



Will we have to consider the low grade fever, chills, or other symptoms as potential symptoms of COVID. Currently, the employee with these symptoms has to be excluded from work until infection is ruled out. How can this potential issue be mitigated?

It is recommended to take into consideration if an individual recently received the vaccine as a cause for the symptoms.

Does this vaccine change our genes in any way?

The "m" in mRNA stands for messenger. The vaccine's messenger RNA instructs host cells to create the viral spike protein that our bodies recognize and target to produce an immune response and build antibodies. Once the spike protein has been made enzymes in the cell break down the mRNA strand. It is important to note that the mRNA strand never enters the cell's nucleus or affects genetic material.

What processes do you recommend for health care employers that have new hire staff who previously received one vaccination from a different provider, and staffing leaving employment after one vaccination? How do we verify what type of vaccination new hires have received, and how can we support exiting staff?

A vaccination pocket card is included as part of the vaccine administration kit. Everyone who receives a vaccine should retain a copy of this card to ensure they receive the appropriate second vaccine. Additionally, the type of vaccine will be uploaded into immunization registries that providers of the second dose may be able to access to verify if the individual doesn't have their pocket card.

Will the vaccine be harmful to those individuals that are positive for COVID, but are asymptomatic?

The general reason for not receiving a vaccine while actively sick is the immune system is already building a response to the current illness. There is no clear recommendation on asymptomatic positive individuals, but it is unlikely to cause harm. Additionally, in those cases where a person is already infected with COVID-19 when they get the vaccine but are asymptomatic or pre-symptomatic, if they later have symptoms of COVID-19 or test positive for it, it does not mean they got COVID-19 from the vaccine.

Some suggest that the vaccine can cause sterility in young women. Is this a side effect?

This is a myth that has been propagated on social media sites. There is no evidence of this as a side effect in any coronavirus vaccine candidate's safety information.

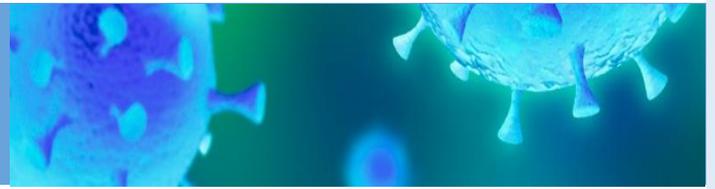
In the way the new vaccines were developed, do you anticipate that this will be the way that new vaccines will be developed in the future?

It is not outside the realm of possibility. Operation Warp Speed thrust mRNA vaccines into the spotlight as a viable way to rapidly scale vaccine development.

We contract to nursing home staff. Will our staff be able to get vaccines?

All nursing home staff are included in Phase 1. This includes all employees, both internal and external, whose occupational responsibilities bring them into LTCFs.





Did the 21 million HCP count include all of those WE might consider reporting need the vaccine, like the accordion player and the pharmacy driver?

The CDCs estimation included all individuals in a nursing home though sub-prioritization may need to occur based on vaccine supply.

Is the vaccine recommended for those who have previously tested positive for COVID-19?

To pull straight from the CDC: There is not enough information currently available to say if or for how long after infection someone is protected from getting COVID-19 again; this is called natural immunity. Early evidence suggests natural immunity from COVID-19 may not last very long, but more studies are needed to better understand this. Until we have a vaccine available and the Advisory Committee on Immunization Practices makes recommendations to CDC on how to best use COVID-19 vaccines, we cannot comment on whether people who had COVID-19 should get a COVID-19 vaccine.

Will Pharmerica have a resource website set up for communities with information on your next steps on the rollout process?

PharMerica maintains and ensures that up to date information and access to information is updated daily on the [PharMerica COVID 19 Webpage](#).

Have there been trials to see if people make the antibodies for this vaccine? How often do you have to get the vaccine is this a one-time (2-step) vaccine?

Phase 1/2 trials ensure initial efficacy of the vaccine to induce antibody production in humans. Studies are ongoing to determine how often these vaccines would need to be re-administered. It is currently unknown what antibody titer level threshold must be met to confer adequate “immunity” from any vaccine candidate. As more information around target titer levels is assessed, it is possible that these 2 shot series may be truncated to single dose vaccines. Alternatively, it is possible that over time, additional booster vaccine doses may be needed to provide continued protection.

Does the area of the country in which we reside affect when the vaccine will be available?

Location does not matter for availability, but may matter for allocated quantity as determined by the federal government.

Do skilled nursing facilities need to provide freezers to house the vaccine?

For the initial Phase 1 distribution facilities are not responsible for ultra-cold freezers if working through a pharmacy partner.

In the studies, are trial participants actually exposed to the virus to determine efficacy?

Vaccine trial challenges were not completed. Efficacy was determined by examining community acquired cases of COVID-19 in vaccinated vs. placebo trial participants.

What does EUA stand for?

Emergency Use Authorization





What is the temperature of the vaccine when it is injected?

The vaccine will be at room temperature when injected. The cold temperatures are for storage only. Once the Pfizer candidate vaccine is thawed and reconstituted, it may stay at room temperature for up to 6 hours for administration. Once the Moderna candidate vaccine is thawed it may stay at room temperature for up to 12 hours for administration.

Would LTCF resident families be part of sub-prioritization?

Sub-prioritization will be handled by each jurisdictional Department of Health individually.

Does the second dose have a hard deadline on timing?

Each vaccine has a recommended administration schedule. It is expected there will be some leeway which will be unknown until an EUA Fact Sheet is developed.

What about long term side effects? How do we find these out?

The CDC and FDA have set-up several new measures for continuous safety review. EUA Fact Sheets will be updated if new safety concerns present themselves.

If we get the vaccine, can we stop wearing masks and close dedicated COVID-19 units in our facilities?

Regardless of staff acceptance of vaccination, PPE requirements should not be lifted until CDC guidance recommends.

What about new staff and new residents in between 1st and 2nd dose clinics?

During Phase 1, staff and residents will only be able to be vaccinated on clinic days.

I have staff saying they will not take the vaccine because they heard it is derived from aborted fetus cells?

The Pfizer and Moderna vaccines are synthetic mRNA-based and do not originate in any human/animal cells/cell products.

Have there been incidences of someone receiving the vaccine and it causing them to test positive for COVID?

A person should not test positive for active infection as those tests look for the actual virus, and to further clarify (between antigen and antibody tests), this is straight from the CDC: Vaccines currently in clinical trials in the United States won't cause you to test positive on viral tests, which are used to see if you have a current infection.

If your body develops an immune response, which is the goal of vaccination, there is a possibility you may test positive on some antibody tests. Antibody tests indicate you had a previous infection and that you may have some level of protection against the virus. Experts are currently looking at how COVID-19 vaccination may affect antibody testing results.

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When states get the first allocations, will that qt be held to account for both doses? Or will 2nd dose subtract from next allocation?

Yes, they are considering a full dose regimen.

Will non-elderly LTCF residents be eligible?

Yes, all LTCF residents and staff are eligible.

Are there any long term concerns with the vaccines in regards to developing possible autoimmune disease?

There is no reason for this to be a concern at this time, however there will be continuous safety monitoring of the coronavirus vaccine(s) just like with any other disease's vaccine.

How would respond to patients with concerns re mRNA vaccines in general with the concerns for increases in cancer?

There is no reason for this to be a concern at this time, however there will be continuous safety monitoring of the coronavirus vaccine(s) just like with any other disease's vaccine.

Will individuals with pre-existing medical conditions be able to take the vaccine?

The vaccine has been studied in individuals with different disease states. The EUA Fact Sheets will indicate if there are populations that should not receive the vaccine.

In regards to the reactogenicity, how long do the mild fever/chills last? I.e. 24-48 hours following the vaccination

Data shared by Pfizer shows median durations of 1-2 days for local reactions (injection site pain, etc) and 1 day for systemic reactions (nausea, fatigue, etc).

Will simple educational materials be available for clients, listing risks and benefits?

There will be a EUA Fact Sheets.

When and where could we access the presentation recording and PPT slides? Do you have a simple PDF form to use for LTC resident education?

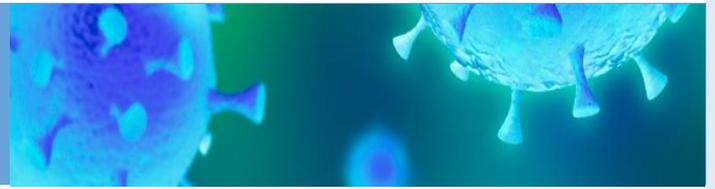
The recording and the presentation were distributed to all registered participants and is also available: <https://illuminate-pharmerica.com/knowledgebase/vaccine-briefing-development-safety-and-distribution/>

Could you elaborate on what you meant by the 3 Clinics set up by CDC, Federal Government and Pharmacies?

For facilities that have enrolled in the Federal Pharmacy Partner Program, the pharmacies are contracted to hold 3 clinics the requisite number of days apart to vaccinate facility residents and staff.

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How many mRNA vaccines have been approved for use on humans?

None to date.

Will the 3 clinics be for both the first and second dose or just for the first dose?

The clinics will be for first and second doses.

After we get the first dose, do they come back 21 days later?

Walgreens will administer the second dose within the appropriate range depending on the vaccine initially administered. All clinic dates will be scheduled during the initial contact between Walgreens and the facility/community.

The consent form seems to be a bit more robust than the flu vaccine consent form. This seems to enhance concerns and hesitancy. How do we respond to these seniors or co-workers with these kinds of reservations?

The consent form was recently shortened to ease the concerns. It includes all the necessary information to ensure flawless management and reporting, all elements that are required as part of the LTC vaccine program.

Will we have to consider the low grade fever, chills, or other symptoms as potential symptoms of COVID. Currently, the employee with these symptoms has to be excluded from work until infection is ruled out. How can this potential issue be mitigated?

It's likely at least some individuals who get vaccinated will exhibit symptoms that would result in failing a screening process. It is recommended to take into consideration if an individual recently received the vaccine as a cause for the symptoms.

Can the vaccine for healthcare workers be mandated as a requirement for working in a healthcare environment, particularly with seniors?

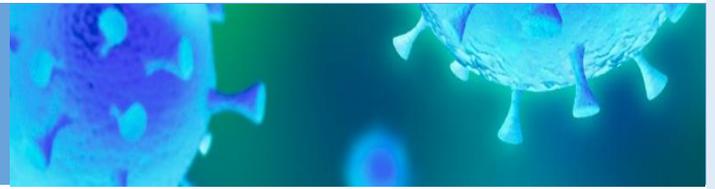
There's currently disagreement as to whether a vaccine authorized for emergency use could be mandated by a state or an employer. Consider promoting the benefits of vaccination and the importance to the populations served, without mandating vaccination - especially while vaccines are marketed under emergency use authorization.

The group hardest hit by COVID are service workers. That is also the group with the most distrust of government vaccines. What proactive, systematic education and engagement systems are being put in place?

There will be a host of education and outreach initiatives going out to the general public from government agencies, pharmacies, and also specifically for the senior living sector. Senior living providers have already begun to share information to help staff, residents, and family members get up to speed. This activity is just starting to ramp up now.

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43,000 participants for a vaccine seems low, what is the usual standard or expected number of participants for a vaccine study?

A research study of the FDA's track record for vaccine approval showed the average trial consisted of 4,161 participants, which the researcher characterized as a rather large sample size. The largest trial conducted for vaccines approved between 1996 and 2015 was 10,058 participants. So by comparison, the COVID-19 phase 3 vaccine trials are very large.

Is there any information on pregnant women or children receiving the vaccine?

None yet, however awaiting Phase 3 data and can expect further guidance from CDC/ACIP when available.

Is it an active or inactive virus we would be receiving?

Neither, it is a mRNA vaccine. This applies to the current front runner as both of the 2 leading candidates for EUA - Pfizer's BNT162 and Moderna's mRNA-1273 - are mRNA vaccines? However, subsequent vaccines being studied that may be approved later, such as Janssen's 3. Ad26COVS1 may use inactivated viral vectors.

As a LTC facility, how can I reach out to the pharmacy providers to make contact to ensure our facility it not missed?

Facilities should contact their selected pharmacies if they selected another pharmacy provider outside of Walgreens. For facilities that selected Walgreens, PharMerica strategic partner for the COVID 19 vaccine program, they may contact them directly by emailing: <mailto:immunizationLTC@walgreens.com>

How soon will expected side effects begin? Same day or later that day?

Data shared by Pfizer shows median onset of Day 0 for local reactions (injection site pain, etc) and Day 1 for systemic reactions (nausea, fatigue, etc).

Can we vaccinate LTC employees under 18?

The data submitted for the vaccine candidates are for individuals 18 or older. The initial recommendations after an authorization will likely not include <18.

Are there preservatives in any of the brands?

More information will be available about the vaccine components once an EUA Fact Sheet is available. However, available information suggests that neither the Pfizer nor Moderna multi-dose vials contain any preservative.

Once a person has been vaccinated, can the vaccinated person spread the virus to an unvaccinated individual? In other words does the virus live in the protected person, and still risk spread to an unprotected individual?

The vaccine does not contain virus and therefore a vaccinated individual cannot spread it.

Are there any specific contraindications for giving the COVID-19 vaccine?

Final recommendations are forthcoming and will be available once a vaccine is authorized.





If I'm due to get my 2nd dose of shingrix this week (at 6 month point) should I wait or potentially get both vaccines within one week?

Final recommendations are forthcoming but speculation is a 14 day period between coronavirus vaccines and any other vaccines.

Do we need primary MD orders or can we get a standing order for staff and residents?

No, standing orders are not needed.

Do we have a fact sheet to give to our families and employee?

All resident facing materials are under development as the information is released. PharMerica is dedicated to providing accurate and timely information as best as possible. As information is available, it will be placed within the PharMerica COVID 19 Resource section of the webpage: <https://pharmerica.com/covid19/>

Looking at the Pfizer 53 page study, only 4.3% of adults over 75 years old were trialed. That doesn't seem like a large sample population to show it's safe. How do we ensure trust with patients and their family?

The Advisory Committee on Immunization Practices met on 12/1/2020 and voted to include Long Term Care Facility residents into Phase 1a of the vaccine distribution based on a review of this and other data. They did not find sufficient evidence of risk to outweigh the potential benefit of protecting our most vulnerable population that has been ravaged by COVID-19.

Additionally, data from published Phase I/II trials in community-dwelling older adults from Moderna and Pfizer trials (≥ 71 years old and 65-85 years old, respectively) showed very few adverse effects following first dose (3 mild effects and 0 total effects, respectively) with increased but still acceptable adverse effects following second doses (only 1 severe ADE - grade 3 fatigue). Additionally, data demonstrated that systemic symptoms were actually lower among older adult populations.

Will a new/updated VAR consent form be provided that is more appropriate to long-term care patients?

A newly designed consent form from Walgreens was recently distributed to all partners. The updated Walgreen's consent form (available via PDF and electronically) has been added to the PharMerica COVID 19 webpage: https://pharmerica.com/wp-content/uploads/2020/12/Walgreens_COVID_VAR-Interactive.pdf

Will TB tests affect administration of the COVID vaccine?

There should be no effect of TB test on COVID vaccine administration.

Are only pharmacies going to do the injections not facility staff?

Walgreens will be on point to administer the COVID 19 vaccines during the scheduled clinics.

Do you only report adverse unknown side effects to VAERS? For instance if I get a fever and a headache after the vaccine would this be reported since these are already recognized potential side effects?

You can report ANY side effect of a vaccine, known or unknown, to VAERS.





When will we know when our clinic days will be?

Walgreens will be in contact with facilities and communities to schedule the clinics as the vaccines are released at the state level.

Why do some of the vaccines have to be stored so cold?

The vaccines are made of mRNA which requires cold storage to maintain their integrity and prevent degradation of the proteins.

How will you communicate the specifics on how Pharmerica will distribute and administer vaccine?

PharMerica is not distributing the vaccines. The selected pharmacies are on point to communicate any specific details, but there are resources outlining the steps for clinical set up and administration on the PharMerica COVID 19 webpage: <https://pharmerica.com/covid19/>

Will you, or the clinic providers (CVS or Walgreens), have a consent form?

The consent forms are being developed and distributed via their communication channels. PharMerica is a dedicated partner for all our clients, and the consent form that has been developed by our strategic pharmacy partner for the COVID 19 vaccine program Walgreens, has been shared via our Account Management team as well as posted on the PharMerica COVID 19 webpage:

https://pharmerica.com/wp-content/uploads/2020/12/Walgreens_COVID_VAR-Interactive.pdf

How will the second dose vaccinations be handled?

The clinics will be scheduled all at the same time, and the second dose will be managed and administered as the first dose.

