

Additional Questions Answered from
***“DoD Contributions to Rapid Vaccine and Therapeutics Development
for COVID and Biological Threats”***

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(as of 8 December 2020)

Q: Full immunity takes 2 shots, but do you have at least some immunity after the first shot?

A: Different vaccines work through different mechanisms. The Pfizer and Moderna vaccines both require two doses to confer the protection which the FDA is considering for emergency use. Now, four other companies are working on their own vaccines, and some of them may only require one injection. However, until we see the results of those clinical trials, we can't make any assessments of their effectiveness.

Q: Are there any concerning side effects that are also common among the different vaccines?

A: To date, no concerning side effects have been revealed among the different OWS vaccine candidates.

Q: mRNA vaccines are known to elicit short term immune response. Were the volunteers in phase I and phase II selected based on strict inclusion/exclusion criteria or at random? Are these data made publicly available for everyone to assess? Considering the vaccine will be provided to everyone, there would be dose-response fluctuations in how each one responds. How will the follow-up be done to evaluate mass efficacy?

A: Companies will share clinical trial data as they feel appropriate. As the trials continue, we will learn more about mass efficacy and that data will be shared through standard processes.

Q: Are you worried about the logistics of the Pfizer vaccine and maintaining the temperature at -90 during the distribution process? How long do providers have after the vaccine is thawed to deliver the vaccine?

A: We will utilize GPS-enabled thermal sensors with a control tower that will track the location and temperature of each vaccine shipment across their pre-set routes, 24 hours a day, seven days a week. These GPS-enabled devices will allow Pfizer to proactively prevent unwanted deviations and act before they happen.

Once a POU receives a thermal shipper with our vaccine, they have three options for storage:

- **Ultra-low-temperature freezers, which are commercially available and can extend shelf life for up to six months**
- **The Pfizer thermal shippers, in which doses will arrive, that can be used as temporary storage units by refilling with dry ice every five days for up to 30 days of storage.**
- **Refrigeration units that are commonly available in hospitals. The vaccine can be stored for five days at refrigerated 2-8°C conditions.**

Q: The CDC has very specific data points which are required to be collected and reported to them in order for an entity to be allowed to distribute the vaccine. Why can't the CDC share this patient level data with it's federal partners, ie VHA so that we can track accurately when our Veterans have been immunized in the community and allow us to target immunization efforts to the unimmunized veterans?

A: OWS defers to the CDC on answering this question.

Q: Can you elaborate on the strengths/benefits brought to OWS by having a Line 4-star as the Senior Leader.

A: Having a 4-star leader of OWS, specifically GEN Gus Perna, has proven extremely beneficial and a key factor in our success. GEN Perna is the senior uniformed military logistician and brings 37 years of leadership experience, including most recently as the Commander of Army Material Command, the largest logistics agency in the world with 129,000 employees around the globe and incredible capability. He has also deployed three times to Iraq and was the lead General for the immense Iraq drawdown effort. Simply put he has been through the fog of war and possesses unmatched leadership ability through his experiences. His humility, instincts, decisiveness and clear communications' have been the foundation of OWS success.

Q: How will someone document they have been immunized? i.e. when traveling overseas?

A: Currently there are no plans to document individuals who have been immunized for travel purposes. This is a policy matter that will be determined outside of OWS' purview.

Q: In watching the BBC today, the first vaccine by Pfizer/BioNTech was given to a (almost) 91 year old in the UK. Which company will most likely be distributed to DoD overseas? Will we receive the vaccine from the US or from Europe given the cold chain storage?

A: Both the Pfizer and Moderna vaccines will be distributed to DoD personnel overseas. At this time all vaccines for American citizens, both at home and abroad, will originate from within the continental United States. Our 3rd party logistics providers, McKesson, UPS and FedEx all have significant worldwide distribution capability and are poised to support overseas shipments. For DoD personnel, the Defense Logistics Agency will coordinate transportation and distribution overseas.

Q: Do you have information about including immunocompromised people as part of trials?

A: Vaccines go through clinical trials before they can be approved by the FDA. The initial coronavirus vaccine trials include healthy, younger adults, as well as older adults and some people with well-controlled health conditions such as diabetes or heart disease, however these initial trials excluded potentially vulnerable populations such as children, pregnant women, and the immunocompromised.

Q: Dr. Hepburn, I realize this is a massive task, and thank you so much for presenting this topic in detail. Since the pandemic has shut down and having lost so many citizens, how would you demystify the dogma of vaccination? Especially, with the underlying competitions between pharma companies to provide the vaccine and the monetary incentives at this time of crisis?

A: Great question. As I indicated a number of times in my remarks, the key to this is full transparency and emphasizing over and over again that we will let science, data and regulatory process dictate which vaccines are authorized for use. Since inception, OWS has been committed to these tenets and been incredibly active in the media and in engaging the scientific community as well as national and local community leaders to spread the message that these vaccines are safe and necessary to stem the tide of this pandemic. We cannot do this alone, however,

and as I said in my remarks I implore you and other public health practitioners to do the same in your communities and with your patience. Studies have proven that people are most likely to trust vaccines when recommended by their own Doctor.

Q: I would dispute that ANY efficacy is a good thing in a vaccine. With the distrust in vaccines and people getting tired of the protection measurements, they will likely stop using those as soon as they are vaccinated and thus, if the vaccine doesn't work, the scenario is not pretty.

A: I couldn't agree more. With two of the vaccines in our portfolio demonstrating nearly 95% efficacy, we at OWS are insisting that our other candidates achieve similarly high efficacy. Clearly, Americans will not take a vaccine that has, for example, 60% efficacy when there are others available that are 95% effective and thus would not be worth the investment. Reinforced by this standard, another benefit to achieving such high efficacy rates among some candidates is that it should compel the other companies to strive for very high quality, safety and effectiveness themselves and thus broaden the portfolio of available vaccines.

Q: Since there is an investment into various science and technology by Public sector, what are the 'patent,' and financial benefit implication to tax payers and private industry?

A: Operation Warp Speed's mission is to introduce safe, effective vaccines for the entire American population. While there are clear economic benefits to ending the pandemic as well as investing in US vaccine development infrastructure, quantifying those benefits is not an OWS core competency.