesivir<sup>1,2</sup> (BIIi)<sup>1,2</sup> |
| Hospitalized and Requires Invasive Mechanical Ventilation or ECMO | Dexamethasone<sup>1</sup> (AI)<sup>1,2</sup> |

Rating of Recommendations: A = Strong; B = Moderate; C = Optional  
Rating of Evidence: I = One or more randomized trials without major limitations; IIa = Other randomized trials or subgroup analyses of randomized trials; IIb = Nonrandomized trials or observational cohort studies; III = Expert opinion
**VACCINE BASICS: HOW WE DEVELOP IMMUNITY**

The body’s adaptive immune system can learn to recognize new, invading pathogens, such as the coronavirus SARS-CoV-2.

1. **Virus enters the body**
   - Coronavirus infection:
     - The virus uses its surface spike protein to lock onto ACE2 receptors on the surface of human cells. Once inside, these cells translate the virus’s RNA to produce more viruses.
   - Spike protein
   - M protein
   - RNA
   - ACE2 receptor

2. **Virus enters a cell**
   - Virus fuses with vesicle and its RNA is released
   - Viral RNA translated into proteins
   - 4. Virus assembly

3. **Virus enters a cell**
   - Virus enters a cell
   - Viral RNA translated into proteins
   - 4. Virus assembly
   - 5. Virus release
   - Virus ingested by antigen-presenting cell (APC)

4. **Virus assembly**
   - Viral RNA translated into proteins
   - 4. Virus assembly
   - 5. Virus release

5. **Virus release**
   - Virus ingested by antigen-presenting cell (APC)
   - T-helper cell
   - B cell
   - Anti-coronavirus antibody
   - Prevents virus from binding, or tags it for destruction
   - Cytotoxic T cell
   - Destroys infected cells

**Immune response**
- Specialized ‘antigen presenting cells’ (APCs) engulf the virus and display portions of it to activate T-helper cells.

**Immune response**
- T-helper cells enable other immune responses:
  - B cells make antibodies that can block the virus from infecting cells, as well as mark the virus for destruction.
  - Cytotoxic T cells identify and destroy virus-infected cells.

**Long-lived ‘memory’**
- B and T cells that recognize the virus can patrol the body for months or years, providing immunity

*Simplified

Graphics: Nik Spencer/Nature
The benefit was greatest in:
- patients with symptoms > 7 days
- patients who required mechanical ventilation.
- No benefit among patients with shorter symptom duration or no supplemental O2
- Improved mortality


- November 5, 2020
- 1,062 patients
- 50% remdesivir, 50% to placebo

<table>
<thead>
<tr>
<th></th>
<th>Remdesivir</th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median recovery time</td>
<td>10</td>
<td>15</td>
</tr>
<tr>
<td>15-day mortality</td>
<td>6.7%</td>
<td>11.9%</td>
</tr>
<tr>
<td>29-day mortality</td>
<td>11.4%</td>
<td>15.2%</td>
</tr>
<tr>
<td>SAE</td>
<td>24.6%</td>
<td>31.6%</td>
</tr>
</tbody>
</table>
Convalescent Plasma

- NIH Update - October 9, 2020
- There are insufficient data for the COVID-19 Treatment Guidelines Panel to recommend either for or against the use of convalescent plasma for the treatment of COVID-19.
Early High-Titer Plasma Therapy to Prevent Severe Covid-19 in Older Adults


- January 6, 2021/February 18, 2021
- Randomized, double-blind, placebo-controlled study in Argentina b/w June 4 - October 25, 2020
- Convalescent Plasma with high antibody titers (1:1000) was given within 72 hrs of onset of symptoms
- 160 patients randomized: over 75yo or b/w 65-74 with significant co-morbidities
- Stopped early because of a decrease in COVID patients
- Progression to Severe Respiratory Disease was 16% in pts receiving CP vs 31% of placebo
- Patients receiving plasma with titers > 1:3200 reduced the risk of progression to severe disease by 73%
Tocilizumab

- **Studies Showing No Benefit:**
  - RCT-TCZ-COVID-19 (n=126)
    - Primary end point- hypoxia, ICU admission or death- Stopped early due to lack of benefit
  - CORIMUNO-19-TOCI(n=131)
    - Toci may have reduced need for mechanical ventilation but no impact on mortality
  - BACC Bay Trial(n=243)- 7 Boston hospitals
    - Placebo controlled
    - Toci did not reduce requirement for intubation or reduce mortality
  - Empacta (n=389)
    - Placebo controlled
    - Toci reduced need for mechanical ventilation but mortality did not improve
  - COVACTA trial
    - First global, randomized, double-blind, placebo-controlled phase III study
    - Primary endpoint - clinical status in hospitalized patients with severe infection
    - Did not meet its primary endpoint of improved clinical status
    - No difference in patient mortality at week 4

- **NIH Recommendations - August 27,2020**
  - The Panel recommends against the use of IL-6 receptor monoclonal antibodies (sarilumab, tocilizumab) or anti-IL-6 monoclonal antibody (siltuximab) for the treatment of COVID-19, except in a clinical trial.
REMCAP

Critically ill adult patients with suspected or confirmed COVID-19

Admitted to the ICU

Receiving respiratory or CV organ support

2046 pts randomized; 353 (tocilumab) vs. 48 (sarilumab) vs. 402 controls

Included steroids as SOC

Outcomes:

- Decreased hospital mortality: 28% vs. 22.2% vs. 35.8%
- Median organ support-free days up to day 21: 10 vs. 11 vs. 0
- 90 day survival significantly improved
Ivermectin is an FDA approved antiparasitic drug - used to treat several neglected tropical diseases, including onchocerciasis, helminthiases, and scabies

- Ivermectin inhibits the host importin alpha/beta-1 nuclear transport proteins
- ICON Study: Retrospective cohort study of consecutive patients hospitalized at four Broward Health hospitals in South Florida with confirmed SARS-CoV-2.
  - Ivermectin was associated with lower mortality during treatment of COVID-19

NIH Recommendation

The COVID-19 Treatment Guidelines Panel recommends against the use of ivermectin for the treatment of COVID-19, except in a clinical trial (AIII).
Hydroxychloroquine

- NIH Recommendations:
  - The Panel recommends against the use of chloroquine or hydroxychloroquine with or without azithromycin for the treatment of COVID-19 in hospitalized patients (AI).
  - In non-hospitalized patient, the Panel recommends against the use of chloroquine or hydroxychloroquine with or without azithromycin for the treatment of COVID-19, except in a clinical trial (AI).
  - The Panel recommends against the use of high-dose chloroquine (600mg twice daily for 10 days) for the treatment of COVID-19 (AI).
MONOCLONAL ANTIBODY: Bamlanivimab

- A neutralizing monoclonal antibody that targets the receptor-binding domain of the spike protein of SARS-CoV-2
- Blocks viral entry into cells
- November 9, 2020, the FDA issued an Emergency Use Authorization (EUA) to make bamlanivimab available for the treatment of non-hospitalized patients with mild to moderate COVID-19 who are at risk for progressing to severe disease and/or hospitalization.
- Criteria:
  - BMI > 35
  - Chronic Kidney Disease
  - Diabetes mellitus
  - Immuno-compromising condition
  - Aged > 65 years
  - Aged 55 years and have:
    - cardiovascular disease, or
    - hypertension, or
    - Chronic obstructive pulmonary disease/other respiratory disease
MONOCLONAL ANTIBODY: Casirivimab Plus Imdevimab

- 2 recombinant human monoclonal antibodies that bind to nonoverlapping epitopes of the spike protein receptor binding domain of SARS-CoV-2
- Blocks binding of the spike protein to the host cell
- November 21, 2020, the FDA issued an Emergency Use Authorization (EUA) to make casirivimab plus imdevimab combination available for the treatment of non-hospitalized patients with mild to moderate COVID-19 who are at risk for progressing to severe disease and/or hospitalization.

Criteria:
- BMI >35
- Chronic Kidney Disease
- Diabetes mellitus
- Immuno-compromising condition
- Aged >65 years
- Aged 55 years and have:
  - cardiovascular disease, or
  - hypertension, or
  - Chronic obstructive pulmonary disease/other respiratory disease
Increased Resistance of SARS-CoV-2 Variants B.1.351 and B.1.1.7 to Antibody Neutralization

Antibody Resistance of SARS-CoV-2 Variants B.1.351 and B.1.1.7

Pengfei Wang, Manoj S. Nair, Lihong Liu, Sho Ik etani, Yang Luo, Yicheng Guo, Maple Wang, Jian Yu, Baoshan Zhang, Peter D. Kwong, Barney S. Graham, John R. Mascola, Jennifer Y. Chang, Michael T. Yin, Magdalena Sobieszczyk, Christos A. Kyratsous, Lawrence Shapiro, Zizhang Sheng, Yaoxing Huang, David D. Ho

doi: https://doi.org/10.1101/2021.01.25.428137

This article is a preprint and has not been certified by peer review [what does this mean?].
Trends in Infectious Disease Mortality in the United States During the 20th Century
SARS-CoV-2 Vaccines: How Did We Get Here?

- Usually a very deliberate process but stakes were too high
- Operation Warpspeed
- Modern Science
- Experiences from MERS/SARS
- A LOT OF LUCK!
• Immunity
Coronavirus Vaccine Tracker

By Carl Zimmer, Jonathan Corum and Sui-Lee Wee  Updated Feb. 23, 2021

<table>
<thead>
<tr>
<th>PHASE 1</th>
<th>PHASE 2</th>
<th>PHASE 3</th>
<th>AUTHORIZED</th>
<th>APPROVED</th>
<th>ABANDONED</th>
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<tbody>
<tr>
<td>40</td>
<td>27</td>
<td>20</td>
<td>7</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Vaccines testing safety and dosage</td>
<td>Vaccines in expanded safety trials</td>
<td>Vaccines in large-scale efficacy tests</td>
<td>Vaccines in early or limited use</td>
<td>Vaccines approved for full use</td>
<td>Vaccines abandoned after trials</td>
</tr>
</tbody>
</table>
Vaccination strategies to combat novel corona virus SARS-CoV-2

Satish Chandra Pandey a, b, Veni Pande a, b, Diksha Sati a, Shobha Upreti a, Mukesh Samant a, b, c

Review article
# Leading vaccines

<table>
<thead>
<tr>
<th>Developer</th>
<th>How It Works</th>
<th>Phase</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer-BioNTech</td>
<td>mRNA</td>
<td>2,3</td>
<td>Approved in several countries. Emergency use in U.S., E.U., other countries.</td>
</tr>
<tr>
<td>Gamaleya</td>
<td>Ad26, Ad5</td>
<td>3</td>
<td>Early use in Russia. Emergency use in other countries.</td>
</tr>
<tr>
<td>Oxford-AstraZeneca</td>
<td>ChAdOx1</td>
<td>2,3</td>
<td>Emergency use in U.K., E.U., other countries.</td>
</tr>
<tr>
<td>CanSino</td>
<td>Ad5</td>
<td>3</td>
<td>Limited use in China.</td>
</tr>
<tr>
<td>Johnson &amp; Johnson</td>
<td>Ad26</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Vector Institute</td>
<td>Protein</td>
<td>3</td>
<td>Early use in Russia.</td>
</tr>
<tr>
<td>Novavax</td>
<td>Protein</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Sinopharm</td>
<td>Inactivated</td>
<td>3</td>
<td>Approved in China, U.A.E., Bahrain. Emergency use in Egypt, other countries.</td>
</tr>
<tr>
<td>Sinovac</td>
<td>Inactivated</td>
<td>3</td>
<td>Approved in China. Emergency use in Brazil, other countries.</td>
</tr>
<tr>
<td>Sinopharm-Wuhan</td>
<td>Inactivated</td>
<td>3</td>
<td>Limited use in China, U.A.E.</td>
</tr>
<tr>
<td>Bharat Biotech</td>
<td>Inactivated</td>
<td>3</td>
<td>Emergency use in India.</td>
</tr>
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OPERATION WARP SPEED
ACCELERATED VACCINE PROCESS

MISSION: Deliver 300 million doses of safe and effective vaccine by 1 January 2021.

TYPICAL PROCESS
3 MONTHS 5 MONTHS 21 MONTHS 23 MONTHS 15 MONTHS 6 MONTHS 73 MONTHS TO COMPLETION

ACCELERATED PROCESS
5 MONTHS 6 MONTHS 3 MONTHS 14 MONTHS TO COMPLETION

1. A typical 8-month process is accelerated by:
   - Creating vaccine candidates immediately after viral genome sequence is available.
   - Using vaccine platforms developed for other diseases.

2. A typical 42-month process is accelerated by:
   - Large scale Phase III clinical trials of 30,000 volunteers allowing for rapid collection and earlier analysis of safety and efficacy data of demographically diverse populations by the FDA, reducing the typical 12-month approval process to three months.
   - Two promising candidates began Phase III clinical trials in July, with others to follow quickly in coming months. Before beginning Phase III, candidates must show safety data from animal and human studies.
   - The U.S. Government funding at-risk, large-scale manufacturing of the most promising vaccine candidates during Phase III clinical trials to ensure any vaccine proven to be safe and effective is available immediately upon FDA Emergency Use Authorization (EUA) approval or licensure.

3. A typical 15-month process is accelerated by:
   - A tiered approach based on CDC recommended allocation methodology used as part of pandemic flu planning and the COVID-19 response will be used to determine vaccine distribution.
   - CDC leading distribution planning with DoD augmentation.

4. A typical 6-month process is accelerated by:
   - Planning for infrastructure and distribution before the vaccines are approved or authorized.

5. A typical 12-month FDA review for EUA approval or licensure is accelerated by:
   - Providing continuous safety and efficacy data collected in large Phase III clinical trials.

R&D + Preclinical Trials Vaccine Candidate/s Identified
Phase I Clinical Trials
Phase II Clinical Trials
Manufacturing
Phase III Clinical Trials
Distribution
mRNA Vaccines
<table>
<thead>
<tr>
<th></th>
<th>BNT 162b2</th>
<th>mRNA-1273</th>
</tr>
</thead>
<tbody>
<tr>
<td>FDA Approved</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>EUA</td>
<td>16+</td>
<td>18+</td>
</tr>
<tr>
<td>Prevention symptomatic disease</td>
<td>95% (8 vs 162 cases)</td>
<td>94% (11 vs 185 cases)</td>
</tr>
<tr>
<td>Prevention asymptomatic disease</td>
<td>? No data yet</td>
<td>Yes, swab at 2nd vaccine 15 vs 39 asymptomatic</td>
</tr>
<tr>
<td>Prevention of severe disease</td>
<td>Yes (1 vs 3 cases) or 1 vs 9</td>
<td>Yes (0 vs 30 cases)</td>
</tr>
<tr>
<td>Prevention of death</td>
<td>? (2 vs 4 deaths)</td>
<td>? (6 vs 7 (1 COVID) death)</td>
</tr>
<tr>
<td>Minimum order</td>
<td>975 doses (5 doses/vial)</td>
<td>100 doses (10 doses/vial)</td>
</tr>
<tr>
<td>Storage</td>
<td>-94F</td>
<td>-4F</td>
</tr>
<tr>
<td>Stability</td>
<td>Thawed - 5 days</td>
<td>Fridge 5 days/Room Temp 12Hr</td>
</tr>
<tr>
<td>Dosing</td>
<td>2 doses 21 days apart</td>
<td>2 doses 28 days apart</td>
</tr>
<tr>
<td>Dose</td>
<td>mRNA 30ug (0.3ml)</td>
<td>MRNA 100ug (0.5ml)</td>
</tr>
</tbody>
</table>
BNT 162b2 (Pfizer/BioNTech)

- mRNA vaccine EU submitted 1/20/202
- Reviewed 1/30/2020 (92 pages)
- C45900 was started as a Phase 1/2 study in the US and amended to expand to a global Phase 2/3 study enrolling ~44,000 participants (1:1 randomization)
- 83% White, 28% Hispanic, 42% >55 yo
- 20% with comorbidity, 30% obese, 23 pregnancies (9 withdrew)
- Ediary in > 6,000 patients
- SAEs, deaths, treatment limiting AEs (0.1%), same in both arms
Figure 8. Geometric Mean Titers: SARS-CoV-2 Neutralization Assay – NT50 – Evaluable Immunogenicity Population – Phase 2
Figure 9. Participants Reporting Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Age Group – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population Age Group: 16-55 Years
Figure 11. Participants Reporting Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Age Group – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population Age Group: 16-55 Years

The diagram illustrates the percentage of subjects experiencing various systemic events (Fever, Fatigue, Headache, Chills, Vomiting, Diarrhea, Muscle pain, Joint pain) within 7 days after each dose (Dose 1 and Dose 2) of different vaccine groups (BNT162b2 20 μg, BNT162b2 10 μg, Placebo) and placebo. The severity of these events is categorized as Mild, Moderate, Severe, or Grade 4.

The severity criteria for Fever are as follows:
- Mild: >38.0°C to 38.4°C
- Moderate: >38.4°C to 38.9°C
- Severe: >38.9°C to 40.0°C
- Grade 4: >40.0°C
<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>Vaccine Group (as Administered)</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>BNT162b2 (30 µg) (N=18801)</td>
<td>Placebo (N=18785)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>n (%)</td>
<td>n (%)</td>
<td></td>
</tr>
<tr>
<td>Any event</td>
<td>5071 (27.0)</td>
<td>2356 (12.5)</td>
<td></td>
</tr>
<tr>
<td>Related\textsuperscript{c}</td>
<td>3915 (20.8)</td>
<td>953 (5.1)</td>
<td></td>
</tr>
<tr>
<td>Severe</td>
<td>220 (1.2)</td>
<td>109 (0.6)</td>
<td></td>
</tr>
<tr>
<td>Life-threatening</td>
<td>18 (0.1)</td>
<td>20 (0.1)</td>
<td></td>
</tr>
<tr>
<td>Any serious adverse event</td>
<td>103 (0.5)</td>
<td>81 (0.4)</td>
<td></td>
</tr>
<tr>
<td>Related\textsuperscript{c}</td>
<td>3 (0.0)</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Severe</td>
<td>57 (0.3)</td>
<td>48 (0.3)</td>
<td></td>
</tr>
<tr>
<td>Life-threatening</td>
<td>18 (0.1)</td>
<td>19 (0.1)</td>
<td></td>
</tr>
<tr>
<td>Any adverse event leading to withdrawal</td>
<td>34 (0.2)</td>
<td>25 (0.1)</td>
<td></td>
</tr>
<tr>
<td>Related\textsuperscript{c}</td>
<td>14 (0.1)</td>
<td>7 (0.0)</td>
<td></td>
</tr>
<tr>
<td>Severe</td>
<td>13 (0.1)</td>
<td>7 (0.0)</td>
<td></td>
</tr>
<tr>
<td>Life-threatening</td>
<td>2 (0.0)</td>
<td>4 (0.0)</td>
<td></td>
</tr>
</tbody>
</table>
Table 9. **Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2 – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population**

<table>
<thead>
<tr>
<th>Efficacy Endpoint</th>
<th>Vaccine Group (as Randomized)</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>BNT162b2 (30 μg) (N=18198)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>n1b</td>
<td>Surveillance Time&lt;sup&gt;c&lt;/sup&gt; (n&lt;sup&gt;2b&lt;/sup&gt;)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>First COVID-19 occurrence from 7 days after Dose 2</td>
<td>8</td>
<td>2.214 (17411)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Placebo (N=18325)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>n1b</td>
<td>Surveillance Time&lt;sup&gt;c&lt;/sup&gt; (n&lt;sup&gt;2b&lt;/sup&gt;)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>162</td>
<td>2.222 (17511)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>VE (%)</td>
<td>95.0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>(95% CI)</td>
<td>(90.3, 97.6)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Pr (VE &gt;30%</td>
<td>data)&lt;sup&gt;f&lt;/sup&gt;</td>
<td>&gt;0.9999</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 16. **Vaccine Efficacy – First Severe COVID-19 Occurrence From 7 Days After Dose 2 – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population**

<table>
<thead>
<tr>
<th>Efficacy Endpoint</th>
<th>Vaccine Group (as Randomized)</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>BNT162b2 (30 μg) (N=18198)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>n1b</td>
<td>Surveillance Time&lt;sup&gt;c&lt;/sup&gt; (n&lt;sup&gt;2b&lt;/sup&gt;)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>First severe COVID-19 occurrence from 7 days after Dose 2</td>
<td>1</td>
<td>2.215 (17411)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Placebo (N=18325)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>n1b</td>
<td>Surveillance Time&lt;sup&gt;c&lt;/sup&gt; (n&lt;sup&gt;2b&lt;/sup&gt;)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>2.232 (17511)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>VE (%)</td>
<td>66.4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>(95% CI)</td>
<td>(-124.8, 96.3)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Pr (VE &gt;30%</td>
<td>data)&lt;sup&gt;f&lt;/sup&gt;</td>
<td>0.7429</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Table 18. Vaccine Efficacy – First Severe COVID-19 Occurrence After Dose 1 – Dose 1 All-Available Efficacy Population

<table>
<thead>
<tr>
<th>Efficacy Endpoint Subgroup</th>
<th>BNT162b2 (30 µg) (N=21669)</th>
<th>Placebo (N=21668)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n1(^b)</td>
<td>Surveillance Time(^c) (n2(^d))</td>
</tr>
<tr>
<td>First severe COVID-19 occurrence after Dose 1</td>
<td>1</td>
<td>4.021 (21314)</td>
</tr>
<tr>
<td>After Dose 1 to before Dose 2</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td>Dose 2 to 7 days after Dose 2</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>≥7 Days after Dose 2</td>
<td>1</td>
<td>4</td>
</tr>
</tbody>
</table>
mRNA-1273 (Moderna)

- mRNA vaccine EUA submitted 11/30/20
- Reviewed 12/17/20 (54 pages)
- mRNA -1273-P301 is a 30,000 participant study done at 99 sites in the US (1:1 randomization)
- 80% White, 20% Hispanic, 25% >65 yo
- 26% with comorbidity, 6.7% severely obese, 13 pregnancies (2 abortions: 1 spontaneous (both in placebo)
- Solicited AE in all patients
- SAE, deaths, treatment limiting AEs (0.1%) - same in both arms
**Injection-Site Adverse Events after First Dose**

- mRNA-1273: 84.2%
- Placebo: 19.8%

**Systemic Adverse Events after Second Dose**

- mRNA-1273: 79.4%
- Placebo: 36.5%

**Sample Sizes**

- mRNA-1273: N=15,168
- Placebo: N=15,155
- mRNA-1273: N=14,677
- Placebo: N=14,566
B Modified Intention-to-Treat Analysis

<table>
<thead>
<tr>
<th>Vaccine Efficacy (95% CI)</th>
<th>Incidence Rate (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo</td>
<td></td>
</tr>
<tr>
<td>mRNA-1273</td>
<td></td>
</tr>
<tr>
<td>93.0 (88.9–95.6)</td>
<td>79.8 (70.5–89.9)</td>
</tr>
</tbody>
</table>

No. at Risk

<table>
<thead>
<tr>
<th></th>
<th>Placebo 14,598</th>
<th>Placebo 14,590</th>
<th>Placebo 14,567</th>
<th>Placebo 14,515</th>
<th>Placebo 13,806</th>
<th>Placebo 12,352</th>
<th>Placebo 12,694</th>
<th>Placebo 11,450</th>
<th>Placebo 9,736</th>
<th>Placebo 6,729</th>
<th>Placebo 4,067</th>
<th>Placebo 1,200</th>
<th>Placebo 0</th>
</tr>
</thead>
<tbody>
<tr>
<td>mRNA-1273</td>
<td>14,550</td>
<td>14,543</td>
<td>14,532</td>
<td>14,504</td>
<td>13,825</td>
<td>13,398</td>
<td>12,791</td>
<td>11,573</td>
<td>9,911</td>
<td>6,871</td>
<td>4,179</td>
<td>1,238</td>
<td>0</td>
</tr>
</tbody>
</table>

Days since Randomization

Covid-19 Onset

<table>
<thead>
<tr>
<th>Placebo (N=14,598)</th>
<th>mRNA-1273 (N=14,550)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Randomization to 14 days after dose 1</td>
<td>11</td>
</tr>
<tr>
<td>14 Days after dose 1 to dose 2</td>
<td>35</td>
</tr>
<tr>
<td>Dose 2 to 14 days after dose 2</td>
<td>19</td>
</tr>
<tr>
<td>Starting 14 days after dose 2</td>
<td>204</td>
</tr>
<tr>
<td>Total (any time after randomization)</td>
<td>269</td>
</tr>
<tr>
<td>Subgroup</td>
<td>Placebo (N=14,073)</td>
</tr>
<tr>
<td>-----------------------------------------</td>
<td>--------------------</td>
</tr>
<tr>
<td>All patients</td>
<td>185/14,073</td>
</tr>
<tr>
<td>Age</td>
<td></td>
</tr>
<tr>
<td>≥18 to &lt;65 yr</td>
<td>156/10,521</td>
</tr>
<tr>
<td>≥65 yr</td>
<td>29/3552</td>
</tr>
<tr>
<td>Age, risk for severe Covid-19</td>
<td></td>
</tr>
<tr>
<td>18 to &lt;65 yr, not at risk</td>
<td>121/8403</td>
</tr>
<tr>
<td>18 to &lt;65 yr, at risk</td>
<td>35/2118</td>
</tr>
<tr>
<td>≥65 yr</td>
<td>29/3552</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>87/7462</td>
</tr>
<tr>
<td>Female</td>
<td>98/6611</td>
</tr>
<tr>
<td>At risk for severe Covid-19</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>43/3167</td>
</tr>
<tr>
<td>No</td>
<td>142/10,906</td>
</tr>
<tr>
<td>Race and ethnic group</td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>144/8916</td>
</tr>
<tr>
<td>Communities of color</td>
<td>41/5132</td>
</tr>
</tbody>
</table>
ChAdOx1 (Oxford/Astra Zeneca)

- Chimpanzee adenovirus chimeric vaccine
- Approved in Canada, UK
- ChAdOx1 combination of 5 studies in UK, SA, Brazil (12k patients)
- 18-55 yo cohort planned as single-dose cohort. The protocol was modified in July 2020 to offer a 2nd dose (after robust booster responses identified in early immunogenicity cohorts)
- >80% white, average BMI 25, female, >80% HCW
- 70% efficacy but only approx. 10% against B1.351 variant
Johnson and Johnson/Janson

- Efficacy 72% in the US, 66% in Latin America, **57% in South Africa** (due to prevalence of B.1.351—95% cases with the variant)
  - 66% effective overall at preventing moderate/severe COVID-19 (**85% effective against severe**)
  - Onset of protection observed as early as day 14
  - No cases reported after day 49
  - Consistent protection across race, age (including >60yo)
- Viable in the refrigerator for 3 months
- US has agreed to purchase 100 million doses
- One dose!
Novavax

- Phase 3: 89.3% efficacy
  - Trial done in UK with the UK (501Y.V1) variant dominating (>50% cases)
- Phase 2b:
  - South Africa with 93% cases attributable to SA (501Y.V2) variant
  - 60.1% efficacy in HIV negative
  - 49.4% overall
- Note: 1/3 of participants had prior COVID-19 infection indicating prior infection may not protect against 501Y.V2 variant
<table>
<thead>
<tr>
<th>Description</th>
<th>Pfizer-BioNTech COVID-19 vaccine</th>
<th>Moderna COVID-19 vaccine</th>
</tr>
</thead>
<tbody>
<tr>
<td>mRNA</td>
<td>Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2</td>
<td>Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2</td>
</tr>
<tr>
<td>Lipids</td>
<td>2[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide</td>
<td>PEG2000-DMG: 1,2-dimyristoyl-rac-glycerol, methoxypolyethylene glycol</td>
</tr>
<tr>
<td></td>
<td>1,2-distearoyl-sn-glycero-3-phosphocholine</td>
<td>1,2-distearoyl-sn-glycero-3-phosphocholine</td>
</tr>
<tr>
<td></td>
<td>Cholesterol</td>
<td>Cholesterol</td>
</tr>
<tr>
<td></td>
<td>(4-hydroxybutyl)azanediyl]bis(hexane-6,1-diyl)bis(2-hexyldecanoate)</td>
<td>SM-102: heptadecan-9-yl 8-((2-hydroxyethyl) (6-oxo-6-(undecyloxy) hexyl) amino) octanoate</td>
</tr>
<tr>
<td>Salts, sugars, buffers</td>
<td>Potassium chloride</td>
<td>Tromethamine</td>
</tr>
<tr>
<td></td>
<td>Monobasic potassium phosphate</td>
<td>Tromethamine hydrochloride</td>
</tr>
<tr>
<td></td>
<td>Sodium chloride</td>
<td>Acetic acid</td>
</tr>
<tr>
<td></td>
<td>Dibasic sodium phosphate dihydrate</td>
<td>Sodium acetate</td>
</tr>
<tr>
<td></td>
<td>Sucrose</td>
<td>Sucrose</td>
</tr>
</tbody>
</table>
Goals of Mass Vaccination

- Decrease Morbidity
  - Vulnerable, elderly, high risk, essential, socially mobile
- Decrease Mortality
  - Elderly, vulnerable, high risk
- Decrease the Transmission/lower R0
  - Socially mobile, essential, ‘anti-maskers/denialist/party animals’
A New Variant

A series of tiny mutations found in many British samples of the coronavirus may help the virus spread more easily. The coronavirus variant is known as B.1.1.7.

By Jonathan Corum | Source: Andrew Rambaut et al., Covid-19 Genomics Consortium U.K.
New Variants

- **B.1.1.7 lineage** (UK variant): RBD mutation at position 501 (N501Y)
  - Increased transmissibility
- B.1.351 lineage (South Africa or Zambia variant): multiple mutations in the spike protein (K417T, E484K, N501Y)
  - Some evidence that the E484K may affect neutralization by some polyclonal/monoclonal antibodies
- P.1 lineage (Brazil variant): 3 mutations in RBD (K417T, E484K, N501Y)
  - Concern for reinfection as well as increase in transmissibility

Serum Neutralizing Activity Elicited by mRNA-1273 Vaccine — Preliminary Report

- Serum obtained 7d after 2nd vax
- Recombinant virus
- Neutralization of B1.117
  - 1.2 fold reduction of titer
- Neutralization of B1.351
  - 6.4 fold reduction of titer
- GMNT was 1:290
- All samples were neutralized
- Engineered mutations into USA-WA1/2020
- 50% plaque reduction neutralization testing
- Sera 2-4 weeks after 2\textsuperscript{nd} Pfizer vax
- GMNT for USA-WA1/2020 was 501
- GMNT for B1.351 was 184
  - Weaker by 2/3
Where do refugees fit in all of this?
Implementation in the Refugee Community

- Multiple barriers to care in general, many of which are illuminated by COVID and vaccination procedures
- Limited information regarding knowledge, attitudes, and practices surrounding vaccines
- Historic mistrust in certain communities
- Turbulent US political environment
- Novelty of COVID-19 vaccines

- Refugee, immigrant, and migrant populations are not homogeneous
  - Attitudes towards vaccinations are varied
  - Need to be familiar with each varying community needs and concerns
Hesitation
Barriers
Hesitation
Hesitation in the Refugee Community

Advocating Agency          Paternalism
Hesitation in the Refugee Community

Advocating Agency

Paternalism
Hesitation in the Refugee Community

What do you know?
Hesitation in the Refugee Community

Hesitation in the Refugee Community

Vaccines & Immunizations

COVID-19 Vaccination
- Product Info by US Vaccine
- Clinical Care
- Provider Requirements and Support
- Training and Education

Recipient Education
- mRNA COVID-19 Vaccines
- Viral Vector COVID-19 Vaccines
- Making a Strong Recommendation for COVID-19 Vaccination

Understanding and Explaining mRNA COVID-19 Vaccines

Messenger RNA vaccines—also called mRNA vaccines—are some of the first COVID-19 vaccines authorized for use in the United States. This page provides vaccine information for healthcare professionals and vaccine providers and tips for explaining mRNA vaccines to patients and answering questions about how mRNA vaccines work, their safety profile, and common misconceptions.

Key Points to Share with Your Patients

In addition to the following key messages, you can refer your patients with questions to CDC’s COVID-19 mRNA vaccine webpage.

- Like all vaccines, COVID-19 mRNA vaccines have been rigorously tested for safety before being authorized for use in the United States.
- mRNA technology is new, but not unknown. They have been studied for more than a decade.
- mRNA vaccines do not contain a live virus and do not carry a risk of causing disease in the vaccinated person.
Hesitation in the Refugee Community

What Clinicians Need to Know About the Pfizer-BioNTech COVID-19 Vaccine

Amanda Cohn, MD
Sarah Mbaeyi, MD, MPH

December 13, 2020
Hesitation in the Refugee Community

What do they know?
Hesitation in the Refugee Community

- Heterogenous groups have heterogeneous needs and hesitations
  - Need to assess to avoid generalizations

- Systemic distrust
  - Doctors may be present in torture
  - May be fleeing an antagonistic government
  - May be traumatized by US government
  - Many predators financial and physical
  - Sharing information could lead to judgement or antagonism
Hesitation in the Refugee Community

- Addressing systemic distrust
  - Avoid wearing a white coat
  - Hear and address their needs (may be far from your specialty)
  - Meet in nonclinical settings, including home visits
    - See family, context
  - Establish community centered activities
    - Tutoring, soccer, language classes, support group, gardening
  - Cultivate agency
- Avoid judgement
- Be consistent
- Good rapport can take years
- If lacking rapport, reach out to a community leader/advocate
Hesitation in the Refugee Community

- Heterogenous groups have heterogeneous needs and hesitations

- Congolese focus group
  - One of our most hesitant groups
  - 20 people involved, some of our most active/receptive community
  - 3 had talked about vaccination with a healthcare professional prior to this meeting
Hesitation in the Refugee Community

- Congolese focus group
  - Nearly all had seen social media posts decrying vaccines
    - Often in French or Swahili, sometimes English
    - Often invoke religion, particularly Christianity
Hesitation in the Refugee Community

Prophecies About A New Virus And Covid-19 Coronavirus Vaccine Warnings

Do not take any vaccines for the Corona Virus or any of the other coming plagues. (See very last article below by Dr Mercola with comments from Senator Robert Kennedy Jr)
Hesitation in the Refugee Community

- Congolese focus group concerns from social media
  - Will this be mandatory? (No, vaccination requires consent.)
  - Will this cost money? (No, it is free.)
  - Will this change my DNA? Give the mark of the beast?
Hesitation in the Refugee Community
Hesitation in the Refugee Community

- Congolese focus group concerns from social media
  - Will this be mandatory? (No, vaccination requires consent.)
  - Will this cost money? (No, it is free.)
  - Will this change my DNA? Give the mark of the beast? (No, it does not interact with DNA.)
  - Are there microchips to track me? (No, the vials and the fluid are clear and there is nothing to see in them. We have given these vaccines to other people and received them ourselves. All ingredients in vaccines are public knowledge. Messenger RNA is a medical term.)
Hesitation in the Refugee Community

- Social media posts/ memes
  - What is in the vaccine? Purported pork products, aborted fetal tissue?
    - No pork
    - No fetal tissue
  - Infertility from S-protein?
    - No

Pope Calls Coronavirus Vaccinations an Ethical Obligation

Saying he will be vaccinated himself next week, Francis described the refusal to get the vaccine as suicidal.
Hesitation in the Refugee Community

- Vaccine effects

- Is this going to give me COVID? Will I need to quarantine after vaccination? (No, this is not an COVID infection, and it will not make you contagious. You will not need to quarantine.)
Hesitation in the Refugee Community

- Social media posts/ memes

  - What about side effects? Death, Bell’s palsy (or stroke), allergy?
Hesitation in the Refugee Community

- Social media posts/ memes

- What about side effects? Death, Bell’s palsy (or stroke), allergy?
Hesitation in the Refugee Community

- Social media posts/ memes
  - What about side effects? Death, Bell’s palsy (or stroke), allergy?

![Graph showing side effects of Pfizer-BioNTech COVID-19 vaccine, dose 1 (N = 749,735)]
Hesitation in the Refugee Community

- Social media posts/ memes

- What about side effects? Death, Bell’s palsy (or stroke), allergy?

![Graph showing percentage of enrollees experiencing different side effects after vaccination](image)
Hesitation in the Refugee Community

- Social media posts/ memes
- What about side effects? Death, Bell’s palsy (or stroke), allergy?
Hesitation in the Refugee Community

- Social media posts/ memes
  - What about side effects? Death, Bell’s palsy (or stroke), allergy?
    - Bell’s palsy
      - Not a stroke
    - Noted in 4 people in Moderna vaccine trial out of 30,000
      - This could be normal population variance
Hesitation in the Refugee Community

- Social media posts/ memes
  - What about side effects? Death, Bell’s palsy (or stroke), allergy?

- Anaphylaxis
  - Sixty-two reports of anaphylaxis have been confirmed, 46 after receipt of the Pfizer-BioNTech vaccine and 16 after receipt of the Moderna vaccine
  - 4.5 cases per million doses administered, is within the range reported after receipt of inactivated influenza vaccine (1.4 per million), pneumococcal polysaccharide vaccine (2.5 per million), and live attenuated herpes zoster vaccine (9.6 per million)
  - Effective treatments for anaphylaxis exist – they live
Hesitation in the Refugee Community

- Social media posts/ memes
  - What about side effects? Death, Bell’s palsy (or stroke), allergy?
  - Elderly deaths
    - Norwegian study suggests a handful of people had died following vaccination
    - Very frail, elderly patients
    - No controls
    - Systemic effects may have been related but difficult to show clear link
Hesitation in the Refugee Community

- While not formally proven yet, it seems likely vaccination decreased viral burden and decreases ability to transmit infection to others
- CDC does not require quarantine for vaccinated people after exposure
- Appealing to health of neighbor can help
- Idea that they could prevent someone else from being sick appears to be more effective than personal worry
Hesitation in the Refugee Community

- Benefits of Vaccination
  - May help prevent spread to other people you care about
  - Avoid missed days of work/ missed pay
  - Long term functionality is protected (brain fog, functional capacity)
  - People who get the vaccination don’t die from COVID
Barriers
Implementation in the Refugee Community

- Policy competence
  - What phase are we in?
  - Who is included?
  - Different from state to state
  - Often unclear even to providers
  - Interpreters are Phase 1a
  - Volunteers working frontline healthcare should be considered
- Check health department guidance

Phase 1a mission-critical workers and individuals include:

- 65+ year olds, regardless of health status or preexisting conditions
- Anesthesiology assistants, registered cardiovascular invasive specialists, and operating room staff
- Athletic Trainers
- American Sign Language (ASL) and other interpreters in healthcare facilities
- Autopsy room staff, coroners, embalmers, and funeral home staff at risk of exposure to bodily fluids
- Chiropractors
- Dentists and dental hygienists and technicians
- Dietary and food services staff in healthcare facilities
- Environmental services staff in healthcare facilities
- Harbor pilots
- Home health and hospice workers
- Hospital transport personnel
- Hospital inpatients 65 and older
- Laboratory personnel and phlebotomists
- Licensed dietitians
- Long-Term Care Facility (LTCF) residents and staff
- Medical assistants
- Medical first responders (paid and volunteer): EMS; fire department and law enforcement personnel who provide emergency medical care
- Nurses, nurse practitioners, and nurse’s aides/assistants
- Opticians and optometrists and assistants/technicians
- Home caregivers for children who have a tracheostomy, are ventilator-dependent or who have a Medically Complex Children’s Waiver. Requires a medical provider’s signed attestation to confirm caregiver meets criteria.
- Persons providing medical care in correctional facilities and correctional officers
- Pharmacists and pharmacy technicians
- Physical and occupational therapists and assistants
- Physicians, including medical house staff (i.e., interns, residents, fellows), and physician assistants
- Podiatrists
- Public health healthcare workers who are frequently interacting with persons with potential COVID-19 infection
- Radiology technicians
- Respiratory care practitioners, such as respiratory therapists
- Speech language pathologists and assistants and audiologists
- State/local government employees and their contractors who are mission-critical for maintaining operations of COVID-19 vaccinations and testing in SC
- Students and interns of the above categories
Implementation in the Refugee Community

- Technological competence
  - Especially in elderly
  - May not know how to access scheduling
  - Register on site
Implementation in the Refugee Community

- Transportation
  - Getting to the vaccination site and back
  - Group transport can be arranged but consider COVID precautions (spaced seating, masks, etc...)

If the driver and passengers are not sick (everyday practices for safe transportation):

- Wear a mask: This is especially important when it’s hard to stay at least 6 feet away from people.
  - Masks should not be placed on:
    - Babies and children younger than 2 years old
    - Anyone who has trouble breathing or is unconscious
    - Anyone who is incapacitated or otherwise unable to remove the mask without help
  - Masks are meant to protect other people in case the wearer is unknowingly infected but does not have symptoms.

Practice social distancing (also called physical distancing) to the extent possible:

- The passengers should sit as far away as possible from the driver and each other.
- Travel with windows open or use the vehicle’s vents for fresh air circulation.

Wash your hands:

- Before you leave home, wash your hands with soap and water for at least 20 seconds or use hand sanitizer with at least 60% alcohol.
Implementation in the Refugee Community

- Language Services
  - Autonomy must not be jeopardized due to a language barrier
  - Resources (registration, consent) available in appropriate language
    - Challenging when dealing with varied small populations
  - [https://switchboardta.org/blog/a-round-up-of-multilingual-resources-on-covid-19/](https://switchboardta.org/blog/a-round-up-of-multilingual-resources-on-covid-19/) (pretty extensive)
- Not everyone can read
- Interpreters or phone lines at vaccination site (confirm this)
Implementation in the Refugee Community

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A Round-Up of Multilingual Resources on COVID-19

9 Comments  By Switchboard  March 10, 2020
Implementation in the Refugee Community

- Availability
  - Being able to take time from work is a major constraint
  - Many vaccination sites have hours during times when people typically work
  - Identify accessible sites at accessible hours
    - Lobby for these sites if not available
    - Consider doctor’s note for medical necessity
      - If can get doctor’s note, consider requesting 2 days given vaccine effects on second day, although most patients are functional
Summary

- COVID-19 is an ongoing threat
- It is evolving new variants
- Testing is available but not perfect
- Treatments are available but not perfect
- Vaccination saves lives and the risks are low
- Refugee and immigrant populations have unique, heterogenous barriers to vaccination that require a proactive approach and good rapport
Questions/Discussion
Thank you for attending this webinar by

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Edwin Hayes II, MD

February 24, 2021

The National Capacity Building Project is a project of the Center for Victims of Torture

www.cvt.org

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