Idaho Hospital Association

COVID-19 Report to Members ~ November 23, 2020

Reports are sent on Mondays and Thursdays, unless there's breaking news.

Editor's note ~ Unless there is breaking news, we will not send out a second Update this week. Our wish for this holiday is that you each know how thankful we are for your continued strength and commitment.

Reimbursement & Policy

Preparing for what's ahead

As preparations continue for the much-anticipated distribution of a vaccine or vaccines in the coming weeks, hospitals have received two critical and time-sensitive emails from IHA over the last few days to lay the groundwork for distribution. These two steps will be critical to making sure hospitals receive the right vaccines in the right quantities for employees and others.

Hospital administrators were sent a unique link to a provider enrollment agreement to allow them to receive and administer COVID-19 vaccines. This agreement will allow the hospital to administer any of the vaccines that become available to employees, providers, contractors and, eventually, the community. This document must be submitted to the Department of Health and Welfare (DHW) in order to receive the vaccines. If you need the link resent or are having issues with your submission, contact: **IDCOVID19Vaccinators@dhw.idaho.gov**.

The second email was a request by DHW that hospitals survey their employees, providers and contractors to know how many at each hospital are likely to accept a vaccine. Because supplies are very limited and due to the special storage needs, DHW wants to make sure to send what's needed to each site to avoid any waste. Frontline healthcare workers are anticipated to be among the first to receive the vaccine.

Idaho's first vaccine allocation

The Governor's Vaccine Advisory Committee learned on Friday that the number of vaccines in Idaho's first allocation could be anywhere between 31,000 and 52,000 doses. Based on the assumption that a vaccine could arrive in Idaho sometime between mid-December and early January, the Committee considered the following distribution formula – provided healthcare worker uptake confirms the needs in each region of the state for this initial allocation:

Regional Distribution	Inpatient HCWs & LTCFs	Number of Doses for Scenario 1*
PHD 1	14.69%	7,590
PHD 2	7.36%	3,803
PHD 3	14.66%	7,578
PHD 4	33.53%	17,327
PHD 5	10.44%	5,392
PHD 6	9.56%	4,940
PHD 7	9.76%	5,046
State Totals	**100%**	**51,675**

**rounded due to minimum shipment of 975 doses*

Vaccine update

As of today, Pfizer and BioNTech, Moderna, and AstraZeneca/University of Oxford have published press releases describing promising efficacy results of Phase III clinical trial results for three SARS-CoV-2 vaccines. Moderna and Pfizer vaccine candidates use mRNA technology, have similar effectiveness according to data release thus far, and have similar side effect profiles.

On November 20, Pfizer and BioNTech submitted a request to the FDA for an Emergency Use Authorization (EUA) of their mRNA SARS-CoV-2 vaccine candidate, BNT162b2. This could enable use of the vaccine in high-risk populations by December 2020. BNT162b2 Phase III clinical trial results showed efficacy of 95% with median of two months follow-up following the second dose. Although follow-up is not complete, no serious safety concerns related to the vaccine were reported by the study's Data Monitoring Committee. This vaccine candidate requires ultra-cold cold storage, for which Pfizer has developed containers to maintain storage conditions (-70°C ±10°C) up to 15 days. Once thawed, vaccine vials can be stored for up to five days at refrigerated (2 - 8°C) conditions. The FDA has scheduled a meeting of its Vaccines and Related Biological Products Advisory Committee (VRBPAC) on December 10 to discuss the BNT162b2 EUA request.

On November 16, Moderna reported vaccine efficacy of 94.5% in the first interim analysis of the Phase III clinical trial of mRNA-1273. The Moderna candidate can be stored in a standard refrigerator (2-8°C) to preserve it for up to 30 days, and a standard freezer (-20°C) for longer storage up to six months.

Both BNT162b2 and mRNA-1273 are mRNA vaccines. The University of Cambridge PHG Foundation describes mRNA as follows: "Conventional vaccines usually contain inactivated disease-causing organisms or proteins made by the pathogen (antigens), which work by mimicking the infectious agent. They stimulate the body's immune response, so it is primed to respond more rapidly and effectively if exposed to the infectious agent in the future. RNA vaccines use a different approach that takes advantage of the process that cells use to make proteins: cells use DNA as the template to make messenger RNA (mRNA) molecules, which are then translated to build proteins. An RNA vaccine consists of an mRNA strand that codes for a disease-specific antigen. Once the mRNA strand in the vaccine is inside the body's cells, the cells use the genetic information to produce the antigen. This antigen is then displayed on the cell surface, where it is recognized by the immune system." Through this approach, the immune system is trained to recognize SARS-CoV-2 as an invader.

Today, a news release for the AstraZeneca/University of Oxford viral vector vaccine candidate, AZD1222, also showed promising initial results in a Phase III clinical trial. Using two full doses administered at least a month apart, the vaccine was 62% effective. But using a half-dose first, followed by a full dose at least a month later, resulted in 90% efficacy. While the initial efficacy data are lower than the Moderna and Pfizer mRNA vaccines, the Oxford candidate may have some advantages, including potentially lower cost and only standard refrigeration for storage.

To date, no mRNA vaccine has been approved by FDA, and there is only one approved viral-vector vaccine (for Ebola). Information on the efficacy and safety of these vaccine candidates has been disclosed via company news releases. We look forward to learning more about safety and efficacy of these vaccine candidates when data are published in peer-reviewed journals.

In October, the FDA launched a new webpage to highlight **new vaccine information** as it becomes available, as well as an updated explanation of the **EUA process**.

Two new treatments receive EUAs

Olumiant (baricitinib), a treatment for those with rheumatoid arthritis, was **granted an EUA** last week to be used in combination with Veklury (remdesivir) to treat hospitalized COVID-19 patients. The treatment is designed for those patients needing supplemental oxygen, invasive mechanical ventilation, or ECMO (extracorporeal membrane oxygenation) and reduces patient recovery time.

On Saturday, **another EUA was granted** for the monoclonal antibodies casirivimab and imdevimab, an antibody cocktail by Regeneron Pharmaceuticals, for treatment in outpatient settings. This therapy is designed for those with mild to moderate COVID-19 but with high risk for progressing to severe illness. HHS will begin allocating the treatment to state health departments based on confirmed cases and data in HHS Protect.

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