



The CENTER for VICTIMS of TORTURE

with



Harvard Program in Refugee Trauma

## NCB Webinar

### COVID Vaccinations: Practical and Ethical Considerations

February 24, 2021


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National Capacity Building Project

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### COVID Vaccinations: Practical and Ethical Considerations

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## 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

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## Presenters



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



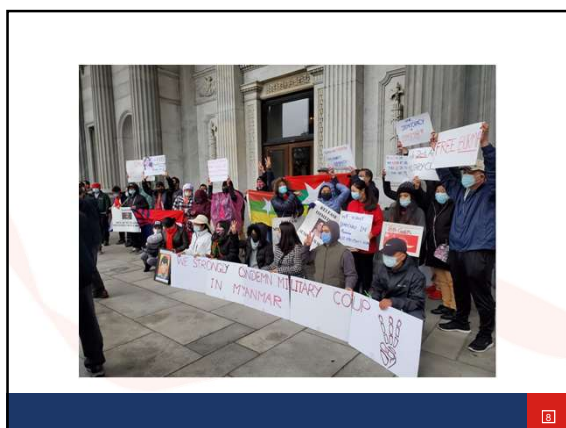
**Edwin Hayes II, MD**  
Co-director  
The Carolina Survivor Clinic at USC

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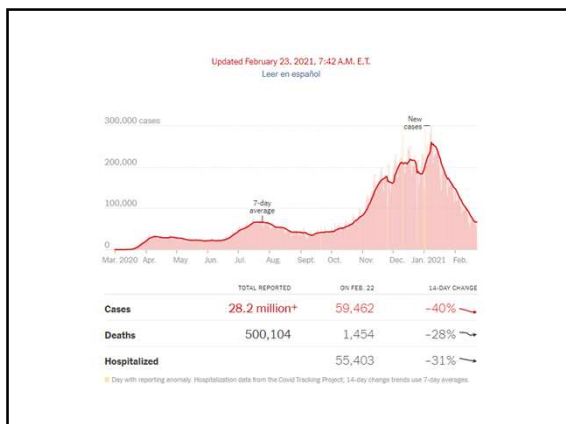
## COVID Vaccinations: Practical and Ethical considerations

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



	TOTAL CASES	PER 100,000	DAILY AVG. IN LAST 7 DAYS	PER 100,000	WEEKLY CHANGES PER CAPITA
					FEWER MORE
South Carolina	505,589	8,820	2,367	48	March 1 Feb. 22
New York	1,598,226	8,216	7,366	38	
New Jersey	769,109	8,659	3,097	35	
Rhode Island	123,980	11,703	313	30	
North Carolina	849,325	8,098	2,936	28	
Florida	1,872,915	8,720	5,991	28	
Delaware	85,090	8,738	264	27	
Georgia	962,215	9,063	2,819	27	
Alaska	57,316	7,835	187	26	
Kentucky	401,579	8,989	1,115	25	

**Original Investigation | Infectious Diseases**  
**SARS-CoV-2 Transmission From People Without COVID-19 Symptoms**  
 Michael A. Johnson, PhD, Tara M. Gianfrancesco, PhD, MPH, Sarah K. Patel, PhD, Pragati Venkata Prasad, MPH, Molly Steiner, PhD, MPH, John T. Brooks, MD, Rachel B. Slayton, PhD, MPH, Matthew R. Lipman, ScD, MPH, Jay C. Butler, MD

- Decision analytical model
- Assessed multiple scenarios for transmission
- Estimated that over 50% of overall transmission from asymptomatic individuals
- Pre-symptomatic individuals and asymptomatic

**COVID-19 rapid tests are inexpensive and fast but sometimes give incorrect results\***

People with symptoms and a negative rapid test should:

- Get a confirmation (RT-PCR) test
- Wear a mask
- Stay home in a separate room

1 in 5 patients with symptoms and confirmed COVID-19 received a negative rapid antigen test result.

**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

DISEASE SEVERITY	PANEL'S RECOMMENDATIONS
Not Hospitalized, Mild to Moderate COVID-19	There are insufficient data to recommend either for or against any specific antiviral or antibody therapy. SARS-CoV-2 neutralizing antibodies (bamlanivir or casirivir plus imdevir) are available through EUA for outpatients who are at high risk of disease progression. The Panel recommends against the use of dexamethasone or other corticosteroids (A3).*
Hospitalized but Does Not Require Supplemental Oxygen	The Panel recommends against the use of dexamethasone (A4) or other corticosteroids (A3). 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.
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** (e.g., for patients who require minimal supplemental oxygen) (B4) • Dexamethasone plus remdesivir** (e.g., for patients who require nonminimal amounts of supplemental oxygen) (B4)† • Dexamethasone (e.g., when combination therapy with remdesivir cannot be used or is not available) (B4)
Hospitalized and Requires Oxygen Delivery Through a High-Flow Device or Noninvasive Ventilation	Use one of the following options: • Dexamethasone** (A4) • Dexamethasone plus remdesivir** (B4)†
Hospitalized and Requires Invasive Mechanical Ventilation or ECMO	Dexamethasone** (A4)†

Rating of Recommendations: A = Strong, B = Moderate, C = Optional.  
 Rating of Evidence: 1 = One or more randomized trials without major limitations; 2 = One or more randomized trials with major limitations; 3 = Other randomized trials or subgroup analysis of randomized trials; 4 = Nonrandomized trials or observational cohort studies; 5 = 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.

**Immune response\***  
 Specialized antigen presenting cells (APCs) ingest the virus and display portions of it to activate T-helper cells.  
 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.  
 Prevents virus from binding, or tags it for destruction.  
 Destroys infected cells.  
 Long-lived "memory" B and T cells that recognize the virus can patrol the body for months or years, providing immunity response.

**ORIGINAL ARTICLE**  
**Dexamethasone in Hospitalized Patients with Covid-19 — Preliminary Report**  
 The RECOVERY Collaborative Group\*

- 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

**ORIGINAL ARTICLE**  
**Remdesivir for the Treatment of Covid-19 — Final Report**  
 John H. Beigel, M.D., Kay M. Tomashek, M.D., M.P.H., Lori E. Dodd, Ph.D., Aneshk K. Mehta, M.D., Barry S. Zingman, M.D., Andre C. Kall, M.D., M.P.H., Elizabeth Hohmann, M.D., Helen Y. Chu, M.D., M.P.H., Annie Luetkeneyer, M.D., Susan Kline, M.D., M.P.H., Diego Lopez de Castilla, M.D., M.P.H., Robert W. Finberg, M.D., et al., for the ACTT-1 Study Group Members\*

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

	Remdesivir	Placebo
Median recovery time	10	15
15-day mortality	6.7%	11.9%
29-day mortality	11.4%	15.2%
SAE	24.6%	31.6%

## 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.**

ORIGINAL ARTICLE

### Early High-Titer Plasma Therapy to Prevent Severe Covid-19 in Older Adults

Romina Libero, M.D., Gonzalo Pérez Marc, M.D., Diego Wagener, M.D., Silvia Covello, M.S., Alejandra Bianchi, Virginia Braem, Ignacio Esteban, M.D., Maurizio T. Caballero, M.D., Cristian Wood, M.D., Mabel Berrueta, M.D., Anibal Rondan, M.D., Gabriela Lescano, M.D., et al., for the Fundación INFANT-COVID-19 Group\*

- 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.

Interleukin-6 Receptor Antagonists in Critically Ill Patients with Covid-19 - Preliminary report

January 25, 2021

- 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 (tocilizumab) 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

- Ivermectin is an FDA approved antiparasitic drug - used to treat several neglected tropical diseases, including onchocerciasis, helminthiasis, 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 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

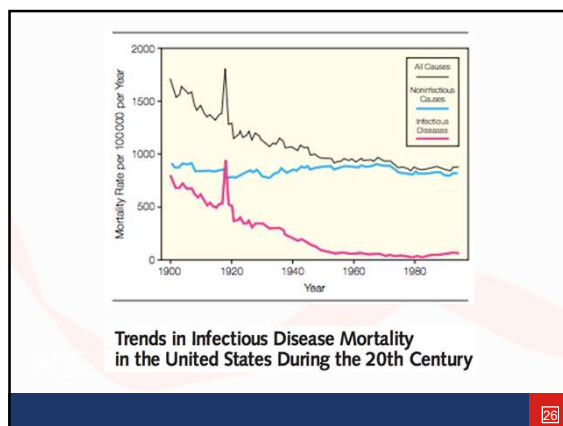
### Increased Resistance of SARS-CoV-2 Variants B.1.351 and B.1.1.7 to Antibody Neutralization

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

Pengfei Wang, Manoj S. Nair, Lihong Liu, Sho Iketani, 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. Kyrtatos, 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?].



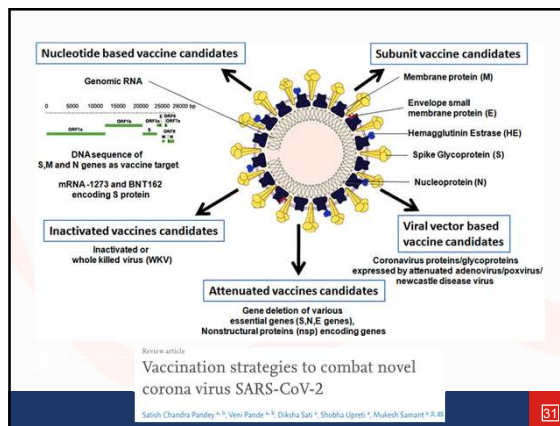
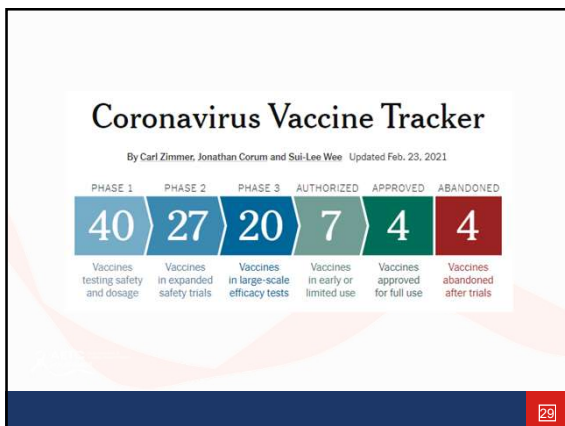
### SARS-CoV-2 Vaccines: How Did We Get Here?

- Usually a very deliberate process but stakes were too high
- Operation Warp speed
- Modern Science
- Experiences from MERS/SARS
- A LOT OF LUCK!

### Immunity

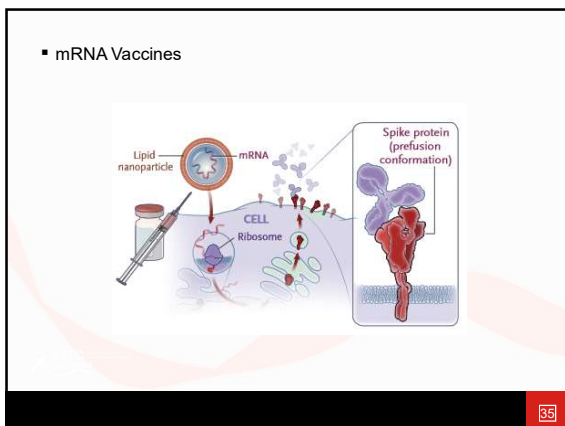
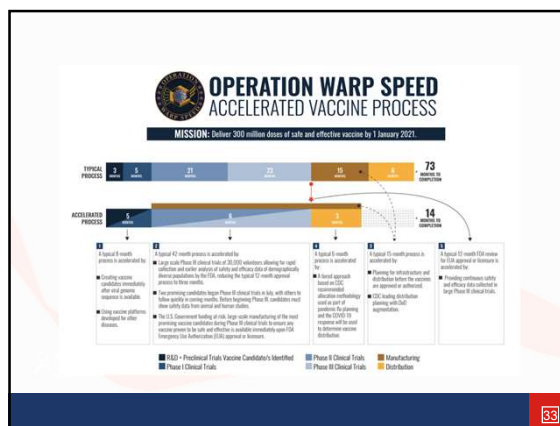
2019 Novel Coronavirus

Protective Immunity against COVID-19: Unravelling the evidences for humoral vs. cellular components



#### Leading vaccines

Developer	How It Works	Phase	Status
Pfizer-BioNTech	mRNA	2/3	Approved in several countries. Emergency use in U.S., E.U., other countries.
Moderna	mRNA	3	Approved in Switzerland. Emergency use in U.S., U.K., E.U., others.
Gamaleya	Ad26, Ad5	3	Early use in Russia. Emergency use in other countries.
Oxford-AstraZeneca	ChAdOx1	2/3	Emergency use in U.K., E.U., other countries.
CanSino	Ad5	3	Limited use in China.
Johnson & Johnson	Ad26	3	
Vector Institute	Protein	3	Early use in Russia.
Novavax	Protein	3	
Sinopharm	Inactivated	3	Approved in China, U.A.E., Bahrain. Emergency use in Egypt, other countries.
Sinovac	Inactivated	3	Approved in China. Emergency use in Brazil, other countries.
Sinopharm-Wuhan	Inactivated	3	Limited use in China, U.A.E.
Bharat Biotech	Inactivated	3	Emergency use in India.

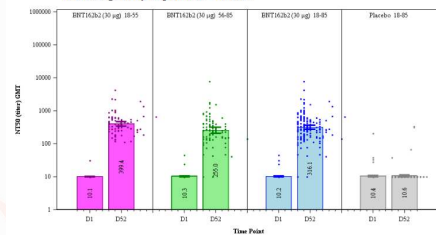


	BNT 162b2	mRNA-1273
FDA Approved	No	No
EUA	16+	18+
Prevention symptomatic disease	95% (8 vs 162 cases)	94% (11 vs 185 cases)
Prevention asymptomatic disease	? No data yet	Yes, swab at 2nd vaccine 15 vs 39 asymptomatic
Prevention of severe disease	Yes (1 vs 3 cases) or 1 vs 9	Yes (0 vs 30 cases)
Prevention of death	? (2 vs 4 deaths)	? (6 vs 7 (1 COVID) death)
Minimum order	975 doses (5 doses/vial)	100 doses (10 doses/vial)
Storage	-94F	-4F
Stability	Thawed - 5 days	Fridge 5 days/Room Temp 12hr
Dosing	2 doses 21 days apart	2 doses 28 days apart
Dose	mRNA 300ug (0.3ml)	MRNA 100ug (0.5ml)

### 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)
- Edairy 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



PFIZER-BIONTECH COVID-19 VACCINE (BNT162B2) – VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE  
BRIEFING DOCUMENT  
MEETING DATE: 19 December 2020

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

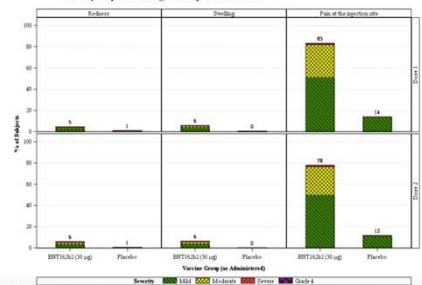


Figure 11. Participants Reporting Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Age Group – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population Age Group: 16-55 Years

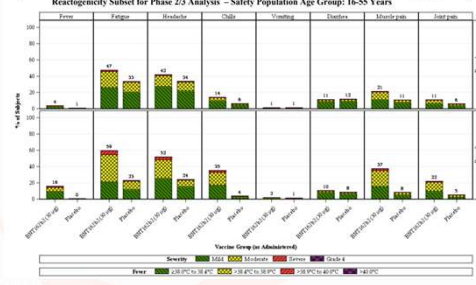


Table 6. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2 – ~38000 Subjects for Phase 2/3 Analysis – Safety Population

Adverse Event	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N=18801) n <sup>a</sup> (%)	Placebo (N=18785) n <sup>a</sup> (%)
Any event	5071 (27.0)	2356 (12.5)
Related <sup>b</sup>	3915 (20.8)	953 (5.1)
Severe	220 (1.2)	109 (0.6)
Life-threatening	18 (0.1)	20 (0.1)
Any serious adverse event	103 (0.5)	81 (0.4)
Related <sup>b</sup>	3 (0.0)	0
Severe	57 (0.3)	48 (0.3)
Life-threatening	18 (0.1)	19 (0.1)
Any adverse event leading to withdrawal	34 (0.2)	25 (0.1)
Related <sup>b</sup>	14 (0.1)	7 (0.0)
Severe	13 (0.1)	7 (0.0)
Life-threatening	2 (0.0)	4 (0.0)

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

Efficacy Endpoint	Vaccine Group (as Randomized)				Pr (VE > 30%   data) <sup>d</sup>
	BNT162b2 (30 µg) (N=18198)	Placebo (N=18325)	a1 <sup>b</sup> Surveillance Time <sup>c</sup> (n2 <sup>b</sup> )	a1 <sup>b</sup> Surveillance Time <sup>c</sup> (n2 <sup>b</sup> )	
First COVID-19 occurrence from 7 days after Dose 2	8	2,214 (17411)	162	2,232 (17511)	95.0 (90.3, 97.6)

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

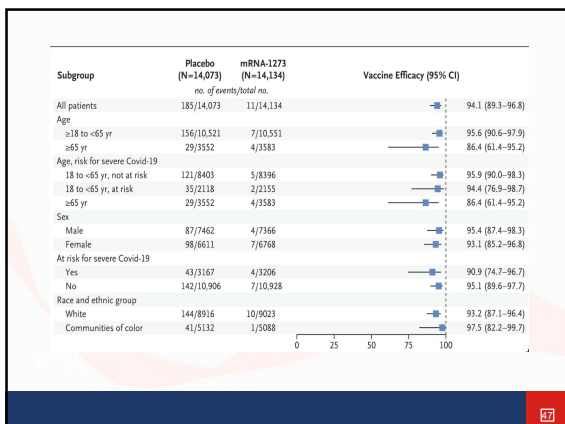
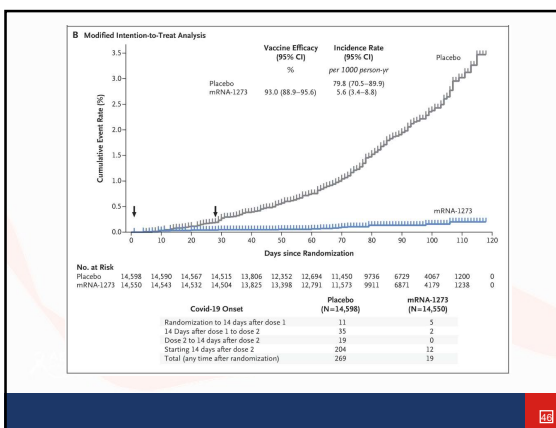
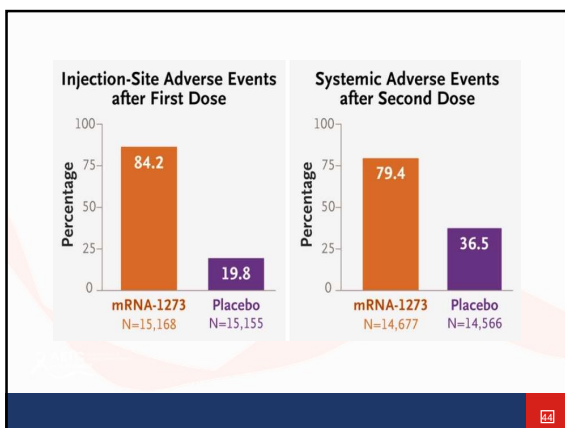
Efficacy Endpoint	Vaccine Group (as Randomized)				Pr (VE > 30%   data) <sup>d</sup>
	BNT162b2 (30 µg) (N=18198)	Placebo (N=18325)	a1 <sup>b</sup> Surveillance Time <sup>c</sup> (n2 <sup>b</sup> )	a1 <sup>b</sup> Surveillance Time <sup>c</sup> (n2 <sup>b</sup> )	
First severe COVID-19 occurrence from 7 days after Dose 2	1	2,215 (17411)	3	2,232 (17511)	66.4 (124.8, 96.5)

**Table 18. Vaccine Efficacy – First Severe COVID-19 Occurrence After Dose 1 – Dose 1 All-Available Efficacy Population**

Efficacy Endpoint Subgroup	Vaccine Group (n; Randomized)		VE (%)	(95% CI) <sup>a</sup>		
	BNT162b2 (30 µg) (N=21609)	Placebo (N=21686)				
First severe COVID-19 occurrence after Dose 1	1	4,021 (21314)	9	4,006 (21259)	88.9	(20.1, 99.7)
After Dose 1 to before Dose 2	0		4		100.0	(-51.5, 100.0)
Dose 2 to 7 days after Dose 2	0		1		100.0	(-3800.0, 100.0)
≥7 Days after Dose 2	1		4		75.0	(-152.6, 99.5)

### 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**



### 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 B.1.351 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

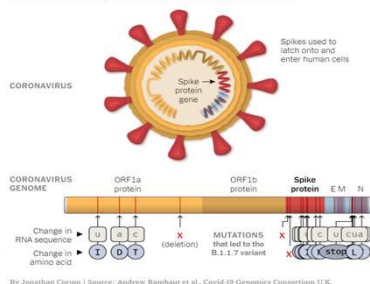
Description	Pfizer-BioNTech COVID-19 vaccine	Moderna COVID-19 vaccine
<b>mRNA</b>	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2
<b>Lipids</b>	2[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide	PEG2000-DMG: 1,2-dimyristoyl-rac-glycerol, methoxypolyethylene glycol
	1,2-distearoyl-sn-glycero-3-phosphocholine	1,2-distearoyl-sn-glycero-3-phosphocholine
	Cholesterol	Cholesterol
	(4-hydroxybutyl)azanediyl[bis(hexane-6,1-diyl)bis(2-hexyldodecanoate)]	SM-102: heptadecan-9-yl 8-(2-hydroxyethyl) (6-oxo-6-(undecyloxy) hexyl) amino octanoate
<b>Salts, sugars, buffers</b>	Potassium chloride	Tromethamine
	Monobasic potassium phosphate	Tromethamine hydrochloride
	Sodium chloride	Acetic acid
	Dibasic sodium phosphate dihydrate	Sodium acetate
	Sucrose	Sucrose

### 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.



### 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**
- <https://www.cdc.gov/coronavirus/2019-ncov/more/science-and-research/scientific-brief-emerging-variants.html>

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

- Serum obtained 7d after 2<sup>nd</sup> vax
- Recombinant virus
- Neutralization of B.1.17
  - 1.2 fold reduction of titer
- Neutralization of B.1.351
  - 6.4 fold reduction of titer
  - GMNT was 1:290
- **All samples were neutralized**

### Neutralizing Activity of BNT162b2-Elicited Serum — Preliminary Report

- Engineered mutations into USA-WA1/2020
- 50% plaque reduction neutralization testing
- Sera 2-4 weeks after 2<sup>nd</sup> Pfizer vax
- GMNT for USA-WA1/2020 was 501
- GMNT for B.1.351 was 184
  - Weaker by 2/3

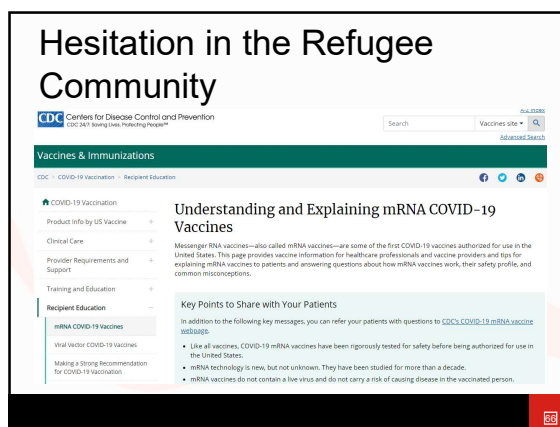
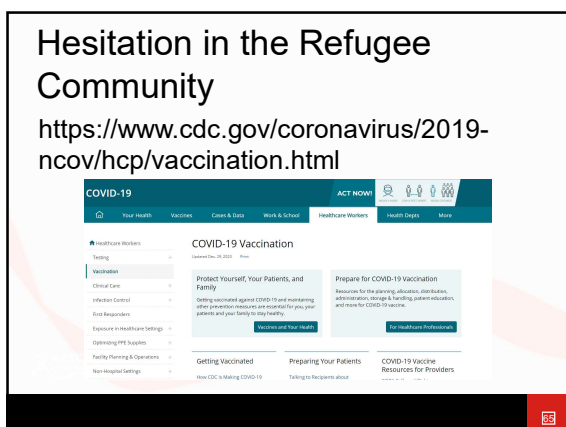
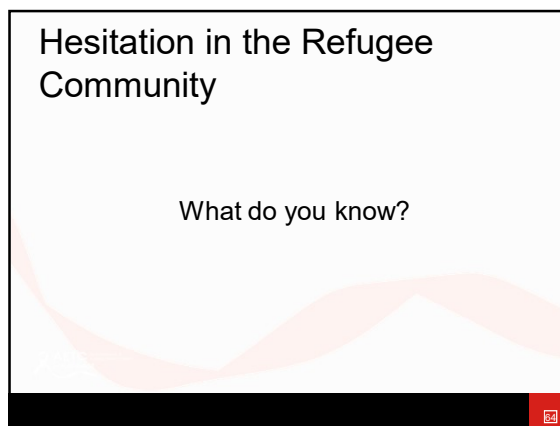
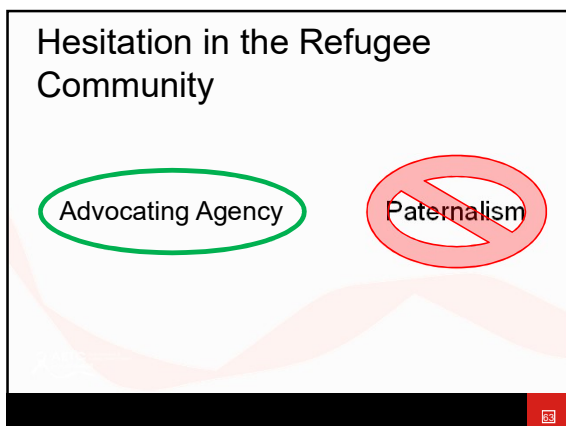
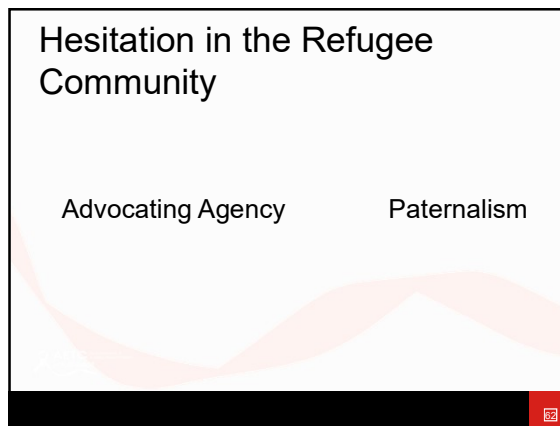
## Where do refugees fit in all of this?

## 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



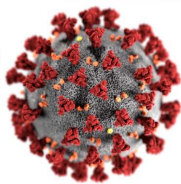

## Hesitation in the Refugee Community

**COVID 19**  
COMMUNITY 2020

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

## 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?



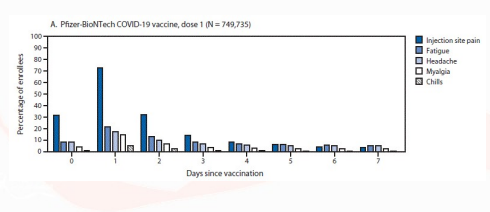
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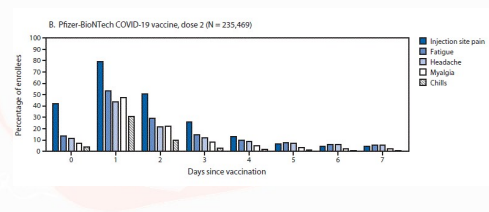
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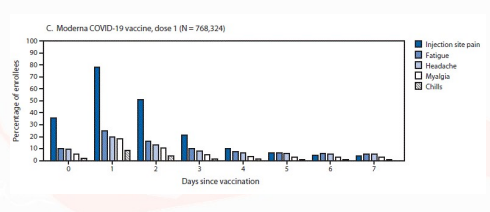
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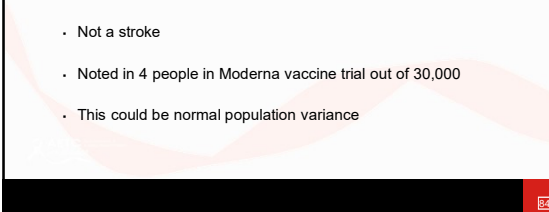
## Hesitation in the Refugee Community

- Social media posts/ memes
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## 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

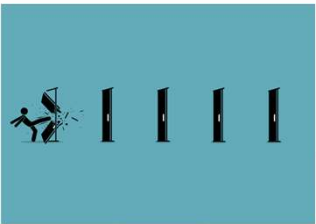
## Hesitation in the Refugee Community

- 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

**Phase 1a mission-critical workers and individuals include:**

- All-year olds, regardless of health status or pre-existing conditions
- Anesthesiology assistants, registered cardiovascular disease 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
- Childprotection
- 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 equipment fit and color
- Laboratory personnel and phlebotomists
- Licensed dentists
- Long-Term Care Facility (LTCF) residents and staff
- Medical assistants
- Medical first responders (paid and volunteers) EMS, fire department and law enforcement personnel who provide emergency medical care
- Nurses, nurse practitioners, and nurse's aides/ assistants
- Radiologic and radiologists and radiologic technicians
- Home caregivers for children who have structuralities, are ventilator dependent or who have life-threatening chronic illness. Requires a medical provider's signed authorization to provide complex medical services.
- Translators providing medical care in correctional facilities and correctional officers
- Pharmacist 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 and local government employees and their contractors, who are mission-critical for maintaining operations of COVID-19 vaccination and testing in SC
- Students and returns of the above categories

- 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

## 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...)

## 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://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/communication-toolkit.html> (doesn't list vaccine)
  - <https://switchboarda.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

## ဆေးကုသနိုင်စွမ်းအား COVID-19 အဖို့


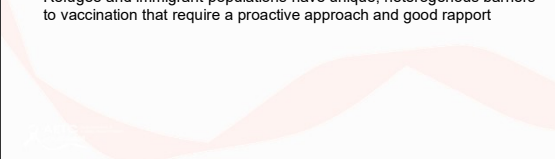
## Implementation in the Refugee Community

- 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



National Capacity Building Project

Please complete the feedback survey that was emailed to you in the webinar or by using this link:  
<https://tinyurl.com/2n3r1rad>


Thank you for attending this webinar by

Rajeev Bais MD, MPH  
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](http://www.cvt.org)

More resources are available at [www.healtorture.org](http://www.healtorture.org)



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