



**August 31, 2020**

Dear Tribal and Urban Indian Organization Leaders:

This week, we are providing a special update on vaccines. In May, the President [announced Operation Warp Speed](#) (OWS), which aims to have substantial quantities of a safe and effective vaccine available. [Operation Warp Speed](#) aims to deliver 300 million doses of a safe, effective vaccine for COVID-19 by January 2021, as part of a broader strategy to accelerate the development, manufacturing, and distribution of COVID-19 vaccines, therapeutics, and diagnostics. Last week, Dr. Moncef Slaoui and Dr. Matthew Hepburn published an article in The New England Journal of Medicine on [Developing Safe and Effective COVID-19 Vaccines](#). The article serves as a great overview of the work of OWS to advance development, manufacturing, and distribution of vaccines, therapeutics, and diagnostics to combat the COVID-19 pandemic. Specifically, its role is to enable, accelerate, harmonize, and advise the companies developing the selected vaccines. The companies will execute the clinical or process development and manufacturing plans, while OWS leverages the full capacity of the U.S. government to ensure that no technical, logistic, or financial hurdles hinder vaccine development or deployment.

Last week, the Food and Drug Administration issued an [emergency use authorization for investigational convalescent plasma for the treatment of COVID-19](#) in hospitalized patients as part of the agency's ongoing efforts to fight COVID-19. Based on scientific evidence available, the FDA concluded, as outlined in its [decision memorandum](#), this product may be effective in treating COVID-19 and that the known and potential benefits of the product outweigh the known and potential risks of the product. The action follows the FDA's extensive review of the science and data generated over the past several months stemming from efforts to facilitate emergency access to convalescent plasma for patients as clinical trials to definitively demonstrate safety and efficacy remain ongoing. President Trump, HHS Secretary Azar, and FDA Commissioner Hahn [delivered remarks on this EUA in a press briefing](#)

Our colleagues at the National Institutes of Health are accelerating research efforts with OWS in therapeutics and vaccine development. On August 11, Dr. Anthony Fauci, Director of [National Institute for Allergy and Infectious Disease](#), signed a [Dear Tribal Leader Letter](#) that not only

introduced efforts at the NIH but also stated the importance of Tribal participation in clinical trials. To date, tribes in the Great Plains Area, the Navajo Nation, tribes in the Pacific Northwest and Southern Arizona have all reached out to NIH to partner in this endeavor, but more are needed. [Resources and tools](#) are available to assist your community in understanding vaccines in development as well as the importance of participating in clinical trials. If you would like to volunteer to participate in a clinical trial, please visit [coronaviruspreventionnetwork.org](https://coronaviruspreventionnetwork.org). It is extremely important that our communities are included in these studies to not only ensure the safety, but also the efficacy of these treatments for American Indians and Alaska Natives. As such, we are encouraging Tribal Institutional Review Boards to seriously consider convening outside of their normal schedule in order to review and make critical decisions on your communities' participation. If you are interested in joining other nations in the potential participation please or would like to learn more, please contact: Dr. Dave Wilson, [dave.wilson2@nih.gov](mailto:dave.wilson2@nih.gov) or Dr. Michele Andrasik, [mandrasik@fredhutch.org](mailto:mandrasik@fredhutch.org).

In addition, from September 1 - 4, the [National Academies](#) will invite public comments on a **Discussion Draft of the Preliminary Framework for Equitable Allocation of COVID-19 Vaccine**, part of a [study](#) commissioned by NIH and CDC. The study will recommend priorities to inform allocation of a limited initial supply of COVID-19 vaccine, taking into account factors such as racial/ethnic inequities and groups at higher risk due to health status, occupation, or living conditions. Input from the public, especially communities highly impacted by COVID-19, is essential to produce a final report that is objective, balanced, and inclusive. There will be a [public listening session](#) on Wednesday, September 2.

Here at IHS, we have been doing a lot of preparation and planning for the potential role IHS might play in COVID vaccine allocation and distribution. As we continue to participate in Operation Warp Speed, IHS will remain a consistent voice and advocate for equitable vaccine allocation within the Indian health system and within tribal communities. Our [National Supply Service Center](#) has a long and successful history of coordinating and managing the distribution of pharmaceuticals, medical, and other health care related supply items to IHS, tribal, and urban Indian health care facilities and programs nationwide.

Last week, Administration for Native Americans, Commissioner Jeannie Hovland and tribal leaders across Indian Country recorded a [COVID-19 Public Service Announcement](#) encouraging everyone to continue practicing safety precautions and remember the strength that is embedded within our Native cultures. "We are a resilient people, we are warriors, and our ancestors have taught us how to survive!"

And finally, we are urging healthcare providers and parents to “[catch-up to get ahead](#)” on childhood immunizations. Vaccines are the best way to protect children from serious diseases like flu, measles, and meningitis. For children who have missed a vaccine appointment, now is the time to catch-up by making sure that children visit their doctor for well-child visits and vaccines. It is one of the best things we can do to protect children and the community. We cannot let down our guard against preventable childhood diseases. Let’s get every child back on track with [recommended vaccines](#).

Respectfully,

Michael

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Director, Indian Health Service

Below is general information on various topics that could be of interest to you and your community. Web links are included where you can find more information on each topic.

**Testing/Supplies/Contact Tracing Resources:**

- [CDC Updated recommendations regarding SARS-CoV-2 testing](#)
- [CDC Step-by-step guide for conducting a COVID-19 case investigation](#)
- [CDC Protocol for the tracing of close contacts](#)
- [CDC Guidance for wearing and selecting masks](#)
- [CDC Updated Guidance on returning to work](#)
- [CDC Updated Information on worker safety and support](#)
- [CDC Updated Frequently asked questions](#)
- [CMS Guidance for nursing homes and clinical laboratories](#)
- [CDC Toolkit for youth and young adults](#)
- [CDC Updated Operation considerations for schools](#)
- [CDC Updated Guidelines, tools, and resources for health departments](#)
- [ASPR COVID-19 Lessons Learned](#)