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CONNECTION

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"Solid Solutions Seeking Sustainability"

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- Dr. Bruce Packard

COVID-19 GUIDANCE ON VENTILATION IN THE WORKPLACE

For more information, visit www.osha.gov/coronavirus or call 1-811-321-OSHA (6742).

Adequate ventilation in work environments can help maintain a safe and healthy workplace. The following tips from OSHA can help reduce the risk of coronavirus exposure:

1. Encourage workers to stay home if they are sick.
2. Ensure all HVAC systems are fully functional, especially those shut down or operating at reduced capacity during the pandemic.
3. Remove or redirect personal fans to prevent blowing air from one worker to another.
4. Use HVAC system filters with a Minimum Efficiency Reporting Value (MERV) rating of 13 or higher, where feasible.
5. Increase the HVAC system's outdoor air intake. Open windows or other sources of fresh air where possible.
6. Be sure exhaust air is not pulled back into the building from HVAC air intakes or open windows.
7. Consider using portable high-efficiency particulate air (HEPA) fan/filtration systems to increaser clean air, especially in higher-risk areas.
8. When changing filters, wear appropriate personal protective equipment. ASHRAE recommends N95 respirators, eye protection (safety glasses, goggles, or face shields), and disposable gloves.
9. Make sure exhaust fans in restrooms are fully functional, operating at maximum capacity, and are set to remain on.
10. Encourage workers to report any safety and health concerns.

Asbestos Licensing COVID-19 Information

Learn more at https://www.dshs.state.tx.us/asbestos/default.aspx

Asbestos exams have reopened! There are some things you may need to know before making the trip to take your exam. Along with needing to bring a mask and pencils, examinees will be required to also bring a completed COVID-19 self-screening form to the exam. Failure to bring any of these items and you will not be allowed to take the exam. Bringing your own water is highly recommended as the public water fountains will not be in use.

You can find additional information regarding the Asbestos program and more on the Texas Department of State Health Services website.

FEDERAL LAW GOVERNING RIGHTS OF NURSING MOTHERS

For more information, visit https://www.dol.gov/newsroom/releases/whd/whd20200810-0

The U.S. Department of Labor's Wage and Hour Division (WHD) investigated Murphy Oil USA Inc. and found Murphy Oil USA failed to provide reasonable, uninterrupted break time and a private area for a nursing mother to express her breast milk. "Employers are required to provide a place for employees to express breast milk, other than a bathroom, shielded from public view and free from intrusion by coworkers and the public." Though Murphy Oil USA representatives claim no knowledge of these accommodation needs, they have agreed with WHD and will be developing and distributing a new corporate policy regarding lactation breaks to comply with federal law which requires employers to provide reasonable breaks, for a one year period after a child's birth, each time employees express the need to express milk for their nursing children. "Once notification is given, the store will be fitted with required equipment designed to retrofit the storerooms and offer the nursing mother a private place free from intrusion. The equipment includes a sign to prohibit entry, a chair, a curtain hung to obstruct security surveillance view and a dedicated refrigerator for the storage of pumped breast milk."

How are your company policies pertaining to nursing mothers in the workplace?

TO VACCINATE OR NOT TO VACCINATE

By Dr. Bruce Packard, MD, MPH

Since I have gotten questions about the recent emergency authorization use for COVID-19 vaccination, I thought I'd answer a few questions on the vaccine. How did it happen so fast? Is it safe? Should I get it? And what else should I know?

The Development Process

Since vaccine development usually takes years, how could it be shorted to under a year? Easy. They had a head start: the administrative steps were prioritized, the financial support was provided to the companies, and sadly, the COVID-19 infection rate increased. But I'm getting ahead of myself. Let's review the development process.

Normal development of vaccines and drugs involves a gated process with a three-phase study. After each phase, a gate pauses the study before the next phase or step begins. Each gate requires a review of the results for the safety and effectiveness by the company and the FDA. Only after the FDA is satisfied with the safety and effectiveness can the FDA authorize the company to start the next step (either the next phase or vaccine release to the public). If the vaccine poses significant safety risks or is not effective, the gate remains closed and the study ends.

Phase I tests the basic safety of the vaccine (or drug) in a small number of healthy patients. Are there any adverse safety affects, and if present, how serious are they (i.e., a sore arm for 24 hours versus, say, hospitalization for some reason)? The primary concern is its safety.

Phase II is given to a slightly larger number of patients to test safety as well as dosing and to see whether a desired effect is achieved (i.e., were antibodies produced and were there no significant safety issues).

Phase III involves a large number of patients and focuses on safety along with a therapeutic result. For vaccinations, that means the patients produced antibodies that actually prevent the illness. (Note: the production of antibodies does not always prevent illness; google for HIV vaccine trials.)

So, how did the COVID-19 vaccine get through so fast? There are three factors at play here: prior development, gate delays and financial incentives.

First, although no vaccine was ever clinically tested, preliminary work was started on a related coronavirus vaccine during the SARS infection. Score one for basic research. This work was helpful in kick starting this vaccine research.

Second, the gates after each phase are not only important stopping points to evaluate the safety, but they also cause delays for unrelated reasons. Pharmaceutical companies have multiple vaccines and drugs in development at any one time, so internal reviews can stack up. Additionally, financial factors influence the company's priority as to which study to move forward and at what speed. Simply put, if they can make more money with Drug A over Vaccine X, they would move Drug A forward first. Studies take time and money to complete, and companies have a limited number of funds for research. As such,

corporations must fit a study into their budget plan (i.e., are there funds available to move this project forward at this time, or should it wait a year or two?).

Likewise, the FDA has multiple requests at any one time that it prioritizes according to administration policy. In this case, the Trump Administration made this vaccine a top priority. That is, reviews of other vaccines or drugs could be delayed while this vaccine is considered.

When you consider budgets and other projects, these gates become convenient holding points that have nothing to do with vaccine or drug safety. And these holds can easily last months or years.

So, how did the Administration speed up the process? While I am not privy to the details, the rapid movement through each gate is simple: guaranteed financial support for the corporations through purchase guarantees (that is, the corporation has a financial incentive to move the project forward now, not later), and the prioritization of the governmental review to ensure that the project is not delayed by paper shuffling or bureaucratic issues. NOTE: Neither financial guarantees nor prioritization of the gate reviews impacts the safety review. The same safety data is reviewed. If it is safe, it will pass the gate. If not, it will be halted.

The Phase III trials for Pfizer-Biontech and Moderna vaccines were completed in December, the initial information is very good. NOTE: Neither budgeting guarantees nor administrative prioritization or reviews affects the safety review. The FDA review of the vaccine safety data is unchanged. At this time, no major safety issues have been reported; however, the full review is in process right now.

Paradoxically, the trials benefited from the increasing rate of COVID-19 in the community. The end point of these trials occurred when there was a statistically meaningful difference of COVID-19 infections between two equal groups of people: vaccinated versus unvaccinated people. Due to high rates of infection and a highly effective vaccine, the early report of results found that 5 vaccinated patients got infected versus 95 unvaccinated patients. Only seeing publicly available information, it is easy to see that being vaccinated is better than not. Of course, the FDA reviewed all the data, not just the scant data publicly released. To summarize, the preliminary research effort, financial guarantees, removal of administrative delays and increased rate of infection resulted in faster studies without compromising safety.

In mid-December, the vaccine advisory committee found the Pfizer-Biontech and Moderna vaccines to be both effective and safe (I will explain shortly) and recommended Emergency Use Authorization of (EUA) of the vaccine. Crossing the final gate after the Phase 3 trial, the FDA and CDC approved the EUA. The Pfizer vaccine was released for “individuals 16 years of age and older”, and the Moderna vaccine was released for “individuals 18 years of age and older.” Initial vaccination efforts are focused on medical personnel and high-risk groups. While it may be another month or more, other vaccines will follow. While I am agnostic on which vaccine would be “best”, I can only comment on the Pfizer and Moderna vaccines at this time.

The Vaccine

Great news! Both vaccines were found to be about 95% effective. That is, 95% of the vaccinated individuals avoided getting the infection because of the vaccine. This exceeds the most optimistic predictions from last spring and is as good or better than most other commonly used vaccines. Since the vaccines contain a small fragment of the virus to trigger antibody production, it is impossible to get

the infection from the vaccine; however, a few of the vaccinated individuals got the vaccine from someone else in the community after being vaccinated (no vaccine is 100%). The great news is that the vaccinated individuals had a milder case of COVID-19 than the unvaccinated individuals.

What about safety? Anyone who has been vaccinated and had a sore arm will attest, minor side effects are common (more on that in a minute). What about serious or life-threatening affects?

With both vaccines, the only people told not to get the vaccine are people with a history of an allergic reaction to the first dose or to a component of the respective vaccine (if you think this applies to you, talk with your doctor or the Public Health Department). As you are probably aware, a small number of allergic reactions have been reported (after 2,000,000 doses, there were 12 reported allergic reactions). In all cases, the reaction occurred within 15-30 minutes of the vaccinated and was easily treated. To date, everyone is doing well. Due to this, the CDC recommends that people wait 15-30 minutes after being vaccinated before leaving. Otherwise, no serious side effects were found in roughly 35,000 study volunteers and nearly 6,000,000 vaccine recipients who received one of the actual vaccines.

Like most vaccines, some side effects have been reported to this vaccine. Before I discuss the side effects, it is helpful for you to know that these side effects are actually the result of your body's immune response. That is, when faced with a viral or bacterial invader, the body responds with inflammatory substances that kicks the immune system into action. Rather than the invading virus or bacteria, these inflammatory substances actually cause the typical symptoms of fever, achiness, chills and generally feeling under the weather. What that means is that your body is responding appropriately. So, a similar reaction to a vaccine is a nuisance AND a good sign. As previously mentioned, this vaccine is only a fragment of the virus. While it is possible to feel under the weather from the body's immune reaction, it is impossible to get the disease from the vaccine.

Honesty is the best policy, so you need to know that the side effects of feeling under the weather are common with this vaccine, and when present, lasts 1-2 days. Soreness at the injection site is very common with roughly half of the people complaining of some fatigue and headache. Roughly one-third had muscle aches or chills, and less than a quarter had joint pain, fever or injection site swelling/redness. Once again, these side effects are annoying when present, but they are also a sign that that your body is responding appropriately to the vaccine. If you can safely take Tylenol, you can take it before you get vaccinated to minimize some of the symptoms. Also, both vaccines require two doses, and people are more likely to report side effects with the second dose. However, failing to get the second dose decreases the effectiveness of the vaccine, so don't forget it. Note, whichever vaccine individuals get, they need to get it for both doses.

Who should talk to their doctor first? As is typical, the initial study cannot include every contingency, and will have some advisories for specific groups of people to talk with their doctor before getting the vaccine. This can be due to potential contraindications or the need for medication adjustments before getting the vaccine. The list is fairly standard. First and foremost, anyone with history of an allergic reaction to the first dose of the vaccine or concern about an allergic reaction should talk to their doctor or the Public Health Department. A reason to delay a few days includes current fever. Situations in which the doctor may want to adjust current treatments include patients with bleeding disorders, on blood thinners, or a compromised immune system compromised due to illness or medication. Finally, due to limited study information, people who reacted to the first does of the COVID-19 vaccine, or

women who are pregnant or breast feeding. In each case, talk with your doctor or the Public Health Department to determine your best option.

What about rare side effects? The FDA has a reporting program to ensure that if other rare events occur, they will be captured and evaluated. Right now, there are no significant issues out of over 6,000,000 recipients, and we know that an infected person of almost any age has a greater chance of serious illness, including hospitalization, complicating symptoms, intubation and/or death. That is, vaccination is safer than getting the disease.

So, yes, the FDA found the vaccine to be effective and safe, gave the Emergency Use Authorization for the vaccine, and I got my COVID-19 vaccine on January 7th. Other than history of allergic reaction to one of these vaccines or a component of it, the Pfizer and Moderna vaccines are cleared for use. For a few people, there are advisories for them to contact their doctor (see above). If you have other questions, please contact your doctor or the Public Health Department.

Other Comments

I have six final comments: *when, but I'm healthy, how often, what if, it's the economy,* and *in the meantime*.

When. It is impossible to instantly produce and distribute several hundred million doses of vaccine, so it will take time for everyone to get the vaccine. Appropriately, the initial doses of vaccine will be given to those at highest risk (healthcare workers, the elderly in group settings, and those with serious risk factors). So, be patient.

But, I'm healthy. For those young and healthy, you should get it when it is available. Since the antibodies to the virus will likely decrease with time, a large unvaccinated group of otherwise healthy people may not be as affected by the disease, but they do get COVID-19 and can keep the virus circulating for years, thus re-infecting those at high risk.

How often? In short, we can't know. It takes time to determine. As of now, we can probably say 4-6 months because people started getting the vaccine 4-5 months ago. Just like it is impossible to predict the weather 1-5 years from now, we cannot accurately predict how long the antibodies from a vaccine will last. We can only know once time elapsed. So, patients in the vaccine studies will continue to be followed to see if or when the vaccine protection declines and whether a booster is needed. Stay tuned.

What if… What if I wait for "herd" immunity (herd immunity relies on everyone else having had it, so no one can pass it to me)? Well, we know that normal antibodies to the coronavirus decrease over time and some people infected with COVID-19 have gotten re-infected. Sadly, herd immunity is a long way away and may never occur with this illness—it only really works when immunity is lifelong.

It's the economy. If your concern is for the economy and jobs, almost all economists agree that the economy will only truly recover when the COVID-19 virus is controlled. Even if you are not concerned, enough people are that they are spending less (i.e., not traveling, eating out or shopping as much). Since people make up two-thirds of the economy, a significant group of people concerned about the virus will continue to drag the economy down.

In the meantime… Until you can get the vaccine (and perhaps longer) continue to follow the best measures we have now: social distance and wear a mask. Yes, they are proven to work.

So, yes, the FDA found the vaccine to be effective and safe, gave the Emergency Use Authorization for the vaccine, and I got the COVID-19 vaccination as soon as it is available to me. Other than history of allergic reaction to one of these vaccines or a component of it, the Pfizer and Moderna vaccines are cleared for use. For a few people, there are advisories for them to contact their doctor (see above). If you have other questions, please contact your doctor or the Public Health Department.

What can you do? Share this information with your employees. If you need help dealing with COVID-19 issues, I am here to help. You can reach me by calling *Caliche, Ltd.*

-Dr. Bruce D Packard, MD, MPH

Caliche is here to help you and your company stay as safe as possible. Some of the service we offer are:

Asbestos

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- Project managers
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  - Benzene, H_2S, LEL, etc.
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- Fit-testing and training
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  - Quantitative

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- Air monitoring
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- NORM
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Indoor Air Quality

- Microbial
- Bacterial
- Bio aerosol

Safety

- Risk assessments
- Written program development