NIH Tribal Health Research Office (THRO)

Division of Program Coordination, Planning, and Strategic Initiatives
Office of the Director

David R. Wilson, Ph.D., Director

National Native Health Research Training Initiative
November 18, 2020
• NIH Tribal Health Research Office

• Accomplishments

• COVID-19
Federal Responsibility

• Since the formation of the Union, the United States (U.S.) has recognized Indian Tribes as sovereign nations.
• Resulted in the transfer of land under treaties
• Federal programs and services that benefit American Indians and Alaska Natives based upon concept of government-to-government relationship
• American Indians are provided healthcare as outlined in treaties
573* federally recognized tribes in the US with total citizenship of about 4.5 million people.

Each Tribe is unique and has different:

• Histories
• Cultural traditions
• Languages
• Government structures
• Institutions and systems
• Only ethnic minority in the US to have “Dual-Citizenship”
Established in 2015, the Tribal Health Research Office is located in the Division of Program Coordination, Planning, and Strategic Initiatives in the Office of the Director (OD), NIH.

The office was created in recognition of the importance of ensuring meaningful input from and collaboration with tribal Nations on NIH programs and policies.

To also ensure the effective implementation of the HHS Tribal Consultation Policy
Building Research Partnerships for Healthy Tribal Nations

Established in 2015, THRO supports the development of culturally relevant research vital to improving AI/AN health.

- Aims to **build trust** in relationships and further research collaboration between Tribal communities and NIH that is acceptable and useful to AI/AN people
- Coordinates Tribal health research **across NIH**
- Gathers **meaningful input** from Tribes on NIH policies, programs, and activities
- **Creates opportunities** for the next generation of AI/AN researchers at NIH
NIH Tribal Advisory Committee

➢ Representatives from 12 geographic areas advise NIH and help ensure NIH policies or activities that affect AI/AN communities are shared with Tribal leaders

➢ Brings together Tribal officials (or their designated representatives) and NIH officials to exchange views, share information, and seek advice
Notable Accomplishments
Navajo Nation Signing Ceremony for the ECHO Data Sharing Agreement

At Navajo Nation Head Start Center in Leupp, AZ

NATURE NEWS
07 MAY 2019

Navajo Nation and US health agency reach data-sharing agreement

Researchers funded by the National Institutes of Health will have access to health information from tribe members.

Sara Reardon
Summer Internship
Students & Activities
SARS-Corona Virus-2

Slide credit: Vaccine Research Center, NIAID
NIH Tribal Consultation

Rapid-Response NIH Tribal Consultation on COVID-19 Research
May 28, 2020

➢ Sought input from Tribes to support time-sensitive research that will provide information to help address COVID-19 in Tribal communities

➢ Informed funding opportunities
History of pandemics in tribal communities

**Historically, pandemics have had significant burden on AI/AN populations.**

**1918 Influenza pandemic**
- Mortality rates among American Indian populations were 4 times higher than rates in larger U.S. cities.
- Across the U.S. and other countries, there was increased mortality rates in indigenous populations, compared to other populations.

**2009 H1N1 pandemic**
- In 12 US states, mortality rates were 4 times higher in Native populations than other populations.
- American Indians in the Southwest U.S. had higher hospitalization rates than other populations in the U.S.
- Diabetes among adults and asthma among children were independent risk factors for hospitalization with H1N1.
What could a COVID-19 vaccine do?

Benefit the individual
- Reduce the severity of illness
- Prevent infection

Benefit the community
- Reduce transmission
- Healthier communities

Photo credit Nina Ritchie

Photo credit Ed Cunicelli
Can vaccines cause SARS-CoV-2 infection or cause COVID-19?

**NO!**

The vaccines being tested are made from synthetic (laboratory made) pieces copied from SARS-CoV-2, not the whole virus. Therefore, the vaccines **CANNOT** cause infection or cause you to get COVID-19.
Stages of clinical trials

Traditional stages:

PHASE 1
12 to 18 months
- Test safety and whether the body can tolerate the product
- Often involves comparing against a placebo with no active ingredients
- Usually <100 people

PHASE 2
Up to 2 years
- Identify the maximum tolerated dose, the best dosing schedule
- Assess the immune responses
- Usually a few hundred to a few thousand people

PHASE 3
2+ years
- Efficacy: “Does this product prevent infections, or help to reduce the severity of disease?”
- Involves thousands of people, including some at risk of infection

With SARS-CoV-2, no phases are skipped. Instead, we overlap the phases, starting the next phase as the necessary safety data are collected and analyzed from the earlier phase. The new phase can start while the long-term follow-up of people in the earlier phase continues. Other steps can be done in parallel, instead of one after the other.
# COVID-19 vaccines in late phase clinical trials in the US

<table>
<thead>
<tr>
<th>Developer</th>
<th>Platform</th>
<th>Planned Start</th>
<th>Eligibility</th>
<th>Number of Doses</th>
<th>Specimens collected</th>
<th>Planned follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moderna</td>
<td>mRNA</td>
<td>July</td>
<td>18+, healthy or medically stable, no prior COVID19</td>
<td>2, 28 days apart</td>
<td>Blood, nasal swab</td>
<td>2 years</td>
</tr>
<tr>
<td>Pfizer/BioNTech</td>
<td>mRNA</td>
<td>August</td>
<td>18-85 years, healthy or medically stable, no prior COVID19</td>
<td>2 doses, 21 days apart</td>
<td>Blood, nasal swab</td>
<td>2 years</td>
</tr>
<tr>
<td>Oxford/Astra-Zeneca</td>
<td>Adenovirus vector</td>
<td>August</td>
<td>18+, healthy or medically stable</td>
<td>2 doses, 28 days apart</td>
<td>Blood, nasal swab, saliva</td>
<td>2 years</td>
</tr>
<tr>
<td>Janssen</td>
<td>Adenovirus vector</td>
<td>September</td>
<td>Healthy 18-59 years old first, then add in 60+, with and without comorbidities</td>
<td>1 or 2 doses, 8 weeks apart</td>
<td>Blood, nasal swab, saliva</td>
<td>1 year and 3 months</td>
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<tr>
<td>Novavax</td>
<td>Protein nanoparticle</td>
<td>October</td>
<td>18+, healthy or medically stable</td>
<td>2 doses, 21 days apart</td>
<td>Blood, nasal swab</td>
<td>2 years</td>
</tr>
<tr>
<td>Sanofi/GSK</td>
<td>Protein Subunit</td>
<td>December</td>
<td>18+</td>
<td>2 doses, 21 days apart</td>
<td>Blood, nasal swab</td>
<td>12 months</td>
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</table>
mRNA Based Vaccine Platform

Moderna/mRNA-1273 The COVE Study

mRNA platform
- Translated in the cytosol to the coronavirus spike protein
- mRNA vaccines are not made with pathogen particles so are non-infectious
- mRNA is degraded after translation; it does not enter the nucleus or become integrated into the host genome
- RNA vaccines are much quicker and simpler to make
- Storage at -70°C

Study timeline: Moderna/mRNA-1273 The COVE Study

- Visit 1 Day 1: Receive injection, Blood sample, Medical history
- Visit 2 Day 28: Blood sample, Nasal smear, Physical exam
- Visit 3 1-Month Follow-up: Blood sample, Nasal smear, Physical exam
- Visit 4 6-Month Follow-up: Blood sample, Nasal smear, Physical exam
- Visit 5 12-Month Follow-up: Blood sample, Nasal smear, Physical exam
- Visit 6 24-Month Follow-up: Blood sample, Nasal smear, Physical exam
Adenovirus Based Vaccine Platform

Astra Zeneca / AZD1222

- ChAdOx1 platform (Adenovirus Vector) non replicating
- Produces coronavirus spike protein
- Development of the vaccine was initiated by the University of Oxford in the United Kingdom

Phase 1/2 results:
- Vaccine elicits antibody immune responses and cellular immunity
- Adverse reactions (fever, fatigue, and chills)

Phase 2/3 currently ongoing:
- The vaccine is now being tested by more than 75 clinical sites in the US.
- Approximately 30,000 participants from the United States will participate
- Participants will be randomized in a 2:1 ratio to receive either a dose of AZD1222 vaccine or placebo.

Study timeline: Astra Zeneca
Protein Based Vaccine Platform

**Novavax 2019nCoV-301**

Protein platform: use part of coronavirus protein with Matrix-M1 to provoke an immune response.

**Phase 1/2 results:** (tested on 131 people aged 18-59)
- Vaccine elicits antibody immune responses and cellular immunity
- Some adverse reactions (fever, fatigue, and chills)
- Phase 2 ongoing

Phase 3: will enroll ~30,000 people aged >18 years from sites globally; enrollment slated to begin in October

**Study timeline: 2019nCoV-301**
Data and Safety Monitoring Board (DSMB)

- DSMB is monitoring all ongoing clinical trials: vaccines, monoclonal antibodies, antivirals, immunomodulators.
- Pauses on clinical trials are very common especially in phase 3 trials enlisting tens of thousands of participants. Demonstrates participant safety is a priority.
- A committee of clinical research experts, such as physicians and statisticians, and patient advocates who monitor the progress of a clinical trial and review safety and effectiveness data while the trial is ongoing. This committee is independent of the people, organizations, and institutions conducting the clinical trial. Data and Safety Monitoring Boards (DSMBs) can recommend that a trial be stopped early because of concerns about participant safety or because the main research question has been answered.
Operation Warp Speed = Interagency Partnership
Includes divisions of the US Dept of Health & Human Services:
• Centers for Disease Control and Prevention (CDC),
• Food and Drug Administration (FDA),
• National Institutes of Health (NIH)
• Biomedical Advanced Research and Development Authority (BARDA)
Other Federal Agencies:
• Department of Defense (DOD),
• Department of Agriculture (USDA)
• Departments of Energy (DOE) & Veterans Affairs (VA)
• Private firms

NIH COVID-19 Prevention Network (CoVPN) – Supports OWS
Created by merging four existing NIAID-funded clinical trials networks:
• HIV Vaccine Trials Network (HVTN), (Seattle)
• HIV Prevention Trials Network (HPTN), based in Durham, N.C.;
• Infectious Diseases Clinical Research Consortium (IDCRC) (Atlanta)
• AIDS Clinical Trials Group (Los Angeles)

THRO Engagement during Vaccine Development

Expert Panels

Research Protocols

Communication materials

Tribal Nations

Clinical Trials

Decision on Participation

Trusted Research Partners

 +/-
Other Highlighted Activities

- NIH Strategic Plan for Tribal Health Research
- Traditional Medicine Summit
- Tribal Epidemiology Centers (TECs)
- Efforts Around HIV/AIDS, COVID-19, Maternal Health, Opioid Use
- Native American Heritage Month
- Novel Strategic Plan tracking system
- FY 2018 AI/AN Portfolio Analysis Update
The Tribal Health Research Office Team

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