

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

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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
- 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
- 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



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

Updated February 23, 2021, 7:42 A.M. E.T. Leer en español



	TOTAL REPORTED	ON FEB. 22	14-DAY CHANGE
Cases	28.2 million+	59,462	-40% 🛶
Deaths	500, 1 04	1,454	-28% ∽
Hospitalized		55,403	-31% ->

Day with reporting anomaly. Hospitalization data from the Covid Tracking Project; 14-day change trends use 7-day averages.

			DAILY AVG.		WEEKL PER (Y CASES CAPITA
	TOTAL CASES	PER 100,000	IN LAST 7 DAYS	▼ PER 100,000	FEWER	MORE
+ South Carolina >	505,589	9,820	2,367	46	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. Johansson, PhD; Talia M. Quandelacy, PhD, MPH; Sarah Kada, PhD; Pragati Venkata Prasad, MPH; Molly Steele, PhD, MPH; John T. Brooks, MD; Rachel B. Slayton, PhD, MPH; Matthew Biggerstaff, 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*



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

* 1,098 paired nasal swabs collected at 2 universities in Wisconsin, September 28–October 9, were tested using Sofia SARS Antipen FIA and compared to rRT-PCR/viral culture results.

People with symptoms and a negative rapid test should



Stay home in a separate room

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





1.Virus

enters

the body

a cell

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., Aneesh K. Mehta, M.D., Barry S. Zingman, M.D., Andre C. Kalil, M.D., M.P.H., Elizabeth Hohmann, M.D., Helen Y. Chu, M.D., M.P.H., Annie Luetkemeyer, M.D., Susan Kline, M.D., M.P.H., Diego Lopez de Castilla, M.D., M.P.H., Robert W. Finberg, M.D., <u>et al.</u>, 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 Libster, M.D., Gonzalo Pérez Marc, M.D., Diego Wappner, M.D., Silvina Coviello, M.S., Alejandra Bianchi, Virginia Braem, Ignacio Esteban, M.D., Mauricio T. Caballero, M.D., Cristian Wood, M.D., Mabel Berrueta, M.D., Aníbal Rondan, M.D., Gabriela Lescano, M.D., <u>et al.</u>, 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.

Covid-19 – Preliminary report

Posted January 09, 2021.

G Previous

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



- 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 withour 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-2Variants B.I.351 and B.I.1.7 to Antibody Neutralization

Antibody Resistance of SARS-CoV-2 Variants B.I.351 and B.I.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. 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





<u>Travel Med Infect Dis</u>. 2021 January-February; 39: 101911. Published online 2020 Nov 10. doi: 10.1016/j.tmaid.2020.101911 PMCID: PMC7654327 PMID: <u>33186686</u>

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







Satish Chandra Pandey ^{a, b}, Veni Pande ^{a, b}, Diksha Sati ^a, Shobha Upreti ^a, Mukesh Samant ^a 😤 🖾



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 coutries.
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.



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





mRNA Vaccines





	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 30ug (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)
- Ediary in > 6,000 patients
- SAEs, deaths, treatment limiting AEs (0.1%), same in both arms





PFIZER-BIONTECH COVID-19 VACCINE (BNT162, PF-07302048)

VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE

BRIEFING DOCUMENT

MEETING DATE: 10 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

	Vaccine Group (as Administered)				
	BNT162b2 (30 μg) (N ^a =18801)	Placebo (Nª=18785)			
Adverse Event	n ^b (%)	n ^b (%)			
Any event	5071 (27.0)	2356 (12.5)			
Related ^c	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 ^c	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 ^c	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

	Vaccine Group (as Randomized)							
	BNT162b2 (30 μg) (N ^a =18198)		Placebo (N ^a =18325)					
Efficacy Endpoint	nl ^b	Surveillance Time ^c (n2 ^d)	nlb	Surveillance Time ^c (n2 ^d)	VE (%)	(95% CI°)	Pr (VE >30% data) ^f	
First COVID-19 occurrence from 7 days after Dose 2	8	2.214 (17411)	162	2.222 (17511)	9 5.0	(90.3, 97.6)	>0.9999	

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

	Vaccine Group (as Randomized)							
Efficacy Endpoint		BNT162b2 (30 μg) (N ^a =18198)		Placebo (Nª=18325)				
		Surveillance Time ^c (n2 ^d)	nlb	Surveillance Time ^c (n2 ^d)	VE (%)	(95% CI*)	Pr (VE >30% data) ^f	
First severe COVID-19 occurrence from 7 days after Dose 2	1	2.215 (17411)	3	2.232 (17511)	66.4	(-124.8, 96.3)	0.7429	

All-Available Effi	cacy	Population	VID-J	I9 Occurrenc	e Alter D	ose I – Dose I	
		Vaccine Group	o (as Ra				
Efficacy Endpoint Subgroup		BNT162b2 (30 μg) (N ^a =21669)		Placebo (N ^a =21686)	_	(95% CI*)	
		nl ^b Surveillance Time ^c (n2 ^d)		Surveillance Time ^c (n2 ^d)	VE (%)		
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)	

Table 18 Vaccine Efficacy - First Severe COVID-19 Occurrence After Dese 1 Dese 1

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





Subgroup	Placebo (N=14,073) no. of even	mRNA-1273 (N=14,134) ts/total no.			Vaccin	e Efficacy (95% Cl)
All patients	185/14,073	11/14,134					94.1 (89.3–96.8)
Age							
≥18 to <65 yr	156/10,521	7/10,551					95.6 (90.6–97.9)
≥65 yr	29/3552	4/3583					86.4 (61.4-95.2)
Age, risk for severe Covid-19							
18 to <65 yr, not at risk	121/8403	5/8396					95.9 (90.0–98.3)
18 to <65 yr, at risk	35/2118	2/2155					94.4 (76.9–98.7)
≥65 yr	29/3552	4/3583					86.4 (61.4–95.2)
Sex							
Male	87/7462	4/7366					95.4 (87.4–98.3)
Female	98/6611	7/6768					93.1 (85.2–96.8)
At risk for severe Covid-19							
Yes	43/3167	4/3206					90.9 (74.7–96.7)
No	142/10,906	7/10,928					95.1 (89.6–97.7)
Race and ethnic group							
White	144/8916	10/9023					93.2 (87.1–96.4)
Communities of color	41/5132	1/5088					97.5 (82.2–99.7)
			0	25	50	75 100	

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

Description	Pfizer-BioNTech COVID-19 vaccine	Moderna COVID-19 vaccine		
mRNA	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		
Lipids	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- hexyldecanoate)	SM-102: heptadecan-9-yl 8-((2-hydroxyethyl) (6-oxo-6-(undecyloxy) hexyl) amino) octanoate		
Salts, sugars,	Potassium chloride	Tromethamine		
bullers	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.



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
- https://www.cdc.gov/coronavirus/2019-ncov/more/science-and-research/scientificbrief-emerging-variants.html

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



Neutralizing Activity of BNT162b2-Elicited Serum — Preliminary Report

- Engineered mutations into USA-WA1/2020
- 50% plaque reduction neutralization testing
- Sera 2-4 weeks after 2nd 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



Advocating Agency

Paternalism







What do you know?

https://www.cdc.gov/coronavirus/2019ncov/hcp/vaccination.html

COVID	-19					ACT NOW!	WEAR A MASK STAY & FEET APART	AVOID CROWDS		
命	Your Health	Vaccines	Cases & Data	Work & School	Healt	thcare Workers	Health Depts	More		
↑ Healthca	re Workers	(COVID-19 Vac							
Testing		+ U	pdated Dec. 29, 2020 Print							
Vaccination			Protect Vourself Vo	our Patients and	Prenare for COVID-19 Vaccination					
Clinical Ca	re	+	Family			Resources for the	planning, allocation, distribution,			
Infection C	Control	+	Getting vaccinated against	COVID-19 and maintaini	ng	administration, storage & handling, patient education, and more for COVID-19 vaccine.				
First Respo	onders		patients and your family to	o stay healthy.	u					
Exposure i	n Healthcare Settings	+		Vaccines and Your Heal	th	For Healthcare Professionals				
Optimizing	g PPE Supplies	+								
Facility Pla	nning & Operations	+	Getting Vaccinated Preparing Yo		ing You	ur Patients	COVID-19 Vaccine			
Non-Hospi	ital Settings	+			Recipien	ts about	Resources for	Providers		



() Centers for Disease Control and Prevention CDC 24/7: Saving Lives, Protecting People™

Vaccines & Immunizations

CDC > COVID-19 Vaccination > Recipient Education

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.

Search

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.

A-Z INDEX

Advanced Search

Vaccines site •



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

Amanda Cohn, MD Sarah Mbaeyi, MD, MPH

December 13, 2020





What do they know?

- 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

- 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

- 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

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


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)

- 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?



- 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.)

- 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.

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- 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.)

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

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

Centers for Disease Control and Prevention CDC 24/7: Saving Lives, Protecting People™	Search	Advan	Ced Sear
Morbidity and Mortality Weekly Report (<i>MMWR</i>)			
CDC	Ð	0	in 🍕

First Month of COVID-19 Vaccine Safety Monitoring — United States, December 14, 2020–January 13, 2021

Early Release / February 19, 2021 / 70

Julianne Gee¹; Paige Marquez¹; John Su¹; Geoffrey M. Calvert¹; Ruiling Liu¹; Tanya Myers¹; Narayan Nair²; Stacey Martin¹; Thomas Clark¹; Lauri Markowitz¹; Nicole Lindsey¹; Bicheng Zhang¹; Charles Licata¹; Amelia Jazwa¹; Mark Sotir¹; Tom Shimabukuro¹ (<u>View author affiliations</u>)

View suggested citation

Summary

Article Metrics

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



A. Pfizer-BioNTech COVID-19 vaccine, dose 1 (N = 749,735)

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



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



- 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

- 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

- 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

- 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

- 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 Phase 1a mission-critical workers and individuals include: Community 65+ year olds, regardless of health status or preexisting conditions staff

- 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

- Anesthesiology assistants, registered cardiovascular invasive specialists, and operating room
- 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

A VAMS is only compatible with the most current stable version of Edge, Chrome, Mozilla Firefox and Safari.				
VAMS Vaccine Administration Management System				
Welcome to VAMS				
Welcome to the Vaccine Administration Management System (VAMS). Registering for this application allows for you to be pre-screened and, if qualified, register for an account and schedule your COVID-19 vaccination. Creating an account will allow for your State Health Department and The Centers for Disease Control and Prevention to collect your information to use in public health data analysis. Your name or other information that may identify you will not appear when we talk about the vaccine or results from the analyses.				
Confirm the following questions to register your account.				
* I have already registered in VAMS to receive my vaccination through another organization I work for.				
Yes				
No				
* I have tested positive for the COVID-19 antibody.				
Yes				
No				

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
 - <u>https://www.cdc.gov/coronavirus/2019-ncov/need-extra-</u> precautions/communication-toolkit.html (doesn't list vaccine)
 - <u>https://switchboardta.org/blog/a-round-up-of-multilingual-resources-on-covid-19/</u> (pretty extensive)
 - Not everyone can read
 - Interpreters or phone lines at vaccination site (confirm this)

Implementation in the Refugee Community



Technical Assistance < Evidence < Learning Resources <

Blog

WANT NEW BLOG POSTS SENT TO YOUR INBOX?



LOOKING FOR A SPECIFIC BLOG POST?

search

TOPICS

Select Topic

v

A Round-Up of Multilingual Resources on COVID-19

💬 9 Comments 🔒 By Switchboard 🛛 🛗 March 10, 2020



ဆဲးကသံဉ်ဇီသဒၢလၢ COVID-19 തറ്റ്

တာ်တြံဆာဒီသဒာထိဒါတွာ်တာ်ဆါသတြဉ်ကိုခံတွာ်ဝဲဒိဉ်မႈ, ဘဉ်ဆဉ်အခဲ ສຳບສິລິຣໍາກວ່ວລິວຣາອ່ອໄດາກຮ້ວງຮາບເດາ COVID-19 ູ້.

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တာ်ဆဲးနှုံးကသံဉ်စီသစာခံဓါလိဉ်လာတလိဉ်တာ်ဟုဉ်အပူးဘဉ်နှဉ်လီးန

ဖဲဉ်ဒရ၊ဉ်ကိၢိစၢဖိုဉ်ပဒိဉ်ကကျ။်ဘၢမ၊စၢ၊နကသံဉ်ကသီအပူးလီ၊နတဂ်တကြားဃ့န၊တၢ်အပူ၊ မတမါတလိဉ်နဟ္ဉဉ်တၢ်အပူးဘဉ်နမှာဟွဉ်မ၊စားတၢ် တကြားဃ့န၊တၢ်အပူးလ၊တၢ်လဲ၊ထဉ်လာသးလ၊ စဲ၊အးဖဲနမ့်၊လဲ၊နှာ်ဒီးလဲ၊ဆဲးထဲကသံဉ်ဒီသအ၏အခါဘဉ်နှဉ်လီ၊န



နကလိဉ်ဆဲးကသံဉ်ခံဘိုလီ၊.

ຂຸດາດຈິວິສໍາດາວ່າວິຮິວມຮາອ່ວາງິ, ຫາສາດາດທີ່ໂດຍບໍ່ເດີດ້ວຍເວົ້າຫຼາດຢູ່ໃຊ້ເດີ້າ.

ကသံဉ်ဒီသဒၢစံဓါလိဉ်နှဉ်ပူးဖွဲးနီးမာတာ်တူးလီးတီးလီးနှဉ်လီး.



(U.S. Food and Drug Administration (FDA)) ທຸລິອິທຸລິຕາອັນຕາມລິຊີລະອາດາຍລິດນາຍາກິດສະດາໃຫ້ແຈງໃຫ້ ဂိုးဆူအဆာကတိုးဒီးတစ်တယ္ဆထံဉ်တစ်မူးဖွဲးတစ်လီးဘဉ်ယိဉ်လာအနာနာကလဲဂ်တဖဉ်ဘဉ်နှဉ်လီး- မူးမောဖိဖိစ်ဉ်နီးလီးဆီ လိၵ်သူးလူအသဘ္မတဖဉ်ဟိုကျပ်ကျူးတစ်ဆုံးတူးထိုဦစီးတဖြူးဖွဲ့၊လူးအပတိုကြစ်စာမှုတော်ထူးလီးတီးလီးတီးပတို ອາຍຸລິສຸລິໜີາ.

ပူးလာအို၌နီးတာ်လီးဘဉ်ယိဉ်လာအအါတဖဉ်ကမာနှုံတာ်ဆဲးကသံဦနီသဒေလာအဆိုလီး.

ဖဲပမၤနှုံအါဏီဉ်ကသံဉ်ဒီသဒၢအခါပု၊ကဆဲးအါဏီဉ်ဘဉ်ကသံဉ်ဒီသဒၢကသ္နနှဉ်လီ၊န တၢ်အို၌ဆည်အိုဉ်ချဝဲ၊ကြိုးမ၊တၢ်ဃွထာဘဉ်ယးဒီးမမြတ်၊ကဆ်းဘဉ်ဆိကသံဦဒီသ ဒၤလဲဉ်ဒီးပညဉ်ပု၊လာအိုဉ်ဒီးတွင်လီ၊ဘဉ်ယိဉ်အါနဉ်လီး၌ ပု၊ကီးဂူးဒီးကဆီးဘဉ်ကသံဉ်ဒီသဒၢတဖဉ်အွံးဖဲပ်အိုဉ်ဒီးကသံဉ်ဒီသွဒၤလျှလူ၊လီဉ်လီဉ်အခါနဉ်လီးန ເບ້າເກຼາີພFindYourPhaseWA.org ຍຸດາຍາດີກໍະ1-800-525-0127 ວ່າເວົ້າຍໍາເດັນ လ၊ကိုဃုထုံဉ်နဆဲးကသံဉ်ဒီသဒ၊ကိုသံ့အခါဖဲလဲဉ်နှဉ်လီ၊ 5(လ၊တဂ်တဲကိုးထိတ်မြာစားတဖဉ်အင်္ဂါယ တဲလ၊နကျိုာ်လ၊တဂ်ကစ်းဆ၊လီတဲစိအခါဖဲလဲဉ်နှဉ်တက္ န်)

နကတူ်ဘဉ်ကသံဉ်အတါ်စီဘဉ်တဖဉ်နှဉ်လီး.

ຮົກໝໍວິຮື່ລະເໝືອໂສກເສລະ. ອອຣູວິການີ້ເໝືວ. ຫາ່ໜ້າທີ່າ. ອີວິສາ. ອຸຫຍ່າ ຫາ່ລຸວິທຳກໍເທັາບໍ່ ອຫາ່ສະຫວິການວິຮຶ ລະຂາດເສດຄ້າຈໍຣຸລົດຈີເ. ຫາ່ອນລົສໍາອາຫາບຊີລິຫອລິດກາກລຳລິຊີລະຍາຫອລິຍາຫາຣູລິດຈີເ.

အိဉ်ဆီးပူးပူးဖွဲးဖွဲး

ອະສະກາວົກກວ່ວວິຊີ້ວາຍາດາສາດໃຫ້, ເລີ່ພວິຊີວິດຖູກົວກອີວິ, ສີວິເພັເຊັ່ະບາສາກເພຣີວິເພີ້າ (ອໍອິເພາວິ), ຊຶ່ະບວິຊີວິເລື່ອວະອາຈາດກ



Vaccinate WA CovidVaccineWA.org



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 chatted to you in the webinar or by using this link: <u>https://tinyurl.com/2n3rjrad</u>

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 <u>www.cvt.org</u>

More resources are available at <u>www.healtorture.org</u>

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