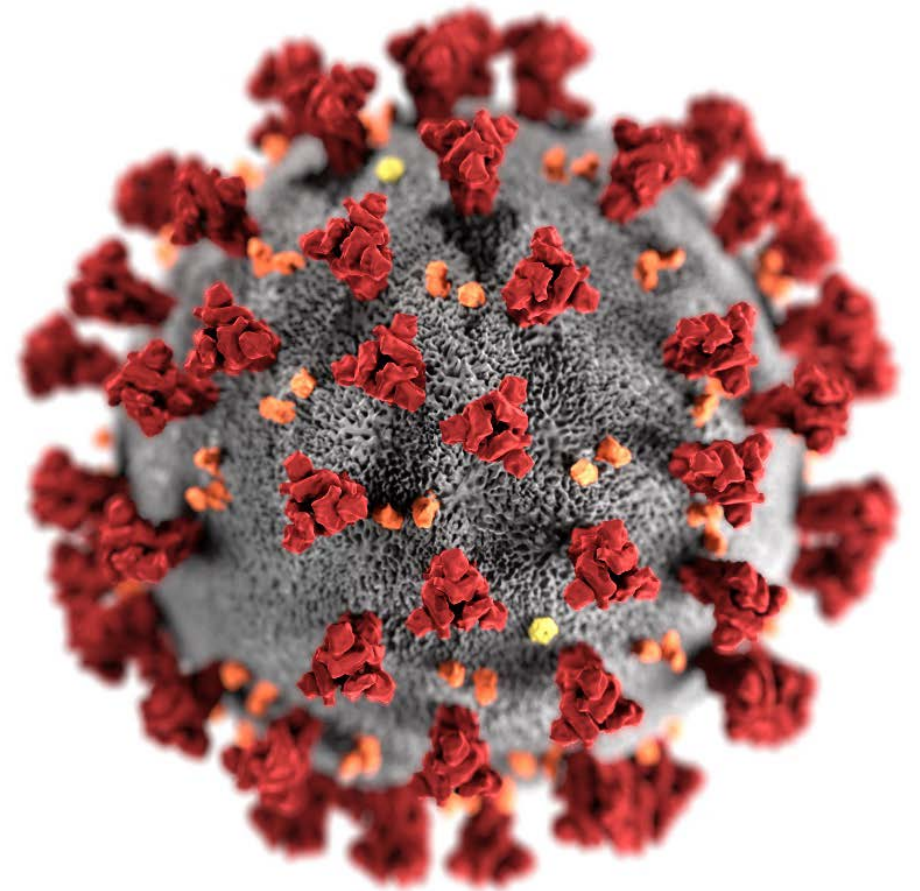


ACIP COVID-19 Vaccines Work Group

Dr. Beth Bell, Work Group Chair

September 22, 2020



Background

- ACIP responding to ongoing pandemic and accelerated vaccine development through scheduling of monthly emergency ACIP meetings
- At the August 26th meeting, ACIP reviewed:
 - Moderna's mRNA COVID-19 vaccine clinical development
 - Pfizer/BioNtech's mRNA COVID-19 vaccine clinical development
 - Overview of post-marketing safety surveillance
 - Epidemiology of individuals at increased risk of severe COVID-19 disease
 - Work Group interpretation
 - Prioritization and Work Group next steps

COVID-19 Work Group activities – September 2020

- COVID-19 Vaccine Work Group meets weekly
- Topics covered in August:
 - Review of published COVID-19 vaccine prioritization and allocation frameworks
 - Qualitative research on a future COVID-19 vaccine
 - Clinical development program for a COVID-19 vaccine, including data from Phase I/II clinical trials and plans for Phase III clinical trials
 - Racial and ethnic disparities in COVID-19 testing, exposure, severity and impact
 - Association between social vulnerability and risk of becoming a COVID-19 hotspot
 - Proposal for Ethics/Equity Framework for COVID-19 vaccine allocation
 - Further discussions regarding COVID-19 vaccine allocation

Today's agenda

- **Overview of COVID-19 vaccine safety:** Dr. Grace Lee (ACIP)
- **Enhanced vaccine safety surveillance:** Dr. Tom Shimabukuro (CDC)
- **Vaccine implementation:** Dr. Janell Routh (CDC)
- **Disparities in COVID-19 epidemiology:** Dr. Megan Wallace (CDC)
- **Overview of vaccine equity and prioritization frameworks:** Dr. Sara Oliver (CDC)
- **Phase 1 allocation for COVID-19 vaccine: Work Group considerations:** Dr. Kathleen Dooling (CDC)

Considerations for prioritization of COVID-19 vaccines

Today's session:

- Disparities among COVID-19 disease and proposal for ACIP's Ethics/Equity Framework
- Review of groups for allocation of initial COVID-19 vaccine

Future sessions:

- Continue to discuss Evidence to Recommendation Framework for COVID-19 vaccines
- Review additional manufacturer data
- Prepare for independent review of safety and efficacy data from Phase III clinical trials

Vaccine Update

- Over 200 COVID-19 vaccines currently under development
- Within the United States:
 - 2 vaccines in Phase III clinical trials, actively enrolling
 - 1 vaccine in Phase III clinical trials, currently on hold
 - 3 vaccines in Phase I/II clinical trials, actively recruiting
- mRNA-1273 vaccine (Moderna)
 - **25,296** participants enrolled as of 9/16/2020
 - 28% of participants enrolled are from “diverse communities”
- BNT162b2 vaccine (Pfizer/BioNtech)
 - **31,928** participants enrolled as of 9/21/2020
 - 26% of participants enrolled have “diverse backgrounds”
 - Proposed expansion to 44,000 participants

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

Candidate	Manufacturer	Type	Phase	Trial characteristics	Trial #	Recruiting
mRNA-1273	Moderna TX, Inc.	mRNA	III	<ul style="list-style-type: none"> • 2 doses (0, 28d) • IM administration • 18-55, 56+ years 	NCT04470427	✓
mRNA-BNT162	Pfizer, Inc./BioNTech	mRNA	II/III	<ul style="list-style-type: none"> • Single or 2 doses • IM administration • 18-85 years 	NCT04368728	✓
AZD1222	University of Oxford/AstraZeneca consortium**	Viral vector (NR)	III	<ul style="list-style-type: none"> • 2 doses (0, 28d) • IM administration • ≥18 years 	NCT04516746	On Hold
Ad26COVS1	Janssen Pharmaceutical Companies	Viral vector (NR)	I/II	<ul style="list-style-type: none"> • Single or 2 doses (0,56d) • IM administration • 18-55, 65+ 	NCT04436276	✓
--	Sanofi/GSK	Protein Subunit	I/II	<ul style="list-style-type: none"> • Single or 2 doses • 18-49, 50+ 	NCT04537208	✓
NVX-CoV2373	Novavax	Protein Subunit	I/II		NCT04368988	✓
AV-COVID-19	Aivita	AuDendritic cell	I/II		NCT04386252	
INO-4800	Inovio Pharmaceuticals, Inc.	DNA plasmid	I	<ul style="list-style-type: none"> • 2 doses (0, 4w) • SC administration/ electroporation • ≥18 years 	NCT04336410	

*As of September 14, 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://vaccineshinyapps.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 - actively recruiting*

Inactivated Vaccines

Candidate	Manufacturer	Type	Trial Location	Phase	Trial #
BBIBP-CorV	Beijing Institute of Biological Products/Sinopharm	Inactivated	China, UAE	I/II, III	ChiCTR2000032459 ChiCTR2000034780
--	Wuhan Institute of Biological Products/Sinopharm	Inactivated	China, UAE	III	ChiCTR2000031809 ChiCTR2000034780
CoronaVac	Sinovac/Instituto Butantan	Inactivated	Indonesia, Brazil	III	NCT04352608, NCT04383574, NCT04456595
--	Inst. of Med. Biology/Chinese Acad. Med. Sciences	Inactivated	China	I/II	NCT04412538, NCT04470609
BBV152	Bharat Biotech	Inactivated	India	I/II	CTRI/2020/07/026300, NCT04471519
QazCovid-in	Research Institute for Biological Safety Problems	Inactivated	Kazakhstan	I/II	NCT04530357

*Trials outside the united states listed here are limited to those actively recruiting and sorted by vaccine type. Candidates **in bold** are currently approved for emergency/limited use.*

*As of September 14, 2020

Sources: <https://milkeninstitute.org/covid-19-tracker>; <https://www.who.int/who-documents-detail/draft-landscape-of-covid-19-candidate-vaccines>; https://vaccineshinyapps.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 - actively recruiting*

Viral Vector Vaccines

Candidate	Manufacturer	Type	Trial Location	Phase	Trial #
--	Medicago	VLP	Canada	I	NCT04450004
Oxford ChAdOx1-S	University of Oxford/AstraZeneca	Viral vector (NR)	Brazil, South Africa	III, I/II	NCT04536051, NCT04444674, ISRCTN89951424
aAPC	Shenzhen Geno-Immune Medical Institute	Viral vector	China	I	NCT04299724
LV-SMENP-DC	Shenzhen Geno-Immune Medical Institute	Viral vector	China	I	NCT04276896
Ad26COVS1	Janssen	Viral Vector (NR)	Belgium, Japan	I/II, I	NCT04436276, NCT04509947
Gam-COVID-Vac	Gamaleya Research Institute	Viral vector (NR)	Russia	III	NCT04437875, NCT04436471
ReiThera GRAd-COV2	ReiThera/Leukocare/Univercells	Viral Vector (NR)	Italy	I	NCT04528641
Merck V591	Merck	Viral Vector	Belgium	I/II	NCT04498247
--	Institut Pasteur/ Themis/ University of Pittsburgh CVR/ Merck Sharp & Dohme	Viral vector	France, Belgium	I	NCT04497298

*As of September 14, 2020

Sources: <https://milkeninstitute.org/covid-19-tracker>; <https://www.who.int/who-documents-detail/draft-landscape-of-covid-19-candidate-vaccines>; https://vaccineshinyapps.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 - actively recruiting*

Protein Subunit Vaccines

Candidate	Manufacturer	Type	Trial Location	Phase	Trial #
NVX-CoV2373	Novavax	Protein subunit	Australia, South Africa	I/II, II	NCT04368988, NCT04533399
SCB-2019	Clover/GSK/Dynavax	Protein subunit	Australia	I	NCT04405908
Covax-19	Vaxine	Protein subunit	Australia	I	NCT04453852
--	University of Queensland/CSL/Seqirus	Protein subunit	Australia	I	NCT04495933; ACTRN12620000674932
Adimmune AdimrSC-2f	Adimmune Corporation	Protein Subunit	Taiwan	I	NCT04522089
Covaxx UB-612	Covaxx/University of Nebraska Medical Center	Protein subunit	Taiwan	I	NCT04545749

*As of September 14, 2020

Sources: <https://milkeninstitute.org/covid-19-tracker>; <https://www.who.int/who-documents-detail/draft-landscape-of-covid-19-candidate-vaccines>; https://vaccineshinyapps.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 - actively recruiting* mRNA/DNA vaccines

Candidate	Manufacturer	Type	Trial Location	Phase	Trial #
CVnCoV	CureVac	mRNA	Belgium, Germany	I/II	NCT04449276, NCT04515147
BioNTech BNT162 (a1/b1/b2/c2)	BioNTech/Fosun Pharma/Pfizer	mRNA	Germany	I/II	NCT04380701
--	Arcturus/Duke-NUS	mRNA	Singapore	I/II	NCT04480957
GX-19	Genexine Consortium	DNA	South Korea	I/II	NCT04445389
--	Osaka University/AnGes	DNA plasmid+adjuvant	Japan	I/II	NCT04463472
Inovio INO-4800	Inovio Pharmaceuticals inc.	DNA	South Korea	I/II	NCT04447781
--	Cadila Healthcare Limited	DNA plasmid	India	I/II	CTRI/2020/07/026352

*As of September 14, 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>



ACIP: Path to COVID-19 vaccine recommendations

- Currently:
 - Work Group meeting weekly; reviewing Phase I/II data from manufacturers as data are available
 - Designing structure for independent data review that will occur once Phase III data are available
- Once data are available from Phase III Clinical Trials:
 - ACIP Work Group will conduct independent review of safety and efficacy data
 - Evidence to Recommendation (EtR) Framework and GRADE
 - Based on this data review, Work Group will present policy options to full ACIP
- If/when an FDA decision is announced:
 - ACIP will have ‘emergency’ meeting with public comment session
 - Review safety and efficacy data using GRADE/EtR
 - ACIP will vote on recommendations for vaccine, populations for use
 - ACIP recommendations could be more targeted or detailed than FDA “Conditions of Use”
- After an ACIP vote:
 - ACIP submits recommendations to CDC Director
 - If recommendations are accepted, they are published in the MMWR and become official CDC Policy

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: Eric Deussing
- 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

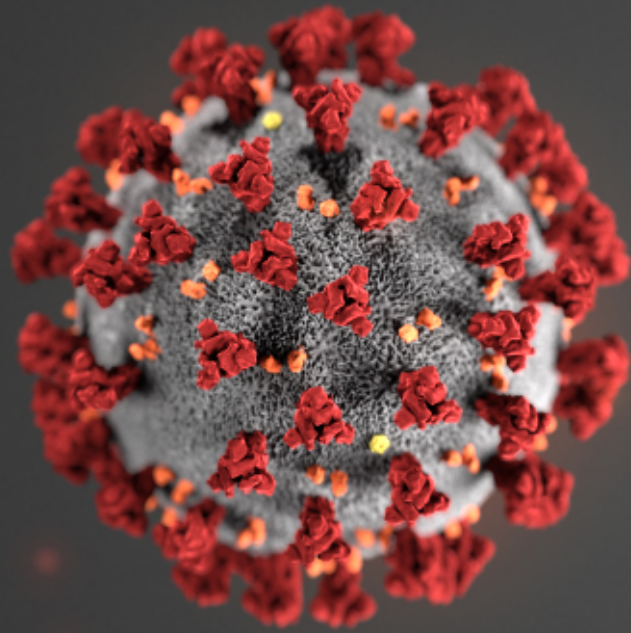
- NACCHO: Matt Zahn (primary), Jeff Duchin (alternate)
- NACI: Matthew Tunis (primary), Linlu Zhao (alternate)
- NFID: Bill Schaffner (primary), Marla Dalton (alternate)
- NMA: Oliver Brooks
- SHEA: Marci Drees

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
- 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
- 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.

