NIH Tribal Advisory Committee (TAC)

December 2-3, 2020
Virtual Meeting Summary Report

TAC Participants

Delegates

Beverly Cook, Nashville Area
Debra Danforth, National At-Large
Denise Dillard, Ph.D., Alaska Area
Herminia Frias, Tucson Area
Donna Galbreath, M.D., National At-Large
Jeffrey Henderson, M.D., Great Plains Area
Jill Jim, Ph.D., Navajo Area Alternate
Stephen Kutz, Portland Area Delegate
Tyler LaPlaunt, Bemidji Area
Gwendena Lee-Gatewood, Phoenix Area
Lynn Malerba, D.N.P., National At-Large
Kim Paul, Ph.D., Billings Area
Bobby Saunkeah, Oklahoma Area
Jeromy Sullivan, Portland Area Alternate
Lisa Sundberg, Chairperson, California Area

Technical Advisors

Christy Duke, Nashville Area
Patty EagleBull, Great Plains Area
Tam Dixon Lutz, Portland Area
Tara Maudrie, Bemidji Area
Michael Peercy, Oklahoma Area
Yvette Roubideaux, M.D., National At-Large
Jessica Rudolfo, Phoenix Area
Suzanne A. Sisley, M.D., California Area
Teshia G. Arambula Solomon, Ph.D., Tucson Area
Tim Thomas, M.D., National At-Large

Absent

Myron Lizer, Navajo Area Delegate

Absent

Ramona Antone-Nez, Navajo Area
Kenneth Smoker, Billings Area

NIH

Lawrence A. Tabak, D.D.S, Ph.D., Principal Deputy Director, NIH
James M. Anderson, M.D., Ph.D., NIH Deputy Director for Program Coordination, Planning and Strategic Initiatives
Dave Wilson, Ph.D., Director, Tribal Health Research Office (THRO)
Juliana Blome, Ph.D., Deputy Director, THRO
Dawn Morales, Ph.D., Program Chief, American Indians and Alaska Natives Mental Health, National Institute of Mental Health (NIMH)
Ted Keane, Health Science Policy Analyst, THRO
Selina Keryte, Health Science Policy Analyst, THRO
Maria Jamela Revilleza, Ph.D., Senior Health Science Policy Analyst, THRO
Bonnie Tabasko, Senior Communications Strategist, THRO
Shawn Thomas, Health Science Policy Analyst, THRO

Jermelina Tupas, Ph.D., NSF Guest Researcher, THRO

Guest Speaker
Larry Corey, M.D., Co-lead for the COVID-19 Prevention Trials Network
and President and Director Emeritus, Fred Hutchinson Cancer Research Center

Contractor Support
Kendra King Bowes, Miami Environmental and Energy Solutions
Laura C. Jackson, Notetaker, Audio Associates

QUORUM: Met

Welcome, Invocation and Tribal Caucus Highlights

TAC Co-Chairperson Lisa Sundberg called the virtual meeting to order at 1:00 p.m. EST. TAC delegates, alternates and technical advisors noted attendance via the Zoom chat. Tam Dixon Lutz, Technical Advisor for the Portland Area, provided the invocation. TAC members then went into Tribal caucus until 2:05 p.m.

Following the Tribal caucus, Ms. Sundberg shared brief comments with NIH, noting that TAC members discussed the coronavirus vaccine and the need for more Tribal research.

Due to the speed of the coronavirus outbreak, Tribal leaders did not fully engage in the research process. Some Tribes could not complete needed agreements to participate in the initial COVID-19 clinical trials. Leaders want to develop and vet engagement language so pharmaceutical companies and others understand the best way to work with Tribes, said Ms. Sundberg.

Tribes also need funding for the aftermath of COVID, added Ms. Sundberg. Follow-up issues include effective vaccine messaging and Indian Health Service (IHS) vaccine distribution. Chickasaw Nation reported that Labcorp, an IHS contractor, requested Tribal member records. This inappropriate action gives a poor example of how to involve Tribes in COVID research, said TAC members.

Ms. Sundberg noted that good data and information will help Tribal leaders educate Native communities and overcome vaccine hesitancy. Portland Area Delegate Stephen Kutz added that those who participated in the vaccine trials had not contracted COVID. Councilman Kutz requested research on coronavirus vaccine safety for those who already had COVID. Many people who experienced symptoms are not getting tested. Further, most of the pharmaceutical

companies did not seem to include this cohort in the vaccine trials, which raises concerns about efficacy and contraindications, said Councilman Kutz.

Introductions, Welcome and THRO Updates

James M. Anderson, M.D., Ph.D.
NIH Deputy Director for Program Coordination, Planning, and Strategic Initiatives (DPCPSI)
Office of the Director, NIH

David R. Wilson, Ph.D.
Director, Tribal Health Research Office (THRO)
Division of Program Coordination, Planning and Strategic Initiatives
Office of the Director, NIH

NIH recognizes the need for more progress in research implementation and distribution, said James M. Anderson, M.D., Ph.D., Deputy Director for Program Coordination, Planning, and Strategic Initiatives (DPCPSI). Researchers must learn from the COVID-19 experience to improve general research and prepare for the next pandemic. THRO, led by Director Dave Wilson, Ph.D., has worked tirelessly to network with pharmaceutical companies and facilitate relationships with Tribal communities. NIH will report on these efforts during the two-day TAC meeting and throughout the next few months, said Dr. Anderson.

Following Dr. Anderson's opening remarks, Dr. Wilson led a presentation on THRO's COVID-19 activities as well as other issues and health disparities the office must address.

Turning first to how the office operates, Dr. Wilson said THRO staff members have received guidance from the Department of Health and Human Services Secretary's Tribal Advisory Committee (STAC). THRO recently adopted STAC rules of order to ensure that staff hear from the TAC delegates while staying on top of COVID-19. Dr. Wilson also reminded the TAC of new Health Science Policy Analyst Selina Keryte, who will serve as the primary contact between the office and the Tribal leaders. Rather than replacing Dr. Wilson's engagement, Ms. Keryte will improve the way THRO communicates with the TAC. Ms. Keryte also will organize subcommittees, create products and monitor outcomes.

The coronavirus pandemic has presented overwhelming challenges and opportunities, added Dr. Wilson. The virus, for instance, has changed how science thinks about Tribes. Despite the need for vaccines and interventions, Native communities do not feel comfortable participating in clinical trials. When the pandemic began early in March, NIH launched a funding opportunity to increase the amount of COVID-19 testing in underserved communities. This led to the May 2020 Rapid Response COVID-19 NIH Tribal Consultation.

The consultation informed funding opportunities for the Rapid Acceleration of Diagnostics (RADx-UP) fast-track program in the spring. In addition, the consultation created an awareness that researchers should not bypass Tribal protocols, even during a crisis.

Insight from existing clinical trials also helped THRO assist Tribal communities. The NIH COVID-19 Prevention Network (CoVPN) developed from a merger of four clinical trial networks funded by the National Institute of Allergy and Infectious Diseases (NIAID). Two of these collaboratives, The HIV Vaccine Trial Network and the HIV Prevention Trial Network, face the same types of engagement, stigma and testing issues that Tribes have confronted during the pandemic.

CoVPN gave Native communities access to early vaccine protocols. THRO continues to work with Tribes and the pharmaceutical companies to develop a data sharing agreement and a biological specimen use agreement. These agreements will serve as templates for other Native communities, particularly for the Tribes that did not have the capacity or infrastructure to participate in the vaccine trials.

NIH also launched the COVID-19 Community Engagement Alliance (CEAL). The CEAL program engaged with 11 of the hardest-hit, highest-need states and provided funding to help minority communities deliver COVID-19 messages, conduct town halls and spark interest in vaccine trial participation. Participating states included Arizona, California, Louisiana, Mississippi and North Carolina.

NIH has talked to principal investigators (PIs) about the research agreements that are in place for these CEAL program efforts, and whether the PIs secured letters of support before going into Tribal communities. Short-term program goals include:

- Understand unique American Indian and Alaska Native needs per CEAL Team
- Delineate what “success” means for each CEAL Team
- Connect CEAL Teams with additional and local entities that could help facilitate Tribal engagement
- Assist with problem-solving
- Disseminate information and provide resources
- Create a re-occurring forum for CEAL Teams to collaborate

In response to a question from Councilman Kutz, Dr. Wilson said NIH also continues to fund collaborative efforts that include Tribal members as part of the research team. One example is the project with Great Plains Area Delegate Jeffrey Henderson, M.D. The Black Hills Center for American Indian Health partners with Tribes and operates two clinical trial sites that will soon host two different COVID-related clinical trials. One trial will occur on the Cheyenne River Sioux Indian Reservation. The other site will be in Rapid City, South Dakota.

The project received a two-month on-boarding start-up award from NIAID. The Rapid City site will enroll Native and non-Native people in vaccine trials. To encourage Tribal involvement in these trials, NIH has developed simple slide presentations that clearly illustrate how the vaccines work and the level of commitment required from trial participants. Phoenix Area Delegate Gwendena Lee-Gatewood asked to share the slides on social media. Ms. Sundberg requested Internet links to more scientific information for those who want to dive into the details.

Dr. Wilson stressed that the vaccine does not prevent infection. Those who are vaccinated will experience a lower level of infection severity, and those individuals can still infect others who have not been vaccinated. This is an important point to share with Tribal communities, said TAC members. As the vaccines become available, pharmaceutical companies will likely also release information about the continued need for masks and other concerns, said Dr. Anderson.

Ms. Sundberg requested more details on how solid messaging specific to Indian Country will get out to Tribal communities and health centers. Tribal members must understand that a vaccine is not a silver bullet, added Councilman Kutz. Native leaders need COVID-19 information for cultural events as well as vaccine guidance for those who may have already contracted the virus. A Frequently Asked Questions (FAQs) section on a Website could help, said TAC members.

Dr. Wilson also discussed minority enrollment in vaccine trials. The Moderna trial did not include much Tribal participation. The Pfizer study is occurring on the Navajo reservation, but participation numbers remain low. NIH hopes to move the needle in subsequent trials, said Dr. Wilson. These numbers reveal that Tribes still distrust scientific research and feel a great deal of uncertainty about vaccine development. NIH and Tribal leaders must work together to build confidence and increase vaccine uptake in Native communities. Leaders also must ensure that Tribal members know the difference between the vaccines and the vaccine research trials, which could include placebos.

Shifting from COVID, Dr. Wilson also discussed the Native American Research Centers for Health (NARCH). A recent funding announcement included a link to the NIH document Critical Considerations for Reviewing AI/AN Research. THRO also collaborated with the Center for Scientific Review (CSR) to provide training sessions for grant reviewers.

In other news, THRO has teamed up with the Office of Evaluation, Performance and Reporting to enhance the NIH Strategic Goals for Tribal Health Research. A new platform will help THRO staff assess all the work across the agency that benefits Indian Country.

Other 2020 THRO activities included:

- World AIDS Day
- Tribal Epidemiology Centers (TECs)
- Efforts Around HIV/AIDS, COVID-19, Maternal Health, Opioid Use
- Native American Heritage Month
- Alaska Native Tribal Health Consortium
- FY 2018 AI/AN Portfolio Analysis Update
- The NIH Tribal Consultation Policy

Ms. Sundberg reminded NIH to consider rural Tribal communities as plans for vaccine distribution continue. Bemidji Area Delegate Tyler LaPlaunt added that NIH funding distribution tends to go to colleges and universities rather than directly to Tribes. Academics often want to study Tribal members without developing partnerships with Native communities. This issue remains a challenge as NIH attempts to understand the relationships between researchers and the communities, said Dr. Wilson. To solve this problem, NIH should identify whether Tribal members serve as research co-authors, said Councilman Kutz. Native leaders continue to push for more participatory research and funding that focuses on what Tribes want to study. THRO remains concerned about research grantees who have not secured appropriate Tribal approvals before launching a research project, added Dr. Wilson.

Past decades have shown that Tribes cannot rely on universities or institutional review boards (IRBs), said Billings Area Delegate Kim Paul, Ph.D. Tribal IRBs must establish research protocols and guidelines for individual protections as well as for biosystems, songs or ceremonies. Native leaders in Blackfeet Country continue to strengthen the IRB based not only on the Common Rule but also on community needs. Tribes also seek regulations for co-authorship, co-publication and co-funding. Further, Tribal researchers should have the primary award, not the subaward, said Dr. Paul.

Oklahoma Area Delegate Bobby Saunkeah noted that a longtime relationship with academia should form the basis of good Tribal research. Tribal co-authors or co-investigators indicate that the Native community has been involved in developing a research project. During recent efforts with the University of Oklahoma, the university IRB has deferred to the Chickasaw Nation IRB. The majority of the funding also came to the nation even though Chickasaw is a subawardee.

Following Dr. Wilson's presentation, TAC delegates and technical advisors dismissed for a break and a second Tribal caucus until 3:50 p.m. During the caucus, the TAC elected Ms. Sundberg as chair and Mr. Saunkeah as vice chair.

Update and Status of COVID-19 Clinical Trials
Larry Corey, M.D.
Co-lead for the COVID-19 Prevention Trials Network
and President and Director Emeritus, Fred Hutchinson Cancer Research Center

As the co-lead for the Coronavirus Prevention Network (CoVPN), Dr. Corey has helped include Tribes in the conversation around each of the vaccine trials.

In March, Dr. Corey began working on plans to develop multiple vaccine platforms in partnership with Tony Fauci, M.D., director of NIAID and NIH Director Francis Collins M.D., Ph.D. Also involved: John Mascola, M.D., director of the NIAID's Vaccine Research Center. By April, the epidemic was spreading at a pace no one had ever seen before in human history. Even the 1918 flu took two years to cause incredible suffering. The COVID-19 pandemic has killed more than 300,000 in the United States in 11 months.

Dr. Corey noted that one manufacturer could not produce enough vaccines for the 4.4 billion adult population on the planet and 3 billion children. The United States has 220 million adults. A coordinated U.S. government effort must involve several manufacturing companies. This effort also must include a coordinated approach to test, deliver and vaccinate people all over the world.

Operation Warp Speed has assessed three major vaccine platforms: protein vaccines, viral vector vaccines, and RNA and DNA technology. All the platforms make antibodies that neutralize the coronavirus.

For most vaccines, researchers make the protein itself but the process can require more time. RNA technology puts in the gene strand that the cell reads to make the protein. The companies that make proteins, such as Sanofi or Novavax, also received the gene but these trials will not begin until late December or January 2021 because the manufacturing takes much longer.

Another way to make antibodies is to use viral vector vaccines. These platforms "shuttle" the gene into the cells of a person's body, said Dr. Corey.

NIH conducted harmonized, randomized, and controlled vaccine trials to generate essential efficacy and safety data for several trials in parallel. The approach accelerated the licensure and distribution of multiple vaccines. The CoVPN serves as the collaborating network. A Data Safety Monitoring Board provides oversight.

In late July, researchers began conducting sequential trials of the vaccines. Phase 3 trials began immediately after the monitoring board and the Food and Drug Administration (FDA) reviewed

Phase 1 and Phase 2 safety and immune response data. The trials were large and included communities of color, although some trials had small numbers of Tribal participants. Dr. Corey noted these communities were most affected by COVID-19 due to density – crowded settings, workplaces and homes. The vaccines needed to work in these environments.

The FDA and Ethics Committees also approved the vaccine trial protocols, and the process included community consultations. Operation Warp Speed compressed administrative time frames down from months into days. The main goal: evaluate each candidate vaccine with high veracity for safety and potential efficacy.

Researchers reached the goal of these trials within about four months. The Moderna and Pfizer vaccines, which are essentially identical, are about 95 percent effective in preventing severe COVID symptoms and hospitalizations. Both require two doses. The side effects are similar to the reactions most adults experience after a vaccine: sore arm, headache, malaise or low-grade fever.

Dr. Corey expects vaccine scarcity during the next few months. Other vaccine trials will continue to help get the U.S. population back to work and school. States will develop plans for vaccine distribution.

Councilman Kutz asked about the speed of vaccines for children. Noting a concerted effort to get children back in school by the fall, Dr. Corey expects the pharmaceutical companies to conduct bridging immunogenicity and safety trials. The trials also must use dose de-escalating to identify the immune response in children, who typically experience milder disease. Researchers must identify a safe dose for youth as well as the dose that provides an adult level of antibody. Pfizer vaccine trial participants were age 14 and older. Moderna's youngest trial participants were 18.

Alaska Area Delegate Denise Dillard, Ph.D., noted the small number of Native participants in the vaccine trials. These communities might need a reassuring message to encourage vaccine use. Dr. Corey said populations with health disparities participated in the trials. Further, the vaccine's efficacy offers a higher benefit than risk. In response to a question from Nashville Area Delegate Beverly Cook, Dr. Corey said the viral vector type of coronavirus vaccine is similar to the Ebola vaccine currently used by millions of people. He added that no one can get coronavirus from the vaccine. The CoVPN team will work with Dr. Wilson to assist in message development for Tribal communities.

Ms. Sundberg asked about "round two" or better versions of the vaccine. Dr. Corey said researchers are unlikely to get better than 95 percent efficacy, and the first vaccines are all

designed for disease protection. Future studies will determine if the vaccines prevent coronavirus transmission because those who have COVID-19 can unknowingly infect others. Monoclonal antibodies can assist during vaccine scarcity in high-density areas or during an outbreak, said Dr. Corey. The antibodies, which come from people who have recovered from coronavirus, can serve as a treatment and possibly prevent infection. In a household or nursing home outbreak, an infected person and all the household contacts could receive the antibody for immediate protection. The household could then receive vaccinations a month or two later. Antibody therapy is a scarce, expensive treatment, and patients must receive it quickly.

Bringing the TAC's first meeting session to a close, Ms. Sundberg asked for vaccine information that clinics can share with Tribal communities. Dr. Wilson said THRO staff will share materials and information for TAC review.

TAC Virtual Meeting -- Day 2

How Can TAC and THRO Collaborate Effectively During This Unprecedented Time?
Juliana Blome, Ph.D.
THRO Deputy Director

Bobby Saunkeah
Oklahoma Area Delegate and TAC Co-Chairperson

The second day of the TAC virtual meeting began at 1:06 p.m. with an opening blessing from Chairwoman Lee-Gatewood. Dr. Blome led a discussion on TAC and THRO focus areas for the next year. Although the coronavirus will remain a top priority until at least fall 2021, THRO staff sought to identify additional priorities for next year. TAC members highlighted these work-group areas:

Consultation Policy: National At-Large Delegate Lynn Malerba, D.N.P., recommended a two-stage process for seeking comments from Tribal leaders. THRO can schedule online consultations on the policy, then host in-person listening sessions to identify problems or tweaks. The process might also include some form of periodic assessment. Mr. LaPlaunt noted that federal funding went through the CDC during the pandemic without any Tribal consultation. A consultation policy and emergency protocols can keep those problems from reoccurring.

All of Us Research Program: *All of Us* program staff provided a recent update. THRO staff seek TAC input on the program's next steps. Chairwoman Lee-Gatewood said the *All of Us* data updates should continue. Chief Malerba requested details on Research Access Board members and the number of agreements between Tribes and the *All of Us* Research Program. TAC

members also seek the status of the recommendations from the *All of Us* Tribal Collaboration Working Group.

Data Management and Sharing Policy: The Office of Science Policy has released a draft policy. THRO will develop guidance for researchers who want to collaborate with Tribes. TAC members can use the current work group or form a new group to give suggestions to THRO staff. TAC members agreed to discuss the issue in Tribal caucus.

A shared drive can help TAC members review all TAC documents, said Tucson Area Technical Advisor Teshia G. Arambula Solomon, Ph.D.

TAC members also were pleased that NARCH has used the Critical Considerations for Reviewing AI/AN Research document. Dr. Blome noted that reviewers appreciated the information. THRO will work with CSR on additional ways to disseminate the document to NIH researchers.

Discussion with NIH Leadership
Lawrence A. Tabak, D.D.S, Ph.D.
Principal Deputy Director, NIH

TAC members discussed access to traditional foods and medicines and asset-based approaches/resiliency with Lawrence A. Tabak, D.D.S., Ph.D., Principal Deputy Director of NIH. Native leaders remain concerned about the commercialization of indigenous products, and Tribes do not want to mention specific foods and medicines due to fears of further loss of access.

NIH will collaborate with the National Science Foundation and the U.S. Department of Agriculture to work with Tribal colleges and universities on building infrastructure and capacity. Ms. Sundberg noted that Tribes want to administer indigenous medicines in Native health care facilities. This effort will require additional research. To protect access, Tribal leaders want to replicate indigenous environments and grow these medicines, added Ms. Sundberg. TAC members also recommended collaboration with the Environmental Protection Agency on land restoration.

Chief Malerba highlighted the importance of resilience in creating healthy Tribal communities. Cultural practices play a role in medicine and food sovereignty. TAC and THRO should work together to encourage holistic approaches to health that include all these components.

Tribal leaders also want to include asset-based research, said National-at-Large member Donna Galbreath, M.D. Although research often highlights stigmatizing disparities and negative outcomes, Native communities seek a greater focus on resilience and cultural strength.

THRO continues to work on resilience, traditional medicine and other issues with the National Center for Complementary and Integrative Health. THRO also has begun to work with the Native American Research Centers for Health at the National Institute of General Medical Sciences. Through these activities, Native researchers can present data from a position of strength and positivity rather than pointing out deficiencies.

As part of a new focus on racism as a health crisis, Tribal leaders seek research that will bring this concern to light, said Ms. Sundberg. Asset-based research and positive approaches also can address the impact of poverty on health care. Infrastructure, policies and Tribal sovereignty can reduce health disparities and ensure that Native people are no longer wards of the government, said Ms. Sundberg. THRO and NIH also must ensure that Native people conduct such research in Tribal communities.

Traditional evidence-based methodologies, however, do not recognize resilient, indigenous ways of addressing behavioral health or substance abuse, said Councilman Kutz. Northwest Tribes, for example, cannot access research dollars to show the benefits of canoe journeys. As a result, Tribes cannot come together to participate in activities that build resilience. COVID has further impacted these gatherings, said Councilman Kutz. THRO and NIH can help Tribes conduct research and acknowledge the foods, languages or cultural activities that work for Native communities. All the NIH Institutes, Centers and study sections should look for ways to support resiliency and asset-based approaches, added Dr. Dillard.

NIH partnerships with local Tribal colleges could initiate some of this research with the next generation, said Dr. Tabak. Dr. Solomon also called for research that looks at systemic issues within social and health care institutions that create inequities.

In addition, COVID has created a lack of providers and resources for mental health and revealed the need for health care infrastructure. Entire families face illness and death due to the inability to quarantine in the midst of poverty, crowded housing and bad roads. And how can states deliver vaccines to communities under these conditions? COVID has forced society to address how leaders, governments and institutions enable systematic health inequities, said Dr. Solomon.

NIH continues to seek TAC assistance in identifying culturally competent application reviewers. TAC can hold NIH accountable for inviting these reviewers to study sections, said Dr. Tabak. Dr. Henderson said strengthor asset-based proposals look completely different than the typical disparate-focused applications that tend to pass NIH review. This fundamental problem cuts across cultures and deserves thorough, pointed examination at NIH, said Dr. Henderson. The Institutes and Centers have launched a trans-NIH group to look at these issues, said Dr. Tabak.

THRO can connect this effort with a TAC work group as agency leaders examine why NIH does not fund more research in health disparities and inequity. Another thorny issue: How does NIH include urban AI/AN populations in clinical research without disrespecting Tribal sovereignty or breaking Tribal laws?

Following the presentation with Dr. Tabak, Tribal leaders noted that the TAC has raised these concerns repeatedly. During the past few years, TAC members have requested review teams that understand traditional and ecological knowledge. Dr. Wilson noted that THRO has existed since 2017 and continues to grow. Further, the CSR and other leaders were not open to these discussions previously. This year, for example, THRO had its first opportunity to train reviewers. The field also still needs more AI/AN reviewers and young researchers. TAC members proposed revisiting a previous list of priorities to gauge progress and ongoing issues.

The COVID-19 Pandemic and Mental Health - with Some Practical Tips
Dawn Morales, Ph.D.
Program Chief, American Indians and Alaska Natives Mental Health
National Institute of Mental Health (NIMH)

Tribal communities continue to feel the social, behavioral and economic impacts of the pandemic, said Dr. Morales. Mass traumas and disasters have factors in common with the current pandemic: Many people simultaneously experience the event, families experience bereavement and profound loss, and communities face ongoing disruption and hardship. Some level of mental health impairment is common after a disaster. Although many people show impressive resilience, some can demonstrate clinically significant levels of impairment.

Dr. Morales noted that meeting immediate needs for food, housing and safety can improve long-term effects. Choosing healthy coping strategies and avoiding substance abuse and other unhelpful activities also can promote recovery.

Unfortunately, research shows disparities in treatment after trauma exist. Social inequality and health disparities both predict and exacerbate vulnerability in marginalized populations. Increased access to effective treatment can reduce the burden of illness.

NIH has taken quick action to address these issues through the RADx-UP initiative. The program received $300 million in funding during Phase 1, September to November 2020. This funding supported supplemental awards for several research programs in Native communities. Another $200 million will be available for Phase 2 in 2021. Dr. Wilson will work with Dr. Morales to get updates on how these projects mitigate mental health issues in Tribal communities.

Jessica Rudolfo, technical advisor for the Phoenix Area, said mental health support seems nonexistent. Many services are tied to reimbursements or service providers. Ms. Rudolfo also noted extensive rules for in-patient assistance and intake. Conversations with mental health experts who understand behavioral health would make a positive impact, said Ms. Rudolfo. Chief Malerba asked about studies that research how to mitigate the effects of the pandemic on health care providers. Dr. Henderson noted that COVID-19 has impacted the way families grieve. Native cultures have a history of large gatherings for important life events. Social distancing has interrupted that fundamental aspect of the grieving process and created a concern worthy of research, said Dr. Henderson. Such information could prepare underserved communities for future pandemics.

Tribes have found ways to respond to all types of trauma, including genocidal colonization and U.S. policies toward cultural and religious practices, said Mr. LaPlaunt. Some Native communities have restored those practices only within the past 40 years. The pandemic has resurfaced traumatic memories for some communities, added Mr. LaPlaunt. Dr. Wilson recommended a TAC call with Alec Thundercloud, M.D., from the Substance Abuse and Mental Health Services Administration. Tribal leaders can share concerns about trauma and get information on behavioral health funding. Kitty Marx from the Centers for Medicare and Medicaid Services also can join the call.

Chief Cook said knowledge and awareness should turn into training for mental health practitioners. With training and a flexible attitude, providers can learn to conduct a sweat lodge or create a ceremonial atmosphere on a virtual platform. Practitioners can use this idea after the pandemic. Mental health professionals also must develop a willingness to leave the office and go to someone's house or conduct a telephone check-in rather than waiting for a person to make an appointment, said Chief Cook.

Tucson Area Delegate Herminia Frias noted that the Tribal workforce will likely experience trauma and delayed grief upon coming back to work and discovering that some fellow colleagues have died during the pandemic. Tribal employees are still members of the community. These employees may have to delay grief to serve the Tribe, said Councilwoman Frias. Other longtime Tribal employees may have experienced loss due to layoffs, said Ms. Danforth.

These are opportunities for research as well as intervention. NIMH remains gravely concerned about the impact of COVID on care providers, said Dr. Morales. Dr. Wilson said NIMH should consider these points when developing future funding announcements. Dr. Wilson also wants to work with Dr. Morales to create monthly behavioral health updates for the TAC.

Dr. Galbreath encouraged more collaboration to help those Tribal employees and caregivers who cannot wait for research. Dr. Morales said the body of work on disasters and mass trauma can inform current efforts.

Next Steps

Dr. Blome wrapped up the day with information on vaccine resources for Tribal communities. Later in December, THRO will share updates with the TAC on work with NIH partners as well other agencies and organizations. A progress report on these communication activities will be available in February. In the meantime, TAC members will receive an e-mail of available resources from CEAL and CoVPN. The CoVPN site, for examples, includes FAQs and helpful videos on the vaccine trial process. TAC members will send back any questions or feedback on Tribal messaging.

Mr. Saunkeah reminded Dr. Wilson about the need to revive or reorganize the working groups. TAC members also should e-mail any additional questions for Dr. Tabak to Ms. Sundberg or Mr. Saunkeah. Ms. Sundberg also asked for a review of a previous TAC priority list.

Following closing prayer by Ms. Sundberg, the TAC adjourned at 4:35 p.m.

Action Items:

1. Check listserv for Steve Kutz and Patty EagleBull's email. (Completed)
2. Provide vaccine graphics from Dave's presentation that can be shared by the TAC. Also, maybe share during a virtual meeting so TAC can take notes and have more background information. (Completed)
3. Collect presentations, send to TAC. (Completed)
4. Dave to email Gwendena Lee-Gatewood regarding Saturday show and she will provide login information. (Completed)
5. Dr. Anderson will get with communications team about how to share information. Bonnie will be drafting information and sharing with TAC next week for review and feedback. (Completed)
6. Create time on the next virtual meeting agenda for a technical advisor breakout session. THRO will keep that in mind for the May 2021 Virtual TAC meeting. (Informational)
7. TAC priority list from early on should be sent back out and reviewed on the next meeting to see progress that has been made. (Completed)
8. Keep the funding for strength-based approaches on the radar and utilize Dr. Henderson's offer to share feedback received from his grants. (Informational)
9. Invite Alec Thundercloud, SAMHSA, and Kitty Marx, CMS, to join a future meeting to discuss behavioral/mental health issues including for providers. Invited Dr. Thundercloud to the January 2021 TAC Meeting. (Completed)
10. Juliana will share communication materials that have been developed. (Completed)

11. Look into creating a shared space for working documents that the TAC can access. SharePoint requires NIH credentials to interface with. Options; DropBox can be used for similar purposes but may not be secured. Box.com is another option but requires a monthly fee. MEES can develop a SharePoint for the TAC. (Completed)
12. Bring back the TAC work groups. Added to the January 2021 TAC agenda. (Completed)
13. Continue to get information from *All of Us* including data updates, the studies that are being approved, membership and process of research access boards, and what recommendations have been implemented. (Informational)