

COVID-19 Report to Members - October 1, 2020

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

Idaho prepares for vaccine; remains in Stage 4

Governor Little announced he will be forming a new Idaho COVID-19 Vaccine Advisory Committee to advise him on the prioritizations of vaccines when in limited supply, on the implementation of the vaccination plan, and on communication and delivery of the vaccine. More information on the committee membership will be coming next week.

Idaho will submit its vaccination plan to the CDC on October 16th. As the initial supply of the vaccine is expected to be limited, the plan will identify priority populations for initial distribution. Governor Little emphasized the vital role of healthcare workers who will likely be the first to be offered a vaccine, although the final decision has not yet been made.

As reported in our Monday COVID Update, Idaho will receive more than a half million Abbott BinaxNOW rapid antigen tests, and the Governor announced the first 35,000 arrived this morning which will be distributed to the public health districts.

The Governor described the tests as a game changer for schools as they are simple to use, more than 95% accurate, and produce results within 15 minutes with a less invasive nasal swab and no machine.

Despite all the good news, COVID-19 is still making its mark in Idaho. Those who have been paying attention to rising COVID-19 cases around the state and a concerning number of hospital admissions in Southeast Idaho, were not surprised at the Governor's announcement that Idaho will remain in Stage 4 in the Idaho Rebounds plan for another two weeks. The Governor emphasized that under Stage 4 there are no statewide restrictions on businesses being open but there are important recommendations for businesses and residents to follow in order to limit spread of COVID-19.

Reimbursement & Policy

Additional relief funding and changes to DSH and MAAPP

Today, HHS **announced** that hospitals and other providers are able to apply for an additional \$20 billion in relief funds aimed at curbing the financial losses and changes in operating expenses caused by the pandemic as well as those who were previously ineligible for relief funds.

Those eligible for this distribution include:

- providers who previously received, rejected or accepted a General Distribution provider relief fund payment (including those who have already received payments of approximately 2% of annual patient care revenue);
- behavioral health providers, including those who previously received funding and new providers; and
- providers who began practicing between January 1 and March 31, 2020.

Applications will be accepted beginning October 5 through November 6. HHS is encouraging applicants to apply early to receive funds.

Once the applications have been received (at this time, Phase 3 Provider Relief Funding application details were not available on the **HHS website**, so please check back), HHS will review to first determine that qualified applicants have received payments equal to approximately 2% of patient care revenues from prior distributions and if not, to fund that. Any remaining balance will be used for an equitable add-on payment for the qualified applicants.

In other Washington, DC news, the President signed a continuing resolution just after 1am today to continue funding the federal government through December 11. In that resolution, Medicaid DSH cuts were delayed, a move that many are hoping to make permanent in future legislation. For providers who received relief funds via a Medicare advanced payment (MAAP – Medicare Accelerated & Advance Payment Programs), the resolution extended the time to repay, delayed recoupment and implemented a lower interest rate.

Resources & Equipment

SARS-CoV-2 vaccine update

While vaccines against SARS-CoV-2 will not be a free pass to returning to pre-pandemic life, rapid and widespread uptake when they are available will be a crucial tool in controlling transmission of the virus that causes COVID-19. There are **presently** seven vaccine studies with U.S. federal funding and 24 vaccine studies accruing patients in the U.S. Four vaccines are now included in Phase III studies in the U.S and additional vaccine candidates are in Phase I/II trials.

Candidate	Type	Manufacturer	Phase III Trial Participants	Effectiveness Goal
Ad26.COV2.S	Viral vector	Johnson & Johnson	60,000	60%
AZD1222	Viral vector	AstraZeneca	30,000	50%
BNT162b2	Messenger RNA	University of Oxford, BioNTech, and Pfizer	44,000	60%
mRNA-1273	Messenger RNA	Moderna	30,000	60%

The size and administration of these clinical trials are the same as development for any other vaccine. What is different for the SARS-CoV-2 vaccine is that phase I/II and III trials are being conducted concurrently, not sequentially, and manufacturing of vaccine is occurring at scale before licensure. As we reported in the July 29 IHA COVID Update, in Phase III trials, vaccine candidates are given to thousands of people and tested for efficacy and safety. Each of the Phase III trials listed above is an "event-driven trial." After a pre-determined number of COVID-19 cases are diagnosed among the participants in each trial, the number of cases in the drug and placebo arms of the trials will be counted. For a trial to be successful, the vaccine should result in at least a 50% reduction in the number of cases.

Multiple technologies are being employed for vaccine candidates, some never used before. For example, INOVIO Pharmaceuticals is developing a DNA vaccine candidate for COVID-19, which administers the vaccine directly into the skin using electrical pulses via a hand-held device. To date, no messenger RNA vaccine has been approved by FDA, and there is only one approved viral-vector vaccine (for Ebola). Traditionally, vaccines are made using a weakened or inactive virus.

Although efficacy is critical, it is not necessarily paramount; transport, storage and handling requirements of different vaccines are also important considerations when selecting vaccines for rapid and population-level vaccination campaigns, i.e. the most efficacious may not be the best candidate for particular public health or clinical application. In the case of messenger RNA vaccines, which require very cold storage, CDC has committed to provide storage freezers if necessary. The Johnson & Johnson vaccine candidate is the only single dose vaccine in Phase III trials.

An estimated one-third of Idaho adults are at risk of severe COVID-19 disease. While state officials are still preparing the vaccine distribution plan, we do know now that vaccines will be free and administration of vaccines by healthcare providers will be reimbursed by insurance. We also know that FDA and CDC will conduct long-term vaccine safety and efficacy monitoring. Regardless of which vaccine or vaccines are first available, limited doses will be available initially. Priority populations for the first phase of vaccination have not been confirmed, but are likely to include healthcare workers, other essential workers, and seniors. The initial vaccination of healthcare workers should lead to greater acceptance of the vaccine by the general public.

Remdesivir update

The drug formerly known as Remdesivir has had a name change. Beginning today, hospitals can purchase Veklury (Remdesivir) directly from the drug's distributor, AmersourceBergan. The antiviral drug was previously allocated by the federal and state governments to hospitals based on reported COVID cases and existing doses on hand. Gilead Sciences, which manufactures the drug, said it can now meet real-time demands in the US.

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