Idaho Hospital Association

COVID-19 Report to Members ~ March 1, 2021

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

Quality & Patient Safety

And now there are three

With the Janssen (Johnson & Johnson) vaccine **receiving emergency use authorization** on February 27, and doses being sent to states this week, three COVID-19 vaccine options will soon be available. The important milestone of a third effective vaccine has been somewhat overshadowed by comparisons in the media of the Janssen vaccine's 66.1% overall efficacy relative to the 95% and 94.1% efficacy of Pfizer and Moderna vaccines, respectively, with the potential implication that individuals should consider the Janssen vaccine to be a "Plan B" against COVID. There will, undoubtedly, be questions from patients and your communities as you continue the herculean efforts necessary to administer record numbers of vaccines.

At the current point in the COVID-19 pandemic, the best decision that we can make for our personal and collective health is to take the vaccine that is available when an individual is eligible to be vaccinated. As Dr. Fauci noted this weekend, "[a]ll three [vaccines] are really quite good, and people should take the one that's most available to them." Below, we describe some of the differences in the vaccines, and some reasons for differing efficacy results as an aid in helping clinical staff and the public navigate vaccine distribution.

The Janssen vaccine is a single-dose vaccine that uses a **recombinant, replication-incompetent human adenovirus vector to carry SARS-CoV-2 viral spike glycoprotein DNA into human cells**. Because DNA is more stable than the mRNA model used in other vaccines, the Janssen vaccine can be stored for up to three months at normal refrigeration temperatures of 2–8°C (36–46°F). The single-dose nature of the vaccine and its less intensive storage requirements are major advantages for administering the vaccine in a community setting.

As noted above, much direct comparison of the relative efficacy for these three vaccines has been made; given the available data, these comparisons are apples-to-oranges and could be misleading, as the clinical trials used to estimate efficacy figures evaluated different outcomes, and were conducted in different contexts.

The multi-country clinical trial evaluating the Janssen vaccine evaluated how well the vaccine protected against a primary outcome of moderate to severe COVID-19, defined as a combination of at least one COVID-19 symptom, e.g. loss of taste, plus a positive SARS-CoV-2 PCR test from 14 or 28 days after their initial (and only) vaccination. By contrast, the Pfizer and Moderna vaccines evaluated slightly different COVID-19 outcomes. The **Pfizer trial** evaluated "confirmed COVID-19", defined as at least one COVID-19 symptom plus a positive PCR test from a specimen collected during or within four days of the participant's symptomatic period starting from seven days after the second dose of the Pfizer vaccine, i.e. 28 days after their initial vaccine. The **Moderna trial** evaluated "symptomatic COVID-19", defined as as at least two of fever, chills, myalgia, headache, sore throat, or new olfactory or taste disorder, or one respiratory sign or symptom and at least one positive for SARS-CoV-2 PCR test. This outcome was evaluated 14 days from the second dose of the Moderna vaccine, or 42 days after a participant's initial dose.

That the Janssen vaccine was evaluated in South Africa and multiple South American countries also has implications for how well it prevented the primary outcome of moderate to severe COVID, effectively testing the Janssen vaccine against different strains of SARS-CoV-2 than those predominating during the Pfizer and Moderna trials. Indeed, U.S. efficacy rates for the Janssen vaccine were 72%, higher than for the overall trial.

All three vaccines provided excellent protection against COVID-19 related hospitalization and death. The Janssen vaccine conferred 85% efficacy against severe disease, with no hospitalizations or deaths reported in the vaccine part of the trial after the development of immunity (28 days post vaccine). The same results were noted in the Pfizer and Moderna trials, with zero deaths or hospitalizations reported in the vaccine phase.

Perception and potential bias when considering these vaccines is a hurdle that healthcare professionals will face as they engage with and educate the public. One thing is clear with all three vaccines, they protect your patients against death and severe disease.

Revised storage guidelines for Pfizer vaccine

The FDA **updated** the storage and transportation instructions for the Pfizer-BioNTech vaccine after a review of data submitted by Pfizer last week. The data shows that the undiluted vials remain stable for up to two weeks at standard freezer temperature. This change will allow for more flexibility when transporting and storing the vials for vaccination sites versus the preferred ultra-low temperatures of -80C to -60C (-112F to -76F).

This change in procedure is not applicable to thawed vials before dilution (which can be held in the refrigerator for up to 5 days) or to thawed vials after dilution (which can be held at refrigerator temperature or room temperature for use within 6 hours). For more information, please review the **Provider Fact Sheet**.

Reimbursement & Policy

State vaccine app launching this week

The Department of Health and Welfare is planning to launch a vaccine pre-registration tool on March 5. According to their announcement, the system will allow Idahoans to pre-register for a vaccine and be put on a wait list for vaccine providers, who will "reach out to eligible Idahoans who have pre-registered." We will share any additional information as it becomes available.

Proiders get back time lost to COVID to implement IPA

Governor Brad Little today signed House Bill 42 into law – giving hospitals and providers until July 1, 2021, if needed, to implement the Idaho Patient Act (IPA). During the 2020 Legislative Session, lawmakers approved the IPA which was designed to improve billing notification and transparency for the patient, while protecting them from excessive attorney's fees for medical debt collection.

Recognizing this might require significant changes to electronic health records and billing systems, the law wasn't scheduled to go into effect until January 1, 2021. However, many providers consumed with responding to COVID-19 were unable to make the necessary changes to comply with the January date. Working with the Idaho Medical Association and after months of negotiations with the sponsors of the IPA, Melaleuca, Inc., we were able to get an additional grace period for providers to implement the Act.

Those providers who **use the grace period** will have additional time to complete the requirements but will not be able to collect attorney's fees.

House sends $1.9 trillion relief package to Senate

On Saturday, the House approved a new $1.9 trillion relief package that is expected to be addressed and amended by the Senate, possibly this week. Congress has a goal of enacting additional relief legislation by mid-March.

The bill contains a number of provisions for hospitals, including $500 million through the Department of Agriculture to cover expenses and lost revenue attributable to the pandemic for which certain rural hospitals may qualify. A few of the other healthcare related provisions include:

- $70 billion for vaccine, testing and workforce efforts.
- $10 billion for medical supplies including PPE, drugs, medical devices and biological products.
- Correction of an unintended consequence of the increased FMAP. Under this bill, CMS will have to recalculate the annual DSH allotments for any year the increased FMAP applies. The goal is to ensure the total DSH payments a state would make (including federal and state shares) is equal to what they would have made in the absence of the temporary FMAP increase.

For more details on the relief bill, please see this **AHA summary**.

Clarification on coverage for testing

CMS issued new **guidance** to clarify that "private group health plans and issuers generally cannot use medical screening criteria to deny coverage for COVID-19 diagnostic tests for individuals with health coverage who are asymptomatic, and who have no known or suspected exposure to COVID-19." The guidance also includes information for providers on how to get reimbursed for diagnostic testing or for administering vaccines to those who are uninsured.

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