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THE PRACTICAL GUIDE TO KEEPING HEALTHCARE WORKERS HEALTHY

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INSIDE

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COVID-19 Vaccines for Healthcare Workers: The Good, the Bad, and the Ugly

Many stepping up amid chaos and confusion

By Gary Evans, Medical Writer

Healthcare workers — some of whom were initially hesitant to take one of the rapidly developed COVID-19 vaccines — are receiving immunization in an uneven national rollout marked by delays, chaos, and disruptions. Although there are reports of some healthcare workers declining vaccination, there is a growing perception that most healthcare workers will welcome immunization at a time when the pandemic is worsening.

"For me, at the end of the day, it came down to, 'Somebody's got to get it,'" says **Courtney Paschal**, ADN, RN, an emergency nurse at a VA hospital in Augusta, GA. "That's how we beat polio and measles — somebody had to get [immunized]. Is there a risk? Absolutely. But this is me standing up and getting this vaccine so we can somehow tackle this virus and save people I care about in the future. That is a small price to pay."

> "THIS IS ME STANDING UP AND GETTING THIS VACCINE SO WE CAN SOMEHOW TACKLE THIS VIRUS AND SAVE PEOPLE I CARE ABOUT IN THE FUTURE. THAT IS A SMALL PRICE TO PAY."

The vaccination program at her facility was just starting when *Hospital Employee Health* talked to Paschal, and she was on the waiting list.

"Our facility was only able to lock in [a limited number of] vaccines," she says. "Ideally, you want to offer it to all healthcare workers, but the priority was

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to set it aside for any clinical worker in the emergency room or the ICU because we primarily handle the COVID patients."

The Food and Drug Administration (FDA) has granted emergency use authorizations (EUA) to two messenger RNA vaccines for COVID-19. Both show an efficacy of about 95%. At a meeting on Dec. 10, 2020, the FDA granted emergency use authorization for the vaccine developed by Pfizer and BioNTech in the United States for those age 16 years and older. The FDA followed at a Dec. 17, 2020, meeting with approving an EUA of a vaccine by Moderna for those age 18 years and older. The Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) has voted in favor of distributing both vaccines, with healthcare workers and long-term care residents the first priority.

However, there has been considerably lower uptake of the vaccine than originally projected, in large part due to erratic logistics in various states trying to immunize these first recommended groups. The lack of federal funding and planning to help states conduct the vaccinations has been "appalling," said ACIP member **Beth Bell**, MD, MPH, of the University of Washington.

"[Public health] jurisdictions are under immense stress now and have been for quite some time," **Nancy Messonnier**, MD, director of CDC's national center for immunization and respiratory diseases, said at a Dec. 30, 2020, press conference. "As the threat of COVID-19 disease and death remains a problem here in the U.S., jurisdictions are supporting the largest vaccine rollout in the country's history and trying to maintain standard public health services." *(The transcript is available at: https://bit.ly/393PaCD.)*

Predicting the numbers of vaccinated workers will steadily increase, Messonnier noted the virus was first detected only a year ago. "So far, more than 2.6 million people, including healthcare professionals and nursing home and assisted living facility residents have received the first dose."

The Pfizer and Moderna vaccines were developed at a record pace, which raised some safety concerns due to perceptions the process had been politicized in an election year.

"I'll be honest with you — at the very beginning, I was one of those who was absolutely not going to do it," Paschal says.

After researching the vaccines and talking to experts, Paschal became convinced it was the best option when she saw two of her colleagues contract coronavirus.

"I'm 32, and I work with two other nurses my age with no comorbidities," she says. "They have both gone to the ICU. It doesn't discriminate. There is no rhyme or reason to who gets [COVID-19] and why some get so sick. It's very unpredictable."

Although there has been some logistical chaos and delays as the vaccine rolls out, the sense of added security with immunization is appealing to some healthcare workers.

"I have two young children and grandparents I take care of, so I am constantly worried about what I'm going to bring home," Paschal says. "I think I'm going to find a little comfort in having some added protection for myself and others around me."

On the other hand, there were reports of vaccine reluctance and refusal in the Los Angeles area, with reports of from 20% to 40%

frontline nurses and doctors declining an initial offer of vaccine in Los Angeles County.[1]

In a bizarre incident still under investigation as this report was filed, a hospital pharmacist at Aurora Medical Center in Grafton, WI, admitted to intentionally removing vials of Moderna vaccine from a refrigerator to render them useless. The hospital reported 57 vials — enough for more than 500 doses — had to be discarded after 12 hours at room temperature.

"We immediately launched an internal review and were led to believe this was caused by inadvertent human error," Aurora Medical said in a statement on Dec. 30, 2020. "The individual in question today acknowledged that they intentionally removed the vaccine from refrigeration. We have notified appropriate authorities for further investigation. We continue to believe that vaccination is our way out of the pandemic. We are more than disappointed that this individual's actions will result in a delay of more than 500 people receiving their vaccine. This was a violation of our core values, and the individual is no longer employed by us." *(The statement is available at: https://bit.ly/3rYtMXY.)*

The pharmacist was subsequently arrested, but close to 60 healthcare workers had been immunized with the first dose of the non-refrigerated vaccine. The employees should be at no risk, but they cannot be assumed to be adequately protected and may be reimmunized.[2] There is no evidence that any other vaccines were tampered with, and the hospital is continuing to immunize employees despite the actions of one "bad actor," **Jeff Bahr**, MD, president of Aurora Health Care Medical Group, said at a press conference.

"It's important to note that despite the actions of one individual, the vaccine program here and [others] across the country remain safe and critical to get us out of the pandemic," he said. *(The statement is available at: https://bit.ly/3rYtMXY.)*

In another unusual incident, 60 ED staff members at Kaiser Permanente San Jose (CA) Medical Center tested positive for COVID-19 between Dec. 27 and Jan. 5, according to multiple news reports. One staff member died. Investigators are looking into whether the outbreak was caused by a staff member's attempt to boost morale by visiting the ED in an air-powered costume on Christmas Day. The staff had received one dose of vaccine 10 days earlier, but both currently approved vaccines require a second dose several weeks after the first.[3]

There is broad consensus that healthcare workers and long-term care residents were the appropriate pick as top priority for the vaccine, but state health jurisdictions have some flexibility to administer immunizations in accordance with their local situations. Texas public health officials recently advised healthcare workers without access to vaccine in their facilities to seek immunization at larger systems and community pharmacies.

"Some healthcare workers who work in smaller settings and are not affiliated with a large institution are reporting difficulty in accessing the vaccine," the health department noted. "Hospitals and other large providers may be in a unique position to assist in this unprecedented situation by serving as community vaccinators for healthcare workers in Phase 1a."[4]

Some healthcare systems reported communication breakdowns and confusion about which staff members should receive the vaccine. An estimated 1,300 resident/fellow physicians in training were left out of first-round vaccination at Stanford University because of a reported problem with an algorithm to guide the process. Stanford officials apologized for the error and moved to correct the situation after the residents protested and sent a blistering letter to administration.

"It is important for us to articulate to you that at this time, residents are hurt, disappointed, frustrated, angry, and feel a deep sense of distrust toward the hospital administration, given the sacrifices we have been making and the promises that were made to us," according to the letter. "Many of us know senior faculty who have worked from home since the pandemic began in March 2020, with no in-person patient responsibilities, who were selected for vaccination. In the meantime, we residents and fellows strap on N95 masks for the tenth month of this pandemic without a transparent and clear plan for our protection in place."[5]

An element of PPE fatigue, particularly concerning the tight-fitting N95 respirators, has some healthcare workers hoping they can scale down a bit after receiving two doses of vaccine. **Hamad Husainy**, DO, FACEP, an emergency physician at Helen Keller Hospital in Sheffield, AL, says at times during the pandemic, he has worn an N95 respirator at all times for all patients. He may revert to a surgical mask after becoming fully immunized.

"Some of my colleagues might debate or question that, but at some point we have to figure out how to revert, and of course the vaccine will help with that," he says. "The temptation is going to be 'I don't need to be as protected [with PPE] because I have had the vaccination.'"

In vaccinating healthcare personnel (HCP), employee health departments should know the systemic signs and symptoms that may follow the first few days after immunization, the CDC advised.

"Systemic signs and symptoms, such as fever, fatigue, headache, chills, myalgia, and arthralgia, can occur following COVID-19 vaccination," the CDC stated.[6] "Inform HCP about the potential for short-term systemic signs and symptoms post-vaccination and potential options for mitigating them if symptoms arise (e.g., nonsteroidal anti-inflammatory medications or acetaminophen)."

These symptoms can appear the same day and the following two days, with most presenting on the day after immunization. The reactions are more frequent and severe following the second dose of vaccine, which is given 21 days later for the Pfizer vaccine and 28 days for Moderna.

In contrast to vaccine reactions, cough, shortness of breath, rhinorrhea, sore throat, or loss of taste or smell are more consistent with SARS-CoV-2 infection. "Strategies are needed for healthcare facilities to appropriately evaluate and manage post-vaccination signs and symptoms among HCP," the CDC said.[6] The idea is to avoid unnecessarily excluding HCP with only post-vaccination signs and symptoms from work while detecting those that may have SARS-CoV-2 or other infections. *(See Table 1.)*

Ideally, workers could be immunized before days off using a system of staggered delivery so not everyone in a single department or unit is vaccinated at the same time, the CDC advised.

Husainy says his hospital uses this approach. He also has scheduled days off after his vaccination — which, at one point, he questioned taking.

"I was very skeptical for a while," he acknowledges. "I knew the science was going to have to come out about it [eventually]. I was able to do a little research and understand the [vaccine] mechanism. It would be prudent to have a little more data and proof, so to speak, that it will not cause adverse events. But being on the frontlines, I recognize the need to make sure that we all stay safe. The other thing is I'm just sort of tired of [COVID-19]. I'm ready for it to be over. I think a lot people are. There is a subset of people who want to take [the vaccine] just to get this thing over with. Let's move on."

Concurring with this sentiment is **Mike Hastings**, MSN, RN, CEN, immediate past president of the Emergency Nurses Association (ENA), which recommends vaccination for its members.

"We looked at the evidence and felt this is our best option," he says. "The vaccines look safe — definitely the benefit gained outweighs any potential risk. It definitely outweighs the risk of prolonging this pandemic and waiting for further information. I'm scheduled to get my vaccine in just a couple of hours, and I look forward to being able to get it."

The logistical delays and confusion at some facilities is due in part to the CDC designating all healthcare workers in the 1a category to receive immunization. There may be insufficient vaccine supplies in many areas, so a lot of the healthcare workforce will be immunized in stages.

If this is the case, the CDC recommends considerations for subprioritization of equal importance:

- HCP with direct patient contact who are unable to telework;
- HCP working in residential care or long-term care facilities;
- HCP with documented acute COVID-19 infection in the preceding 90 days may choose to delay vaccination until near the end of the 90-day period to facilitate vaccination of HCP susceptible to infection, as evidence suggests reinfection is uncommon during this period after initial infection.

"Every healthcare organization is essentially having to figure out how they are administering them and getting them out to the frontline staff," Hastings says. "Hospitals are having to decide who do we do first. Out of all of our employees, who are the most at risk? What we are seeing is that emergency departments, the ICU, and the units where COVID-19 patients are being housed are kind of the priority right now. The goal is to vaccinate all staff, and it's just going to be a matter of time before we vaccinate everyone."

Having looked at the risks and benefits of immunization, Hastings says the shortened timeline for vaccine development essentially cut out a lot of "red tape."

"The research studies — with a [large] number of people who got the vaccine — met the standards," he says. "They were completely blinded studies that met the level of evidence that one would want. It's reassuring to know that."

Having seen people ill with COVID-19 come into the ED, Hastings saw the risk of remaining unvaccinated.

"It will put me more at ease to know that I have helped my own body's self-defense," he says. "I'm not going to lighten up on wearing my mask [or stop] social distancing. I will still adhere to those things until we get the community immunity we need."

Table 1. Suggested Approaches to Evaluating and Managing New-Onset Systemic Post-Vaccination Signs and Symptoms in HCP

HCP Signs and Symptoms	Suggested Approach	Additional Notes
Signs and symptoms *unlikely* to be from COVID-19 vaccination: Presence of **ANY** systemic signs and symptoms consistent with SARS-CoV-2 infection (e.g., cough, shortness of breath, rhinorrhea, sore throat, loss of taste or smell) or another infectious etiology (e.g., influenza) that are not typical for post-vaccination signs and symptoms.	Exclude from work pending evaluation for possible etiologies, including SARS-CoV-2 infection, as appropriate. Criteria for return to work depends on the suspected or confirmed diagnosis. Information on return to work for HCP with SARS-CoV-2 infection is available at: https://www.cdc.gov/coronavirus/2019-ncov/hcp/return-to-work.html.	If performed, a negative SARS-CoV-2 antigen test in HCP with signs and symptoms that are not typical for post-vaccination signs and symptoms should be confirmed by SARS-CoV-2 nucleic acid amplification test (NAAT). Further information on testing is available here: https://www.cdc.gov/coronavirus/2019-nCoV/lab/index.html
Signs and symptoms *that may be* from either COVID-19 vaccination, SARS-CoV-2 infection, or another infection: Presence of **ANY** systemic signs and symptoms (e.g., fever, fatigue, headache, chills, myalgia, arthralgia) that are consistent with post-vaccination signs and symptoms, SARS-CoV-2 infection or another infectious etiology (e.g., influenza). Fever in healthcare settings is defined as a measured temperature of 100.0°F (37.8°C) or higher.	Evaluate the HCP. HCP who meet the following criteria may be considered for return to work without viral testing for SARS-CoV-2: • Feel well enough and are willing to work and • Are afebrile* and • Systemic signs and symptoms are limited only to those observed following COVID-19 vaccination (i.e., do **not** have other signs and symptoms of COVID-19 including cough, shortness of breath, sore throat, or change in smell or taste). If symptomatic HCP return to work, they should be advised to contact occupational health services (or another designated individual) if symptoms are not improving or persist for more than two days. Pending further evaluation, they should be excluded from work and viral testing should be considered. If feasible, viral testing could be considered for symptomatic HCP earlier to increase confidence in the cause of their symptoms. *HCP with fever should, ideally, be excluded from work pending further evaluation, including consideration for SARS-CoV-2 testing. If an infectious etiology is not suspected or confirmed as the source of their fever, they may return to work when they feel well enough. In facilities where critical staffing shortages are anticipated or occurring, HCP with fever and systemic signs and symptoms limited **only** to those observed following vaccination could be considered for work if they feel well enough and are willing. These HCP should be re-evaluated, and viral testing for SARS-CoV-2 considered, if fever does not resolve within two days.	If performed, a negative SARS-CoV-2 antigen test in HCP who have symptoms that are limited only to those observed following COVID-19 vaccination (i.e., do not have cough, shortness of breath, sore throat, or change in smell or taste) may not require confirmatory SARS-CoV-2 NAAT testing. Additional information is available here: https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html

SOURCE: Centers for Disease Control and Prevention, https://www.cdc.gov/coronavirus/2019-ncov/hcp/post-vaccine-considerations-healthcare-personnel.html

Editor's note: The ENA has posted "COVID Bytes" audio and video clips that include an explanation of how the vaccines work and advice modeling model science-driven behavior, at: https://bit.ly/38guJDh. ■

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Rare, but Real: Anaphylaxis After COVID-19 Vaccination

Be ready to recognize and respond to allergic reactions

As COVID-19 vaccinations roll out, a handful of people have experienced anaphylactic allergic reactions after receiving the Pfizer vaccine. These cases appear to be extremely rare, but the Centers for Disease Control and Prevention (CDC) advises several measures to recognize and respond to severe allergic reactions to the vaccine.

Thomas Clark, MD, MPH, deputy director of the CDC division of viral diseases, recently updated the situation at a Dec. 19, 2020, meeting of the CDC's Advisory Committee on Immunization Practices (ACIP).

"As of Dec. 18, 2020, the CDC has identified six case reports of anaphylaxis following Pfizer-BioNTech vaccine," Clark said. "Additional case reports have been reviewed and determined not [to be] anaphylaxis. These cases occurred within recommended observation window for vaccination and were promptly treated. Investigations are ongoing, although we do know that one case had a history of anaphylaxis following rabies vaccination."[1]

Two cases occurred in healthcare workers in the United Kingdom. In addition, two U.S. healthcare workers, including one who needed intensive care, experienced severe allergic reactions after receiving the vaccination at the same hospital in Alaska.

"Persons with anaphylaxis have received vaccine from more than one production line," Clark said. "Multiple lots have been distributed and are being used. You may have seen in the news a couple of cases in Alaska, but we have had reports from other jurisdictions and there is no obvious clustering geographically."

Severe allergic reaction to any component of the vaccine is a contraindication to vaccination. Appropriate medical treatment must be immediately available in the event an acute anaphylactic reaction occurs following administration of the vaccine, Clark emphasized. Notification of these anaphylactic incidents has been timely, indicating the national surveillance for adverse reactions to the vaccine is working.

"Persons with anaphylaxis following COVID-19 vaccination should not receive additional doses of COVID-19 vaccine," he said.

Contraindications

Also speaking at the ACIP meeting was **Doran Fink**, MD, PhD, an ex officio member of the panel representing the Food and Drug Administration.

"We are working closely with the manufacturer to identify what the causes of these reactions might be," Fink said. "We will update the public in a timely manner if we find anything that would cause us to change the conditions of the emergency use authorization [EUA]. However, I want to stress at this time

the totality of the data continues to support vaccination under the Pfizer EUA without any new restrictions."

Contraindications to the Pfizer-BioNTech and Moderna COVID-19 vaccines include:

• Severe allergic reaction (e.g., anaphylaxis) after a previous dose of an mRNA COVID-19 vaccine or any of its components;

• Immediate allergic reaction of any severity to a previous dose of an mRNA COVID-19 vaccine or any of its components (including polyethylene glycol [PEG]);

• Immediate allergic reaction of any severity to polysorbate (due to potential cross-reactive hypersensitivity with the vaccine ingredient PEG).

"These persons should not receive mRNA COVID-19 vaccination at this time unless they have been evaluated by an allergist-immunologist and it is determined that the person can safely receive the vaccine under observation in a setting with advanced medical care available," the CDC stated.[2,3]

The CDC considers a history of any immediate allergic reaction to any other vaccine or injectable therapy (unrelated to a component of mRNA COVID-19 vaccines or polysorbate) as a precaution but not a contraindication to vaccination for COVID-19. People with such a history should be counseled about the unknown risks of developing a severe allergic reaction and balance these risks against the benefits of vaccination.

"People with a history of allergies to oral medications or a family history of severe allergic reactions, or who might have a milder allergy to vaccines (no anaphylaxis), may also still get vaccinated," the CDC advised.

All who receive a COVID-19 vaccine should be monitored on site. Those will a history of severe allergic reactions should be monitored for 30 minutes. All others should be monitored for 15 minutes after receiving the vaccine.

"Vaccination providers should have appropriate medications and equipment, such as epinephrine, antihistamines, stethoscopes, blood pressure cuffs, and timing devices to check pulse, at all COVID-19 vaccination sites," the CDC stated. "Appropriate medical treatment for severe allergic reactions must be immediately available in the event that an acute anaphylactic reaction occurs."

Because anaphylaxis requires immediate treatment, diagnosis primarily is based on recognition of clinical signs and symptoms, including:

• **Respiratory:** sensation of throat closing, stridor, shortness of breath, wheeze, cough;

• **Gastrointestinal:** nausea, vomiting, diarrhea, abdominal pain;

• **Cardiovascular:** dizziness, fainting, tachycardia, hypotension;

• **Skin/mucosal:** generalized hives; itching; or swelling of lips, face, throat.

"Early signs of anaphylaxis can resemble a mild allergic reaction, and it is often difficult to predict whether initial, mild symptoms will progress to become an anaphylactic reaction," the CDC noted.

Patients who develop itching and swelling confined to the injection site should be observed closely for the development of generalized symptoms — beyond the recommended observation period, if necessary.

"If symptoms are generalized, epinephrine should be administered as soon as possible and emergency medical services should be sought," the CDC emphasized. ■

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CDC Advisors Draw Fire for COVID-19 Vaccine Recommendations

Trying to 'thread the needle' in rationing vaccine

A Centers for Disease Control and Prevention (CDC) advisory panel has designated frontline essential workers and those age 75 years and older as the next priority groups to receive COVID-19 vaccine in the United States.

The decision came amid considerable criticism and controversy at an emergency meeting on Dec. 20, 2020, with the CDC Advisory Committee on Immunization Practices (ACIP) voting to continue the rationing process while vaccine stocks are insufficient.[1]

"We are faced with the situation, at least in the short term, where we have a limited supply of vaccine available to us," said **Nancy Messonnier**, MD, director of CDC's National Center for Immunization and Respiratory Diseases. "What that means is that there will be difficult choices about who gets that vaccine first."[2]

Eventually, there should be adequate supplies for national vaccination. In the interim, ACIP has held some agonizing debates on the benefits and risks of choosing which group should be immunized before another.

"These are difficult decisions," said ACIP member **Sharon Frey**, MD, of Saint Louis (MO) University Medical School. "There are no perfect recommendations. People will continue to become ill with this disease and die from [it] until there is adequate vaccine."

ACIP has drawn criticism for not reaching out enough to minority communities, as well as showing bias against white people by making its most recent selection "essential frontline workers" ahead of all people aged 65 to 74. At the meeting, ACIP Chairman **José Romero**, MD, addressed this issue openly in a statement he read before the full committee.

> "FOR EVERY GROUP THAT WE ADD, WE NEED TO SUBTRACT A GROUP. FOR EVERY GROUP THAT WE SUBTRACT, THEY DON'T GET THE VACCINE. IT HAS BEEN VERY HUMBLING AND HEARTBREAKING."

"[There has been] disinformation and statements made to impugn and undermine the work that the ACIP has carried out over these last nine months — and more specifically, over the last two months — that has caused doubt among the American public as to our motives and decisions," he said. "It has been said that our recommendations are excluding specific racial groups. It is important that the public understands that throughout the long period of deliberations, thoughtful discussions, and careful evaluation of the data, the ACIP has struggled painfully to deal with distribution of a limited resource of vaccines. Our attempt has been always to achieve equitable, ethical, and fair distribution of that resource. We have never targeted a specific ethnic nor racial group for receipt of the vaccine. All of our decisions and recommendations for the priority groups take into account the burden of disease within those groups. And within those groups, white, Caucasian individuals predominate. The statements being made and carried by various outlets undermine the careful work that we have provided, and undermine the trust of the American public in our committee. I want to emphasize again: We have never focused on any particular racial group in coming to our recommendations."[3]

Priority Groups Designated

Given limited supplies and ongoing distribution challenges, ACIP is recommending priority groups receive the vaccine based on medical and ethical models to provide the greatest societal benefit. CDC recommendations are not mandatory, but represent the best ACIP consensus recommendations to state and local health officials administering the vaccines.

As an update to the recent 1a recommendations to vaccinate healthcare workers, including those in long-term care, and residents of nursing homes, ACIP designated the next priority groups for immunization while vaccine supplies are limited as follows. The estimated total population in each group is listed in parentheses:

1b: Persons age 75 years and older (21 million) and frontline essential workers (30 million). The latter group includes first responders, firefighters, police, teachers, food and agriculture, manufacturing, corrections workers, postal workers, public transit, and grocery store workers.

1c: Persons age 65 to 74 years (32 million); persons age 16 to 64 years with high-risk medical conditions like heart disease and diabetes (110 million); and other essential workers (37 million). The latter group includes transportation, food service, construction, finance, communications, energy, media, legal, public safety engineers, and water and wastewater.

With many critics saying the 65 to 74 age group should be prioritized over younger frontline essential workers, several states shifted the vaccination groups to do just that after the ACIP guidelines were released.

One aim of immunizing essential frontline workers rather than a larger group of the elderly is "preservation of societal functioning," ACIP meeting materials indicate. As approved, the recommendations essentially call for vaccinating a large frail population as well as one subjected to frequent exposures in the community.

"Persons 75 years and older represent 8% of the population, 25% of hospitalizations, and have a very high death rate," said ACIP member **Katherine Poehling**, MD, MPH, of Wake Forest School of Medicine in Winston-Salem, NC. "Frontline essential workers have high exposure. They include a disproportionate share of racial and ethnic persons who also have a disproportionate share of hospitalizations."[3]

However, one ACIP member, **Henry Bernstein**, DO, of the Zucker School of Medicine at Hofstra/Northwell, voted against the recommendation.

"I am in full support of [vaccinating] persons 75 and older and frontline essential workers being in phase 1b," he said at the meeting. "However, I voted no because I feel that the science regarding COVID-19 morbidity and mortality supports notable similarities between the 65- and 74-year-old group and the 75 years and older group. Therefore, inclusion of the 65- to 74-year-old group in phase 1b made more sense to me. I also believe overall implementation of this unprecedented, complex national vaccination would be simplified by doing so."[3]

A Difficult Choice

Even some members who voted to approve the aforementioned priority groups expressed consternation about bypassing the 65-74 age group.

"I really want to reiterate my concern," said ACIP member **Pablo Sanchez**, MD, of Nationwide Children's Hospital in Columbus, OH. "I feel strongly that the elderly and those with high-risk medical conditions really should be up front over some potential workers who may be younger."[3]

Several ACIP members said it was the most difficult vote during their tenure on the advisory panel. "For every group that we add, we need to subtract a group," said ACIP member **Helen Talbot**, MD, MPH, of Vanderbilt University. "For every group that we subtract, they don't get the vaccine. It has been very humbling and heartbreaking."[3]

In approving the recommendation, the committee was "trying to thread the needle," said ACIP member **Peter Szilagyi**, MD, MPH, of UCLA Health.

"I voted for this recommendation because, in my opinion, it follows the evidence about the risk of coronavirus and the ethical principles that we have developed at ACIP to maximize benefits and minimize harm, and to mitigate health inequity," he said.[3]

ACIP member **Grace Lee**, MD, of Stanford University, said the panel's goal is to provide safe and effective vaccines for the entire population. In working toward this aim, vaccines can bring unity and hope to people.

"However, we have seen vaccines become used as a tool for disinformation, fears about allocation, and division within our communities," she said. "We are currently prioritizing vaccine to people at the greatest risk of infections due to their occupation, such as frontline healthcare workers, providers, and essential workers; and those of greatest risk of hospitalizations and deaths, such as long-term care facility residents, older adults, and those with underlying conditions. These priorities reflect the racial, ethnic, and the socioeconomic diversity of the U.S. population."[3]

Still, many public comments submitted to ACIP were critical of the decision to immunize frontline essential workers before those age 65 to 74 years.

"As a physician who has treated COVID cases and a concerned citizen, I want to state that the ACIP guidelines are not well thought through and contain extremely dubious claims," commented **Vikram Vaz**, MD, a radiologist in Houston. "Continuing to prioritize essential workers — many of whom are younger and at lower risk than the elderly or immunocompromised — will directly result in the avoidable deaths of tens of thousands [of] Americans of all races."[4]

In additional guidance and clarification issued after the ACIP meeting, the CDC said adults of any age with "certain underlying medical conditions are at increased risk for severe illness from the virus that causes COVID-19 and can be immunized with the approved mRNA COVID-19 vaccine provided they have not had a severe allergic reaction to any of the ingredients in the vaccine."[5]

This includes people with HIV and those with weakened immunity due to other illnesses or medication. However, they should be aware of the limited vaccine safety data, the CDC emphasized.

"People with weakened immune systems should also be aware of the potential for reduced immune responses to the vaccine, as well as the need to continue following all current guidance to protect themselves against COVID-19," the CDC noted.

According to the CDC, people with autoimmune conditions or those who were previously diagnosed with Guillain-Barré syndrome may receive an mRNA COVID-19 vaccine. Again, they should be aware of the dearth of vaccine clinical trial data in weighing the risk and benefits.

"Cases of Bell's palsy were reported in participants in the mRNA COVID-19 vaccine clinical trials," the CDC noted. "However, the FDA does not consider these to be above the rate expected in the general population. They have not concluded these cases were caused by vaccination. Therefore, persons who have previously had Bell's palsy may receive an mRNA COVID-19 vaccine." ■

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Emerging Coronavirus Variants Are Highly Transmissible

More transmissible variants of the SARS-CoV-2 virus are emerging globally and had been detected in three U.S. states as this report was filed.

The mutated strains do not appear more virulent, but the enhanced transmission narrows the margin of error for breaks in personal protective equipment and other exposures as healthcare workers begin to take their first doses of the COVID-19 vaccines.

The Centers for Disease Control and Prevention (CDC) held a press conference on Dec. 30, 2020, to update the rapidly evolving situation.

"Health officials in the United Kingdom and South Africa recently reported two new variants of SARS CoV-2," said **Henry Walke**, MD, incident manager for the CDC's COVID-19 response. "Both appear to infect people more easily. It is important to know that at this time,

there is no evidence that either of these variants causes more severe disease or increases the risk of death."[1]

The B117 U.K. variant has undergone multiple mutations, some apparently allowing the spike protein of the virus to bind more easily to cells to enhance transmission.

Bad News for Swamped Healthcare

Urging more vigilance with masks, social distancing, and hand hygiene, Walke cited the risk that an increase in cases due to heightened transmissibility could hit a healthcare system that is running on the thinnest of margins in many areas.

"Because the variants spread more rapidly, they could lead to more cases and put even more strain on our heavily burdened healthcare systems," he said.

The variant first seen in the U.K. — which is now spreading among people in the United States with no travel history — is 56% more transmissible than the original pandemic coronavirus, researchers reported in a paper under review.[2] Some models have suggested a higher transmissibility than that, with estimates in the range of 70%.

"As a result of this increased transmissibility, existing control measures are likely to be less effective, and countries may require stronger proactive interventions to achieve the same level of control," the researchers concluded. "We found no evidence that the new variant is associated with higher disease severity, but without strengthened controls, there is a clear risk that future epidemic waves may be larger — and hence associated with greater burden — than previous waves."

The U.K. variant likely has circulated there since September 2020, Walke said. The second variant was first identified in South Africa and has been circulating there since October 2020.

"This second variant developed independently of the first variant," he said. "Both variants have been detected in other countries."

The first case with the U.K. variant recently was identified in Colorado. "The lack of reported travel history suggests that this variant has been transmitted from person to person in the United States," Walke said. "The arrival of this variant in the U.S. was expected, considering how widespread it is in the U.K. and how frequently people travel between the U.S. and the U.K. The evidence to date indicates that both newly emerging variants spread more easily and quickly than other strains."

Vaccines Should Work

A lot remains unknown, including whether the variant in South Africa is spreading within the United States. It had not been detected in the United States as this report was filed.

"Based on our present knowledge, experts believe our current vaccines will be effective against these strains," Walke said. "We're still learning how these variants might respond to drugs and other COVID-19 treatments, including monoclonal antibodies and convalescent plasma."

Gregory Armstrong, MD, director of the CDC Office of Advanced Molecular Detection, also weighed in on the vaccine efficacy issue.

"From what we know from experience with this mutation and other mutations is that it's unlikely to have a large impact on vaccine-induced immunity or on an existing immunity from previous strains," Armstrong said. "It may cause a small impact, but keep in mind that it's likely that the amount of immunity that is induced by either natural infection or by vaccination is great enough that [variant infection] may not have any noticeable effect at all."[1]

The CDC is expanding a national surveillance system rapidly to collect and genetically sequence SARS-CoV-2 strains in the U.S. to identify variant strains.

"We anticipate scaling up to 3,500 whole genome sequences per week," Armstrong said. "This is a consortium of over 160 groups around the U.S. that are doing sequencing. It includes public health, academia, nongovernmental organizations, and industry." ■

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COMING IN FUTURE MONTHS

- The next COVID-19 vaccines for the United States
- Highlights from the AOHP virtual conference
- Administering routine HCP vaccinations during the pandemic
- Medical and nursing students may fall through vaccination cracks

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CE QUESTIONS

1. **Most COVID-19 vaccine-related reactions, such as fever and fatigue, occur:**

   a. on the day of vaccination.
   b. one day after vaccination.
   c. two days after vaccination.
   d. three days after vaccination.

2. **The Centers for Disease Control and Prevention (CDC) considers a history of any immediate allergic reaction to any other vaccine or injectable therapy not related to a component of mRNA COVID-19 vaccines or polysorbate to be:**

   a. an indication for allergy testing before vaccination.
   b. a contraindication for COVID-19 vaccination.
   c. reason for a cross-reactivity test.
   d. a precaution but not a contraindication for COVID-19 vaccination.

3. **Which priority group for COVID-19 vaccine was the source of much debate and consternation at the CDC vaccine advisory committee meeting?**

   a. Those age 75 years and older
   b. Other essential workers
   c. Those age 65 to 74 years
   d. Nursing home workers

4. **What did the CDC recommend regarding Bell's palsy and COVID-19 vaccine?**

   a. Those who have previously been diagnosed with Bell's palsy should not receive the vaccine.
   b. Those who developed Bell's palsy after any type of vaccination should be given the COVID-19 vaccine in a hospital setting.
   c. Those with a history of Bell's palsy should receive only one dose of COVID-19 vaccine.
   d. Those who previously had Bell's palsy can receive the vaccine.

CE OBJECTIVES

After reading each issue of *Hospital Employee Health*, the nurse will be able to do the following:

1. Identify particular clinical, administrative, or regulatory issues related to the care of hospital employees;
2. Describe how the clinical, administrative, and regulatory issues particular to the care of hospital employees affect health care workers, hospitals, or the healthcare industry at large;
3. Cite solutions to the problems faced in the care of hospital employees based on expert guidelines from relevant regulatory bodies, or the independent recommendations of other employee health professionals.