From: Schwartz, David

Subject: SARS-CoV-2 Vaccine Update

Date: Thursday, December 3, 2020 6:45:55 PM **Attachments:** Tiered allocation for Colorado.png

Dear Friends and Colleagues.

As we enter into December and plan for the stresses that the COVID-19 winter surge will bring, we are fortunate that November also brought good reasons for celebration. Among the welcome tidings were reports that two mRNA-based vaccines directed at the SARS-CoV-2 spike protein have reported clinical trial efficacies in the 95% range, including in the elderly and other higher risk populations (Pfizer-BioNTech and Moderna). It is these two vaccines that will be distributed first.

The attached file shows the overall priorities for administration in Colorado. The exact vaccine rollout details are being worked out by CDPHE and the Governor's office but Phase 1 will focus on the state's critical workforce including health care workers who see patients, and presumably also our research lab workers who do work with live SARS-CoV-2. The FDA meets on Dec. 10 for the Pfizer-BioNTech vaccine EUA review and on Dec. 17 for the Moderna one. There will also be a review by the CDC's Advisory Committee on Immunization Practices (ACIP).

The state of Colorado and CDPHE have developed a COVID-19 vaccine distribution plan, and UCHealth will follow its gudielines. As reviewed by Tom Gronow at last night's town hall (https://youtu.be/kByneYiedck), UCHealth is working on the mRNA vaccine distribution plan in coordination with the state agencies and committees. Initial supplies of COVID-19 could arrive at several UCHealth locations in late December or early January. More information will be provided at a special DOM town hall on vaccine distribution plans next Thursday, December 10, 7-8 PM.

Much about the two mRNA vaccines is fascinating and exciting, including their being the first mRNA vaccines for widescale human use, their remarkable efficacies in the trial setting, the way the designs carefully encompassed and showed efficacy in important subgroups like the elderly and people of color, the lack of significant toxicities or major adverse events so far, and the occurrence of COVID-19 disease manifestations almost solely in the placebo groups. The trials were reassuringly large and multi-center, with over 30,000 patients in the Moderna trial (in which our campus participated under the direction of Tom Campbell), and over 40,000 in the Pfizer-BNT trial. It is also heartening to consider how they were developed so quickly and tested this year but were nevertheless based on many years of incremental lab, animal and clinical research on mRNA therapeutics. This is truly a triumph of biomedical research. The vaccines differ in some ways, such as different cold chain needs. But both vaccines express a full-length SARS-CoV-2 Spike protein and both appear to be efficacious to a similar degree at this point. Pandemic effectiveness will of course depend on a number of real world factors

including, most importantly, uptake.

The results reported (by press release so far) with the Astrazeneca vaccine (based on a replication-defective chimpanzee adenoviral vector) are more problematic at this point, and this vaccine may require further study in an additional trial. Additional vaccines using different technology platforms are likely to come fairly soon.

Some recent vaccine-relevant presentations can be found here:

- Oct 28, 2020: <u>The Neutralizing Antibody Response to SARS-CoV-2</u>
 Infection (https://www.youtube.com/watch?v=5XVf3myts0k&feature=youtu.be&t=2)
- Oct 28, 2020: <u>COVID-19: What's Next?</u>
- Nov 12, 2020: Treatment: what's known and what's in the pipeline (https://youtu.be/lywhVB3U5BY?t=1)
- Nov 19, 2020: Vaccine Development, Trials, and Distribution (https://youtu.be/GsL-str-onk)

Let us know if you have any questions. Best regards,

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