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 22\textsuperscript{nd} 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.COV2.S 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

Sources:
- https://www.modernatx.com/cove-study
- https://connect.trialscope.com/studies/34986a8ab779-4169-a350-5d929149d426
Vaccine Update: Phase III clinical trials in the U.S.

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

22% healthcare personnel

Sources: https://www.modernatx.com/sites/default/files/content_documents/2020-COVE-Study-Enrollment-Completion-10.22.20.pdf
COVID-19 vaccines in human clinical trials – United States*

<table>
<thead>
<tr>
<th>Candidate</th>
<th>Manufacturer</th>
<th>Type</th>
<th>Phase</th>
<th>Trial characteristics</th>
<th>Trial #</th>
<th>Recruiting</th>
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</thead>
<tbody>
<tr>
<td>mRNA-1273</td>
<td>Moderna TX, Inc.</td>
<td>mRNA</td>
<td>III</td>
<td>2 doses (0, 28d)</td>
<td>NCT04470427</td>
<td>Enrollment complete</td>
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<td>IM administration</td>
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<td>18-55, 56+ years</td>
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<tr>
<td>mRNA-BNT162</td>
<td>Pfizer, Inc./BioNTech</td>
<td>mRNA</td>
<td>II/III</td>
<td>2 doses (0, 21d)</td>
<td>NCT04368728</td>
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<td>18-85 years</td>
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<tr>
<td>AZD1222</td>
<td>University of Oxford/AstraZeneca</td>
<td>Viral vector (NR)</td>
<td>III</td>
<td>2 doses (0, 28d)</td>
<td>NCT04516746</td>
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<td>consortium**</td>
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<td>≥18 years</td>
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<tr>
<td>Ad26COVS1</td>
<td>Janssen Pharmaceutical Companies</td>
<td>Viral vector (NR)</td>
<td>III</td>
<td>1 dose</td>
<td>NCT04436276</td>
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<td>18-55, 65+</td>
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<td>--</td>
<td>Sanofi/GSK</td>
<td>Protein Subunit</td>
<td>I/II</td>
<td>Single or 2 doses</td>
<td>NCT04537208</td>
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<td>18-49, 50+</td>
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<td>NVX-CoV2373</td>
<td>Novavax</td>
<td>Protein Subunit</td>
<td>I/II</td>
<td>2 doses (0, 21d)</td>
<td>NCT04368988</td>
<td>Enrollment complete</td>
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<td>18-84</td>
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<tr>
<td>V591</td>
<td>Merck</td>
<td>Viral Vector</td>
<td>I/II</td>
<td>2 doses (1, 57d)</td>
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<td>18-55</td>
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*As of October 27, 2020
**Currently on hold in US
### COVID-19 vaccines in human clinical trials – United States*

*As of October 27, 2020


<table>
<thead>
<tr>
<th>Candidate</th>
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<th>Recruiting</th>
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<tbody>
<tr>
<td>AV-COVID-19</td>
<td>Aivita</td>
<td>AuDendritic cell</td>
<td>I/II</td>
<td>• 1 dose</td>
<td>NCT04386252</td>
<td>Not yet recruiting</td>
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<td>• 18+</td>
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<tr>
<td>VXA-CoV2-1</td>
<td>Vaxart</td>
<td>Viral vector (NR)</td>
<td>I</td>
<td>• 2 doses (1, 29d)</td>
<td>NCT04563702</td>
<td>Active</td>
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<td>• Oral tablet</td>
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<td></td>
<td>• 18-54</td>
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<tr>
<td>INO-4800</td>
<td>Inovio Pharmaceuticals, Inc.</td>
<td>DNA plasmid</td>
<td>I</td>
<td>• 2 doses (0, 4w)</td>
<td>NCT04336410</td>
<td>Active, not recruiting</td>
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<td>• SC administration/</td>
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<td>electroporation</td>
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<td>• ≥18 years</td>
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*As of October 27, 2020

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

**Inactivated Vaccines**

<table>
<thead>
<tr>
<th>Candidate</th>
<th>Manufacturer/Institute</th>
<th>Type</th>
<th>Location</th>
<th>Phase</th>
<th>Trial number</th>
</tr>
</thead>
<tbody>
<tr>
<td>BIBP/Sinopharm BBIBP-CorV</td>
<td>Beijing Institute of Biological Products/Sinopharm</td>
<td>Inactivated</td>
<td>Argentina</td>
<td>Phase III</td>
<td>NCT04560881</td>
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<tr>
<td>Sinovac CoronaVac</td>
<td>Sinovac/Instituto Butantan</td>
<td>Inactivated</td>
<td>Turkey, Brazil, Indonesia</td>
<td>Phase III</td>
<td>NCT04582344; NCT04456595; NCT04508075</td>
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<tr>
<td>WIBP vaccine</td>
<td>Wuhan Institute of Biological Products/Sinopharm</td>
<td>Inactivated</td>
<td>Morocco</td>
<td>Phase III</td>
<td>ChiCTR2000039000</td>
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<tr>
<td>WIBP/BIBP/Sinopharm vaccines</td>
<td>Beijing Institute of Biological Products/Wuhan Institute of Biological Products/Sinopharm</td>
<td>Inactivated</td>
<td>UAE, Bahrain, Jordan, Egypt</td>
<td>Phase III</td>
<td>NCT04510207</td>
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**Protein Subunit Vaccines**

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<tr>
<th>Candidate</th>
<th>Manufacturer/Institute</th>
<th>Type</th>
<th>Location</th>
<th>Phase</th>
<th>Trial number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Novavax NVX-CoV2373</td>
<td>Novavax</td>
<td>Protein subunit</td>
<td>UK</td>
<td>Phase III</td>
<td>NCT04583995</td>
</tr>
</tbody>
</table>

*As of October 19, 2020
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

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

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

**RNA Vaccines**

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<thead>
<tr>
<th>Candidate</th>
<th>Manufacturer/Institute</th>
<th>Type</th>
<th>Location</th>
<th>Phase</th>
<th>Trial number</th>
</tr>
</thead>
<tbody>
<tr>
<td>BioNTech BNT162 (b1/b2)</td>
<td>BioNTech/Fosun Pharma/Pfizer</td>
<td>RNA</td>
<td>USA, Argentina, Brazil, others</td>
<td>Phase II/III</td>
<td>NCT04368728</td>
</tr>
</tbody>
</table>

*As of October 19, 2020
Sources:  
- https://milkeninstitute.org/covid-19-tracker  
- https://vac-lshtm.shinyapps.io/ncov_vaccine_landscape/  
- https://clinicaltrials.gov/  


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
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.