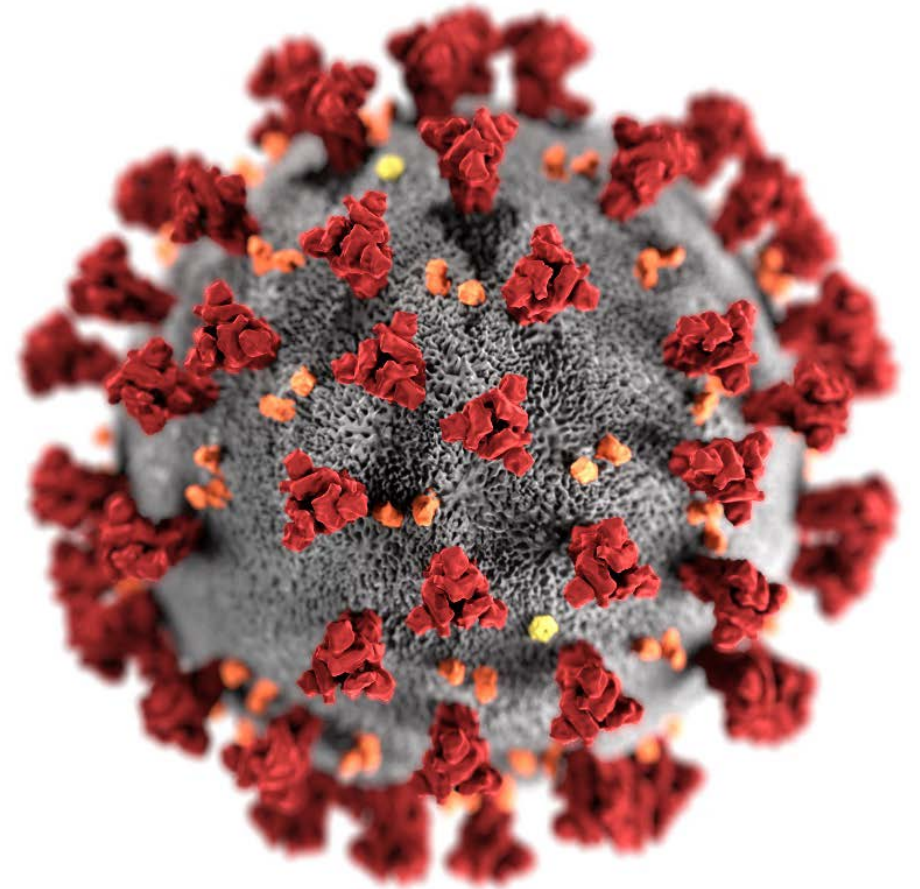


ACIP COVID-19 Vaccines Work Group

Dr. Beth Bell, Work Group Chair

October 30, 2020



Background

- ACIP responding to ongoing pandemic and accelerated vaccine development through scheduling of additional ACIP meetings
- At the September 22nd meeting, ACIP reviewed:
 - Overview of COVID-19 vaccine safety
 - Enhanced vaccine safety surveillance
 - Vaccine implementation
 - Disparities among COVID-19 epidemiology
 - Overview of vaccine equity and prioritization frameworks
 - Phase 1 allocation for COVID-19 vaccine: Work Group considerations

COVID-19 Work Group activities – October 2020

- COVID-19 Vaccine Work Group meets weekly

- Topics covered in October:
 - Review of available information on reinfection of COVID-19
 - Post-infection immunity
 - Discussions to finalize the Outcomes for GRADE
 - Modeling data for initial allocation of vaccine
 - Current epidemiology of COVID-19 in pregnant women
 - Review of ethical principles to inform initial allocation of vaccine
 - Clinical development program for two COVID-19 vaccines, including data from Phase I/II clinical trials and plans for Phase III clinical trials
 - Further discussions regarding COVID-19 vaccine allocation

Today's agenda

Vaccine Development & Regulatory

- **Update from VRBPAC meeting:**
Dr. Doran Fink (FDA)
- **NVX-CoV2373 Vaccine Candidate:**
Dr. Filip Dubovsky (Novavax)
- **Janssen's SARS-CoV-2 Vaccine Program:**
Dr. Jerry Sadoff (Janssen)

Implementation

- **Update on vaccine implementation planning:**
Dr. Janell Routh (CDC)
- **Vaccinate with Confidence:**
Dr. Amanda Cohn (CDC)

Safety

- **FDA safety surveillance systems:**
Dr. Steven Anderson (FDA)
- **Post-authorization safety monitoring plans:**
Dr. Tom Shimabukuro (CDC)

Allocation and Epidemiology

- **Modeling strategies for the initial allocation of COVID-19 vaccines:** Dr. Matthew Biggerstaff (CDC)
- **Updates to immunity and epidemiology to inform COVID-19 vaccine policy:** Dr. Megan Wallace (CDC)
- **Ethical principles for early vaccine allocation:**
Dr. Mary Chamberland (CDC)

Work Group Interpretation

- **Work Group interpretation of data:** Dr. Sara Oliver (CDC)
- **Policy questions, Evidence to Recommendation Framework, and outcomes:** Dr. Kathleen Dooling (CDC)

Vaccine Update

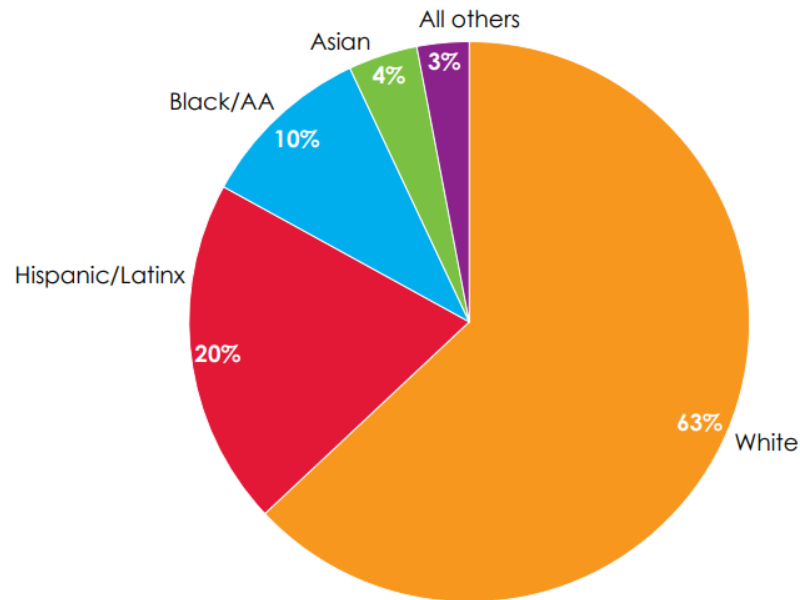
- Over 200 COVID-19 vaccines currently under development
- Within the United States:
 - **Four** vaccines in active Phase III clinical trials
 - **Five** vaccines in active Phase I/II clinical trials

Vaccine Update: Phase III clinical trials in the U.S.

- AZD1222 vaccine (AstraZeneca) announced removal of FDA hold 10/23, resuming Phase III trials
- Ad26.COVS vaccine (Janssen) announced lifting of safety pause 10/23, resuming Phase III trials
- BNT162b2 vaccine (Pfizer/BioNtech)
 - **42,133** participants enrolled as of 10/26/2020
 - 35,771 participants have received their second vaccination
 - 30% of U.S. participants enrolled have “diverse backgrounds”
- mRNA-1273 vaccine (Moderna): ***Enrollment Complete***
 - **30,000** participants enrolled as of 10/22/2020
 - 25,654 participants have received their second vaccination

Vaccine Update: Phase III clinical trials in the U.S.

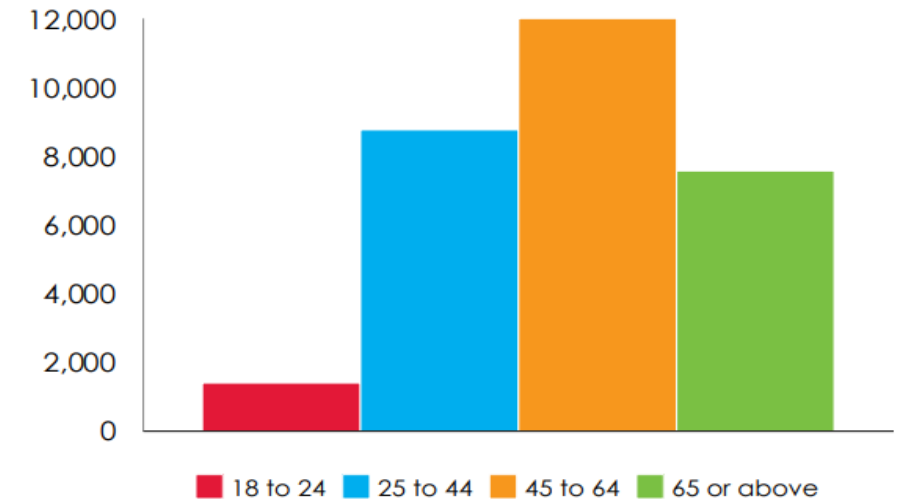
Race and ethnicity



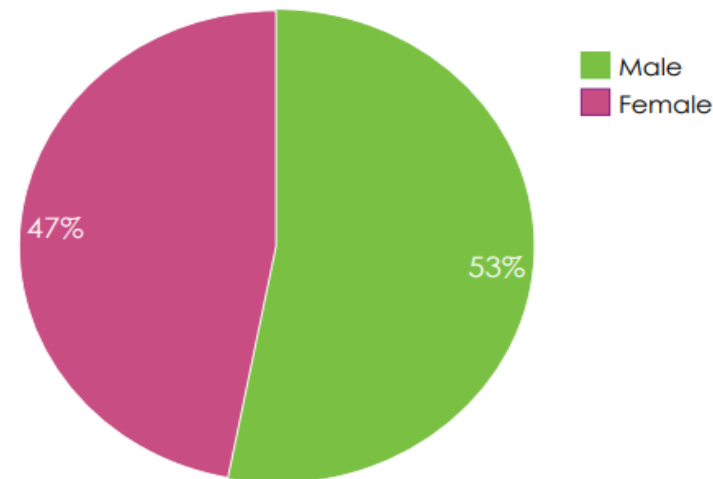
22% healthcare personnel

27% of participants living with comorbidities:
including diabetes, cardiac disease,
lung disease, obesity

Cove Study age breakdown



Cove Study gender distribution



Age and gender

moderna

COVID-19 vaccines in human clinical trials – United States*

Candidate	Manufacturer	Type	Phase	Trial characteristics	Trial #	Recruiting
mRNA-1273	Moderna TX, Inc.	mRNA	III	2 doses (0, 28d) - IM administration 18-55, 56+ years	NCT04470427	Enrollment complete
mRNA-BNT162	Pfizer, Inc./BioNTech	mRNA	II/III	2 doses (0, 21d) - IM administration 18-85 years	NCT04368728	✓
AZD1222	University of Oxford/AstraZeneca consortium**	Viral vector (NR)	III	2 doses (0, 28d) - IM administration ≥18 years	NCT04516746	✓
Ad26COVS1	Janssen Pharmaceutical Companies	Viral vector (NR)	III	1 dose - IM administration 18-55, 65+	NCT04436276	✓
--	Sanofi/GSK	Protein Subunit	I/II	- Single or 2 doses - IM administration 18-49, 50+	NCT04537208	✓
NVX-CoV2373	Novavax	Protein Subunit	I/II	2 doses (0, 21d) - IM administration 18-84	NCT04368988	Enrollment complete
V591	Merck	Viral Vector	I/II	2 doses (1, 57d) - IM administration 18-55	NCT04498247	✓

*As of October 27, 2020

**Currently on hold in US

Sources: <https://milkeninstitute.org/covid-19-tracker>; <https://www.who.int/who-documents-detail/draft-landscape-of-covid-19-candidate-vaccines>; https://vaccine.shinyapps.io/ncov_vaccine_landscape/; <https://clinicaltrials.gov/>; <https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html>



COVID-19 vaccines in human clinical trials – United States*

Candidate	Manufacturer	Type	Phase	Trial characteristics	Trial #	Recruiting
AV-COVID-19	Aivita	AuDendritic cell	I/II	1 dose 18+	NCT04386252	Not yet recruiting
VXA-CoV2-1	Vaxart	Viral vector (NR)	I	2 doses (1, 29d) - Oral tablet 18-54	NCT04563702	✓
INO-4800	Inovio Pharmaceuticals, Inc.	DNA plasmid	I	2 doses (0, 4w) - SC administration/ electroporation ≥18 years	NCT04336410	Active, not recruiting

*As of October 27, 2020

Sources: <https://milkeninstitute.org/covid-19-tracker>; <https://www.who.int/who-documents-detail/draft-landscape-of-covid-19-candidate-vaccines>; https://vaccine.shinyapps.io/ncov_vaccine_landscape/; <https://clinicaltrials.gov/>; <https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html>



COVID-19 vaccines in human clinical trials outside United States – Phase III actively recruiting*

Inactivated Vaccines

3 inactivated vaccines candidates are in Phase I/II

Candidate	Manufacturer/Institute	Type	Location	Phase	Trial number
BIBP/Sinopharm BBIBP-CorV	Beijing Institute of Biological Products/Sinopharm	Inactivated	Argentina	Phase III	NCT04560881
Sinovac CoronaVac	Sinovac/Instituto Butantan	Inactivated	Turkey, Brazil, Indonesia	Phase III	NCT04582344; NCT04456595; NCT04508075
WIBP vaccine	Wuhan Institute of Biological Products/Sinopharm	Inactivated	Morocco	Phase III	ChiCTR2000039000
WIBP/BIBP/Sinopharm vaccines	Beijing Institute of Biological Products/Wuhan Institute of Biological Products/Sinopharm	Inactivated	UAE, Bahrain, Jordan, Egypt	Phase III	NCT04510207

Protein Subunit Vaccines

10 protein subunit vaccines candidates are in Phase I/II

Candidate	Manufacturer/Institute	Type	Location	Phase	Trial number
Novavax NVX-CoV2373	Novavax	Protein subunit	UK	Phase III	NCT04583995

*As of October 19, 2020

Sources: <https://milkeninstitute.org/covid-19-tracker>; <https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines>; https://vaccine.shinyapps.io/ncov_vaccine_landscape/; <https://clinicaltrials.gov/>; <https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html>



COVID-19 vaccines in human clinical trials outside United States – Phase III actively recruiting*

Viral Vector Vaccines (non-replicating)

7 non-replicating viral vector vaccines candidates are in Phase I/II

Candidate	Manufacturer/Institute	Type	Location	Phase	Trial number
Cansino Ad5-nCoV	CanSino Biological Inc/ Beijing Institute of Biotechnology	Non-replicating viral vector	Pakistan, Russia	Phase III	NCT04526990; NCT04540419
Gamaleya Gam-COVID- Vac	Gamaleya Research Institute	Non-replicating viral vector	Belarus, Russia	Phase III	NCT04530396; NCT04564716
Janssen Ad26.COV2.S	Janssen Pharmaceutical Companies	Non-replicating viral vector	USA, Argentina, Brazil, others	Phase III	NCT04505722
Oxford ChAdOx1-S	University of Oxford/AstraZeneca	Non-replicating viral vector	UK, Brazil, India	Phase II/III	NCT04400838; NCT04536051; CTRI/2020/08/027170

RNA Vaccines

7 RNA vaccines candidates are in Phase I/II

Candidate	Manufacturer/Institute	Type	Location	Phase	Trial number
BioNTech BNT162 (b1/b2)	BioNTech/Fosun Pharma/Pfizer	RNA	USA, Argentina, Brazil, others	Phase II/III	NCT04368728



*As of October 19, 2020

Sources: <https://milkeninstitute.org/covid-19-tracker/>; <https://www.who.int/who-documents-detail/draft-landscape-of-covid-19-candidate-vaccines>; https://vaccines.shinyapps.io/ncov_vaccine_landscape/; <https://clinicaltrials.gov/>; <https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html>

Work group members

ACIP members

- Beth Bell (chair)
- Grace Lee
- Jose Romero
- Keipp Talbot

Ex-officio/government members

- FDA: Doran Fink, Rachel Zhang
- NIH: Chris Roberts
- IHS: Thomas Weiser, Jillian Doss-Walker
- DOD: Bryan Schumacher
- CMS: Jeff Kelman
- BARDA: Christine Oshansky
- HHS: David Kim

CDC Co-leads

- Kathleen Dooling
- Sara Oliver

Liaisons

- AAFP: Jonathan Temte
- AAP: Sean O’Leary
- ACOG: Denise Jamieson (primary), Laura Riley (alternate)
- ACP: Jason Goldman
- AGS: Ken Schmader
- AIM: Rob Shechter (primary), Jane Zucker (alternate)
- AMA: Sandra Fryhofer
- ANA: Kendra McMillan (primary), Ruth Francis (alternate)
- APhA: Michael Hogue
- ASTHO: Marcus Plescia
- CSTE: Susan Lett
- IDSA: Jeff Duchin (primary), Carol Baker (alternate)

Liaisons, cont’d

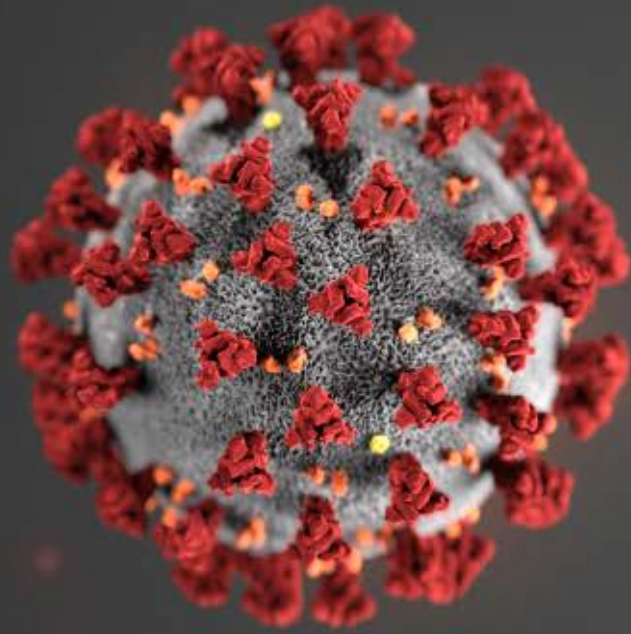
- NACCHO: Matt Zahn (primary), Jeff Duchin (alternate)
- NACI: Matthew Tunis (primary), Linlu Zhao (alternate)
- NFID: Bill Schaffner (primary), Marla Dalton (alternate)
- NMA: Oliver Brooks
- SHEA: Marci Drees

Consultants

- Ed Belongia (safety)
- Matthew Daley (safety)
- Kathy Kinlaw (ethics)
- Dayna Matthew (health equity)
- Kathleen Neuzil (vaccinology)
- Stanley Perlman (microbiology/immunology)

CDC participants

- Doug Campos-Outcalt
- Mary Chamberland
- Thomas Clark
- Amanda Cohn
- Jean Cox-Ganser
- Katie Curran
- Jonathan Duffy
- Anthony Fiore
- Mark Freedman
- Sue Gerber
- Jack Gersten
- Susan Goldstein
- Sam Graitcer
- Lisa Grohskopf
- Rita Helfand
- Terri Hyde
- Tara Jatlaoui
- Cynthia Jorgensen
- Erin Kennedy
- Ram Koppaka
- Jessica MacNeil
- Sarah Mbaeyi
- Nancy McClung
- Lucy McNamara
- Rebecca Morgan
- Titilope Oduyebo
- Christina Ottis
- Anita Patel
- Janell Routh
- Stephanie Schrag
- Tom Shimabukuro
- Natalie Thornburg
- Jennifer Verani
- Megan Wallace
- Cindy Weinbaum
- Yon Yu
- Jane Zucker



For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

Thank you!

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

