CoVPN Overview

Stephaun E. Wallace, PhD, MS
Director of External Relations, COVID-19 Prevention Network
Staff Scientist, Vaccine and Infectious Disease Division, Fred Hutch
Clinical Assistant Professor, University of Washington
What is the COVID-19 PREVENTION NETWORK?

The HVTN was formed 2 decades ago by Dr. Anthony Fauci of the National Institute of Allergy and Infectious Diseases, part of the National Institutes of Health, to address HIV and other global vaccine needs. The network quickly pivoted to COVID-19 and studies to ensure a safe and effective COVID-19 vaccine. Comprised of the foremost infectious disease and vaccine experts in the country, the research network and its global partners are working hand in hand to address this urgent need in our fight against the pandemic.
CoVPN: NIH funded clinical trial network to conduct Ph3 trials

Vaccine Efficacy Trials
- Larry Corey and Kathy Neuzil

mAb Prevention Trials
- Mike Cohen and David Stephens
CoVPN Operations Center at Fred Hutch

• Built around structure of the HIV Vaccine Trials Network founded in 1999 at Fred Hutchinson Cancer Research Center

• Extensive clinical trials network: in early 2020, 52 sites in US and Latin America, and another 56 sites in sub-Saharan Africa. Now over 220 sites.

• Academically based CRO with Operations Center (Corey and Kublin), Statistical Data Management Center (Peter Gilbert PI) and centralized world class immunology and virology labs (Julie McElrath PI)
  - McElrath T cell Lab; Montefiori Pseudovirus Lab; Tomaras Binding Antibody Lab; and UW Virology/Jerome Lab are all HVTN Laboratories; all validated in the HIV assays they perform and are now involved in OWS
We need to develop multiple vaccine platforms.

No single vaccine platform can be manufactured at enough scale to immunize the 4.4 billion adult population on the planet and 3 billion children, 220 million adults in US alone.

Use known platforms to cover the field scientifically. Manufacturing scalability is a key factor.

Coordinated USG effort to involve global vaccine manufacturing companies.

There must be an unprecedented coordinated approach to test, manufacture the vaccine at scale, and deliver the vaccine into peoples’ arms throughout the world.
Vaccine Designs

SARS-CoV-2 VACCINE AND RELATED* DESIGNS

- WHOLE-INACTIVATED (INACTIVATED SARS-CoV-2)
- LIVE-ATTENUATED (WEAKENED SARS-CoV-2)
- SYNTHETIC PEPTIDE (LABORATORY-MADE PIECE OF PROTEIN)
- RECOMBINANT VIRAL VECTOR (ANOTHER VIRUS CARRIES PIECES OF SARS-CoV-2)
- mRNA (mRNA DELIVERS SARS-CoV-2 SPike PROTEIN INSTRUCTIONS, WHICH IS MADE BY HOST CELL AND PRESENTED ON SURFACE)
- MONOCLONAL ANTIBODIES (CIRCULATE IN THE BODY AND ATTACH TO AND NEUTRALIZE SARS-CoV-2)
- VIRUS-LIKE PARTICLES (SAME SHAPE AS SARS-CoV-2, INSIDES CHANGED)

AstraZeneca
Janssen
Moderna
Pfizer
Novavax
Sanofi

*These designs are not approved or in use.
## Protocol pipeline: COVID-19 studies

<table>
<thead>
<tr>
<th>Protocol Name</th>
<th>Concept Name</th>
<th>Study N</th>
<th>Protocol Open</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moderna phase 3</td>
<td>Moderna phase 3</td>
<td>30000</td>
<td>7/27/2020</td>
</tr>
<tr>
<td>AstraZeneca phase 3</td>
<td>AstraZeneca phase 3</td>
<td>30000</td>
<td>8/29/2020</td>
</tr>
<tr>
<td>Janssen phase 3</td>
<td>Janssen phase 3</td>
<td>60000</td>
<td>9/21/2020</td>
</tr>
<tr>
<td>Novavax phase 3</td>
<td>Novavax phase 3</td>
<td>30000</td>
<td>10/12/2020</td>
</tr>
<tr>
<td>Sanofi phase 3</td>
<td>Sanofi phase 3</td>
<td>30000</td>
<td>12/1/2020</td>
</tr>
</tbody>
</table>
What are we hoping to learn from these studies?

In general, the vaccines we are studying seek to answer the following main questions:

• Does the vaccine create an immune response that protects people against moderate to severe COVID-19 illness? Or can the immune response protect against infection with SARS-CoV-2?

• Does the vaccine continue to show that it is safe when tested in thousands of people?

• Do the vaccine side effects continue to be well tolerated?
Interested in volunteering for a COVID-19 Prevention Clinical Study?

Thank you for your interest in our studies. Science can't move forward without your help!

Selecting the button below will take you to the CoVPN Volunteer Screening Registry.

The purpose of this screening registry is to create a list of potential volunteers who want to take part in current or future COVID-19 prevention clinical trials. You must be 18 years or older to participate. Participation involves completing a short online survey that includes some personal questions. Your participation is voluntary.

 Volunteer Now!

www.preventcovid.org
www.coronaviruspreventionnetwork.org
COVID-19 Inequities
Social and structural factors impacting COVID Risk

- People of color are overrepresented in essential service industries with increased exposure

- Low wage jobs often do not provide:
  - Health insurance
  - Paid sick leave
  - Childcare
  - Options to work from home
  - Other benefits (e.g., retirement savings)

- Residential Segregation
  - People of color are more likely to live in residentially segregated settings with high housing density
  - Poor access to healthy foods
  - More multigenerational households with limited space

- Increased levels of Chronic Stress
  - Resulting from structural racism, increased incidence of violence, everyday aggressions and trauma

CDC, 2020; Poteat, Millet, Nelson and Beyrer, 2020; van Dorn A, Cooney R, Sabin ML, 2020; Yancy, 2020
CDC: Reported COVID-19 Cases By Race/Ethnicity

Reported Cases of COVID-19*

<table>
<thead>
<tr>
<th>Race/Ethnicity</th>
<th>% of Total Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>American Indian and Alaska Native,</td>
<td>1.2</td>
</tr>
<tr>
<td>Non-Hispanic</td>
<td></td>
</tr>
<tr>
<td>Asian, Non-Hispanic</td>
<td>3.1</td>
</tr>
<tr>
<td>Black, Non-Hispanic</td>
<td>15.9</td>
</tr>
<tr>
<td>Hispanic or Latino</td>
<td>26.6</td>
</tr>
<tr>
<td>Multiple/Other, Non-Hispanic</td>
<td>4.6</td>
</tr>
<tr>
<td>Native Hawaiian/Other Pacific Islander</td>
<td>.4</td>
</tr>
<tr>
<td>Non-Hispanic</td>
<td></td>
</tr>
<tr>
<td>White, Non-Hispanic</td>
<td>48.3</td>
</tr>
</tbody>
</table>

*Last updated November 9, 2020. Includes race/ethnicity data available for 3,973,551 (53%) of 7,482,736 cases.

Comparison of Distribution of United States Population to Distribution of COVID-19 Cases by Race/Ethnicity


*Last updated October 26, 2020. Data from 6,530,618. RE data available from 3,447,486 (52%) of cases.


Slide credit: clinicaloptions.com

<table>
<thead>
<tr>
<th>Race/Ethnicity</th>
<th>Population</th>
<th>COVID-19 Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>American Indian and Alaska Native, Non-Hispanic</td>
<td>0.712</td>
<td>60.2</td>
</tr>
<tr>
<td>Asian, Non-Hispanic</td>
<td>5.6</td>
<td>46.2</td>
</tr>
<tr>
<td>Black, Non-Hispanic</td>
<td>12.3</td>
<td></td>
</tr>
<tr>
<td>Hispanic or Latino</td>
<td>16.8</td>
<td></td>
</tr>
<tr>
<td>Multiple/Other, Non-Hispanic</td>
<td>18.3</td>
<td></td>
</tr>
<tr>
<td>Native Hawaiian/Other Pacific Islander, Non-Hispanic</td>
<td>2.5</td>
<td></td>
</tr>
<tr>
<td>White, Non-Hispanic</td>
<td>46.2</td>
<td>27.6</td>
</tr>
</tbody>
</table>
COVID-NET: COVID-19–Associated Hospitalization By Race and Ethnicity

COVID-19-associated hospitalization rates are highest among people who are Hispanic/Latino, non-Hispanic Black, and non-Hispanic American Indian/Alaska Native.

RACE AND ETHNICITY

Rates are statistically adjusted to account for differences in age distributions within race/ethnicity strata in the COVID-NET catchment area. Rates are based on available race and ethnicity data which is now complete in 94.2% of cases from COVID-NET sites. COVID-19-associated hospitalization rates for American Indian and Alaska Natives may be impacted by recent outbreaks among specific communities within this population and the small numbers of American Indian and Alaska Natives cases included in COVID-NET.

CDC COVID Data Tracker: COVID-19 Deaths by Race/Ethnicity

Deaths by Race/Ethnicity*

<table>
<thead>
<tr>
<th>Race/Ethnicity</th>
<th>% of Total Deaths</th>
<th>(n =)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hispanic/Latino</td>
<td>16.1</td>
<td>21,569</td>
</tr>
<tr>
<td>American Indian/Alaska Native, Non-Hispanic</td>
<td>0.8</td>
<td>1090</td>
</tr>
<tr>
<td>Asian, Non-Hispanic</td>
<td>4.8</td>
<td>6355</td>
</tr>
<tr>
<td>Black, Non-Hispanic</td>
<td>20.3</td>
<td>27,154</td>
</tr>
<tr>
<td>Native Hawaiian/Other Pacific Islander, Non-Hispanic</td>
<td>0.2</td>
<td>297</td>
</tr>
<tr>
<td>White, Non-Hispanic</td>
<td>53.8</td>
<td>71,942</td>
</tr>
<tr>
<td>Multiple/Other, Non-Hispanic</td>
<td>4.1</td>
<td>5438</td>
</tr>
</tbody>
</table>

*Last updated October 26, 2020. Data from 164,608 deaths. Race/Ethnicity was available for 133,845 (81%) deaths.

https://www.cdc.gov/covid-data-tracker/index.html#demographics

Slide credit: clinicaloptions.com
CoVPN Community & Stakeholder Engagement
CoVPN Over-arching Community Engagement Effort

COVID-19 Prevention Network

NIH National Institute of Allergy and Infectious Diseases

U.S. Department of Veterans Affairs

WRAIR Walter Reed Army Institute of Research
Soldier Health • World Health

FRED HUTCH

BAI BLACK AIDS INSTITUTE
BLACK AIDS INSTITUTE

BARDA Biomedical Advanced Research and Development Authority

HANC HIV/AIDS Network Coordination

CDC Centers for Disease Control and Prevention

JOHNS HOPKINS UNIVERSITY

UNIVERSITY of WASHINGTON

METRO
Engagement and Participation Foci with Priority Populations

PRIORITY POPULATIONS

- Native/Indigenous
- African American/Black
- Latinx
- Asian American/Pacific Islander
- Occupational Engagement
- People with pre-existing health conditions
- Communities experiencing health disparities
- Older Adults/Veterans Administration
  - Nursing Home (mAb trials)
  - Assisted Living Facility residents (vaccine trials)

- All activities are tailored for each of these vital priority populations
- Priority populations require varying:
  - Outreach
  - Engagement
  - Recruitment approaches
- Building and maintaining relationships with experts working with these groups
Community Engagement Activities (i)

I. Materials for participants/potential participants (English & Spanish)
   A. Community-based presentation of trial specific principles
   B. CoVPN public website w/ registry – [www.PreventCOVID.org]

II. Materials for sites (various languages)
   A. Standardized informational tools for site staff involved in community engagement
   B. Great ideas for community engagement
   C. FAQs – incorporated in website
   D. COVID inequities slide set
   E. General recruitment materials for use across vaccine studies: poster, flyer, postcard, palm cards
   F. Site training/Preparation/Q&A calls in advance of each study
   G. Educational Videos
   H. National Heart, Lung, and Blood Institute Partnership w/ site specific support
Community Engagement Activities (ii)

III. Priority Population Expert Panels
A. Scientists from and working with priority populations
   • Modeled after NIH review committees
   • Convene and discuss each protocol and related materials
   • Generate reports on significance, impact, ethics, etc. for larger priority population community
B. Native/Indigenous
C. African American/Black
D. Latinx
E. Older Adults/Veterans Administration

IV. Convening Community Working Groups with research familiarity for discussion
A. Utilizing Community Advisory Board and Community Action Board Models
B. Community Working Group convened and meeting regularly
<table>
<thead>
<tr>
<th>Date</th>
<th>Title</th>
<th>Organizer(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>11/5/20</td>
<td>Iman &amp; COVID: Reflections from the Muslim Community – Episode 1: The Election Results &amp; COVID: Where Do We Go From Here?</td>
<td>RAHMA, CoVPN</td>
</tr>
<tr>
<td>11/10/20</td>
<td>American Indian Health Coalition Annual Meeting</td>
<td>American Indian Health Coalition, CoVPN</td>
</tr>
<tr>
<td>11/11/20</td>
<td>COVID &amp; Clinical Trials (Chicago Edition)</td>
<td>BlackDoctor.org, CoVPN</td>
</tr>
<tr>
<td>11/12/20</td>
<td>COVID in Black Episode 4: Faith and COVID-19: A Pathway Forward</td>
<td>CoVPN</td>
</tr>
<tr>
<td>11/14/20</td>
<td>COVID &amp; Clinical Trials (Atlanta/Miami Edition)</td>
<td>BlackDoctor.org, CoVPN</td>
</tr>
<tr>
<td>11/17/20</td>
<td>COVID &amp; Clinical Trials (Los Angeles &amp; Orange County Edition)</td>
<td>BlackDoctor.org, CoVPN</td>
</tr>
<tr>
<td>11/18/20</td>
<td>COVID in Black Episode 5: Black Health Providers Can Help End the Uncertainty</td>
<td>National Medical Association, Cobb Institute, National Black Nurses Association, BIO, Meharry Medical College, Morehouse School of Medicine, Howard University, Charles Drew University, CoVPN</td>
</tr>
<tr>
<td>11/18/20</td>
<td>Iman &amp; COVID: Reflections from the Muslim Community – Episode 3: Incarceration, Surviving Marriage, and COVID</td>
<td>RAHMA, CoVPN</td>
</tr>
<tr>
<td>11/19/20</td>
<td>Is Stigma Killing Us? – A Conversation with the Trans Community at the International Conference on Stigma</td>
<td>CoVPN</td>
</tr>
<tr>
<td>11/24/20</td>
<td>COVID-19 Prevention Network (CoVPN) Webinar</td>
<td>TAG, CoVPN</td>
</tr>
<tr>
<td>11/25/20</td>
<td>COVID &amp; Clinical Trials (Dallas/Houston Edition)</td>
<td>BlackDoctor.org, CoVPN</td>
</tr>
<tr>
<td>11/30/20</td>
<td>Souls, Storms, and Science: Building Faith Leadership in the Age of COVID-19 (Hosted by Dr. Bambi Gaddist)</td>
<td>Wright Wellness Center, CoVPN</td>
</tr>
</tbody>
</table>
V. Stakeholder Engagement and Building Trust

A. Convening Community Listening Sessions (ongoing and iterative)
   • Opportunities for community to hear research updates

B. Virtual Town Halls/Webinars
   • Education sessions presenting and discussing community-level considerations for research engagement

C. Trade Unions
   • Meat/Poultry Industry, Restaurants, Factories

D. Grass Roots Organizations working on COVID and Social Justice (not exhaustive list)
   • ThriveSS, BYP100, Urban Indian Health Institute

E. National Organizations (not exhaustive list)
   • AARP, NAACP, National Urban League, YWCA/YMCA, UnidosUS

F. Political Entities (not exhaustive list)
   • Black Caucus, Hispanic Caucus, Asian Pacific American Caucus, Progressive Caucus

G. CoVPN Faith Initiative - faith-based engagement

H. National Scientific Panels highlighting scientists of color
CoVPN Faith Initiative

• Faith Ambassadors & Clergy/Faith Leaders
  • Geographically distributed across the US
  • Speaking to the intersection between faith and science
  • Establishing and enhancing networks of faith leaders to conduct COVID & CoVPN educational activities

• Establish and Maintain a faith-based advisory council
  • Provide guidance and direction for CE activities

• Implementation of National faith-focused COVID & CoVPN Education program
  • Educators will represent diverse faith, racial and ethnic identities
  • Program will integrate anti-racist, anti-xenophobic, anti-homophobic and Good Participatory Practice principles
Community Engagement Activities (iv)

VI. Communications Creatives & Community Influencers
   I. Lift up voices of people with lived experiences
   II. Celebrity Champions
   III. Marketing Campaign launched September 2020

VII. Sponsor CE Advisory Committees
WHAT STANDS IN OUR WAY?

People are bombarded with myths and misinformation

People who want to help don’t know how

Volunteers may be stigmatized by a vocal anti-vax movement

A higher than normal number of US citizens are doubting the vaccine development process for COVID-19

Politics are interfering with science like never before
Next Steps

Vaccine Interim Results - lots of unknowns/questions remain

• Vaccine primary endpoints are prevent disease, not prevent infection- is infection prevention possible?
• If I get a vaccine, and I get SARS-CoV-2, can I spread the infection to others?
• Dosing and roll-out processes

• COVID-19 prevention considerations should continue
• Vaccine Dissemination
• Plans via CDC/State HDs
• Framework for equitable allocation of COVID-19 vaccine- National Academy of Sciences, Engineering, and Medicine
## Thank You!

[www.PreventCOVID.org](http://www.PreventCOVID.org)

### COVPN Executive Committee
- Larry Corey and Kathy Neuzil
- David Stephens and Myron Cohen

### Study Chairs

### NIH Executive Team
- Mary Marovich
- Emily Erbelding
- Carl Dieffenbach
- Hilary Marston
- Cliff Lane

### VRC
- John Mascola
- Barney Graham
- Julie Ledgerwood
- Sandra Sitar

### CoVPN Staff
- Merlin Robb

### NIH
- Tony Fauci
- Francis Collins
- Doug Lowy

### HHS
### Oracle
### Fred Hutch