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High Efficacy of COVID-19 Vaccines Buoys Hopes

But safety and public trust must be addressed

By Gary Evans, Medical Writer

Although questions and caveats remain, preliminary reports of two new COVID-19 vaccines in the 90% to 95% effectiveness range have bolstered hopes that healthcare workers may soon be protected and potentially large portions of the public immunized in 2021.

"The effectiveness was stunning," says **William Schaffner**, MD, a professor of health policy at Vanderbilt University and a national vaccine advocate and expert as medical director of the National Foundation for Infectious Diseases (NFID).

Moderna, Inc. recently announced that an independent, National Institutes of Health-appointed Data Safety Monitoring Board determined its Phase III study of a "messenger RNA vaccine," mRNA-1273, has achieved efficacy of 94.5%. The study authors enrolled more than 30,000 participants in the United States. They conducted the work in collaboration with the National Institute of Allergy and Infectious Diseases (NIAID).[1] This was preceded by an announcement from Pfizer Inc. and BioNTech that a similar messenger RNA vaccine had achieved more than 90% efficacy in a Phase III trial with 43,538 participants.[2]

Of course, safety and efficacy data of both vaccines must undergo a thorough review by the Food and Drug

WITH THE U.S. COVID-19 DEATH TOLL AT 250,000, THE VACCINE BREAKTHROUGHS PROVIDED SOME RESPITE AS A "DARK WINTER" OF SURGING CASES BEGAN.

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Administration (FDA), its vaccine and biologic committees, and the CDC's Advisory Committee on Immunization Practices (ACIP). Should those hurdles be cleared, there remain the logistical challenges of delivering the vaccines and assuring a suspect public that it is safe to be immunized. Still, with the U.S. COVID-19 death toll at 250,000 people as of Nov. 19, 2020, the vaccine breakthroughs provided some respite as a "dark winter" of surging cases began.

"The light at the end of the tunnel just got a little brighter," says Schaffner, an ACIP liaison member representing NFID. "We will look at all these data, and I think we will all get a chance to see them when they apply for an Emergency Use Authorization [EUA] and it goes to the FDA."

The companies released some details, but questions remain, including more efficacy data in the elderly and other risk groups, and the longer-term implications for use in pregnancy and children.

"We also don't have the answer for how long the vaccines will protect someone. That will have to be determined going forward," Schaffner says. "By that time, there will be a lot more safety data, and that will be very important. There is hesitancy on the part of so many people, including healthcare professionals of all kinds — doctors, nurses, physician assistants, pharmacists, everybody."

Much of these concerns can be traced to the speed at which vaccines were developed and the fear of political influence during the buildup to the presidential election. Healthcare workers are expected to be the first group immunized when a safe and effective vaccine is approved. The American Medical Association (AMA) recently released a statement noting physicians have an ethical obligation to be immunized when a safe and effective COVID-19 vaccine is developed. The ethical opinion adopted by the AMA House of Delegates also states doctors "have an ethical responsibility to encourage patients to accept immunization when the patient can do so safely, and to take appropriate measures in their own practice to prevent the spread of infectious disease in healthcare settings."[3]

"In the context of a highly transmissible disease that poses significant medical risk for vulnerable patients or colleagues, or threatens the availability of the healthcare workforce, particularly a disease that has potential to become epidemic or pandemic, and for which there is an available, safe, and effective vaccine, physicians have a responsibility to accept immunization absent a recognized medical contraindication or when a specific vaccine would pose a significant risk to the physician's patients," according to the policy.[3]

'Plug and Play' Vaccines

Paul Offit, MD, a member of the FDA Vaccine Advisory Committee, predicted recently at the IDWeek 2020 infectious disease conference that vaccines using the messenger RNA platform would be the first to roll out.

"The reason that the messenger RNA vaccines will be the first is because they are the easiest to construct and mass produce," said Offit, an infectious diseases physician and director of the Vaccine Education Center at Children's Hospital of Philadelphia. "It is not necessarily because they are going to be the last, best vaccines. It is because they are they the easiest to make.

They are the so-called 'plug and play' vaccines. You just take the gene of interest — in this case, the gene that causes the coronavirus spike protein — and plug it into your system."

Indeed, the spike protein, which the coronavirus uses to attack and invade cells, is the target of many other vaccines still under development with different platforms, creating the possibility that several effective vaccines eventually will be developed, said **Anthony Fauci**, MD, director of NIAID.

"I think it is quite conceivable that will occur," he noted in a news interview. "The Moderna and Pfizer [vaccines] are strikingly similar, but other types of platforms are [also targeting] the spike protein of the coronavirus."[4]

Both the Moderna and Pfizer vaccines are administered in two doses, with the former at four weeks apart and the latter at three weeks.

"The primary endpoint of the Phase 3 COVE study is based on the analysis of COVID-19 cases confirmed and adjudicated starting two weeks following the second dose of vaccine," Moderna stated. "This first interim analysis was based on 95 cases, of which 90 cases of COVID-19 were observed in the placebo group vs. five cases observed in the mRNA-1273 group, resulting in a point estimate of vaccine efficacy of 94.5%."[1]

For its part, Pfizer said, "the case split between vaccinated individuals and those who received the placebo indicates a vaccine efficacy rate above 90%, at 7 days after the second dose. … Analysis evaluated 94 confirmed cases of COVID-19 in trial participants … [The vaccine] BNT162b2, against SARS-CoV-2, has demonstrated evidence of efficacy against COVID-19 in participants without prior evidence of SARS-CoV-2 infection, based on the first interim efficacy analysis conducted on Nov. 8, 2020, by an external, independent [review board] from the Phase 3 clinical study."[2]

"Now, we have two vaccines that are really quite effective," Fauci said. "This is a really a strong step forward to where we want to be [in terms of] getting control of this outbreak." Fauci projected that vaccines from both companies should be available by the end of December 2020, with larger stockpiles accessible in 2021.[4]

One key difference in the two vaccines is Pfizer requires subfreezing storage and handling, while the Moderna vaccine requires less demanding frozen storage.

"The storage and handling requirements of the Moderna vaccine are less stringent than those of the Pfizer vaccine," Schaffner says. "They resemble the requirements of most routinely used vaccines. That will ease the logistical complexities of distribution and administration, permitting it to be used in local doctors' offices, clinics, and pharmacies. This will allow us to bring the vaccine to the people rather than having to bring the people to the vaccine."

If both vaccines are approved and made available, Pfizer's could be deployed to facilities that have the capacity to maintain the extreme temperature levels.

"I would guess that probably the only reasonable way to do this is to establish vaccine centers for the Pfizer vaccine," Offit said in a recent interview. "The center is just devoted to giving vaccine, [along] with hospitals, assuming [their] pharmacies would be willing to take this on. I think otherwise it would be really hard to do this, but we'll see."[5]

Both vaccines must be thoroughly analyzed and reviewed by the FDA, including a safety requirement to follow at least 50% of vaccine recipients for a median of two months. Pfizer previously began this requirement. The company filed an EUA application with the FDA on Nov. 20, 2020.

According to its industry news release, 42% of Pfizer vaccine recipients come from diverse backgrounds. No serious safety issues have been observed thus far. The protective effect is at 28 days, one week after the second dose. The vaccine can cause local and systemic reactions, Schaffner says.

"One of the things that is characteristic of this vaccine — like shingles vaccine, but worse — is that it is very reactogenic," Schaffner says. "A lot of people get sore arms that can last a day or two. There are other people who feel rather puny for days, with aches and pains, headaches, even a degree of fever."

Complicating matters, in terms of getting people to return for the second dose, is that the side effects are worse after the final shot. "It's also reactogenic systemically," he says. "Not everybody, of course, but it is a notable percentage, and we will have to alert recipients to this. Some people are going to make that calculation that 80% of people with COVID do pretty well — is it worth taking another dose?"

With healthcare workers designated a top priority, arrangements to immunize them in shifts may have to account for possible sick staff the following day.

"You don't want to give it to all the workers in a long-term care facility and have a third of them not come in to work the next day," Schaffner says. "That would complicate the scheduling considerably as we go forward. Even larger hospitals, given the shortage of workers we have now, will need to be careful about their scheduling."

While Schaffner described the Pfizer side effects in the absence of company-released data, Moderna released specifics that nevertheless made direct comparisons difficult.

"The majority of adverse events were mild or moderate in severity," Moderna stated. "Grade 3 (severe) events greater than or equal to 2% in frequency after the first dose included injection site pain (2.7%), and after the second dose included fatigue (9.7%), myalgia (8.9%), arthralgia (5.2%), headache (4.5%), pain (4.1%), and erythema/redness at the injection site (2.0%). These solicited adverse events were generally short-lived."[1]

Reaching At-Risk Groups

The Moderna trial was a randomized, 1:1, placebo-controlled study testing of the mRNA-1273 vaccine at the 100-µg dose level in 30,000 participants in the U.S., ages 18 years and older. The study included more than 7,000 participants older than age 65 years. It also included 5,000 Americans younger than age 65 years with high-risk, chronic diseases, such as diabetes, severe obesity, and cardiac disease, that put them at increased risk of severe COVID-19 infection.

"These medically high-risk groups represent 42% of the total participants in the Phase 3 COVE study," Moderna noted. "The study also included communities that have historically been underrepresented in clinical research and have been disproportionately impacted by COVID-19. The study included more than 11,000 participants from communities of color, representing 37% of the study population, which is similar to the diversity of the U.S. at large. This includes more than 6,000 participants who identify as Hispanic or Latinx, and more than 3,000 participants who identify as Black or African American."

Of 11 severe cases of COVID-19 cases in the trial, all occurred in the placebo group and none in the vaccinated group. "The 95 COVID-19 cases included 15 older adults (ages 65+) and 20 participants identifying as being from diverse communities — including 12 Hispanic or Latinx, four Black or African Americans, three Asian Americans, and one multiracial," Moderna stated.[1]

By the end of 2020, Moderna expects to produce approximately 20 million doses of mRNA-1273 to ship in the United States. The company estimates it will manufacture 500 million to 1 billion doses globally in 2021.

Pfizer and BioNTech expect to produce up to 50 million vaccine doses in 2020 and up to 1.3 billion doses in 2021. They also plan to submit data from the full Phase III trial to a scientific peer-reviewed publication.[2] ■

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Occupational COVID-19 Exposures to Colleagues

PPE fatigue, breaks are factors

Healthcare workers may be vigilant with personal protective equipment (PPE) around COVID-19 patients, but inadvertently expose themselves to colleagues when they take breaks, socialize, and eat, said **Connie Steed**, MSN, RN, CIC, FAPIC, director of infection prevention and control at Prisma Health in Greenville, SC.

"When we have seen clustering, our drill-down investigations have identified that, typically, our healthcare providers are not being exposed by patients infected with COVID-19," she said recently at the IDWeek 2020 conference, held Oct. 21-25. "When they are with patients, they follow protocol. What we have found is that our healthcare providers will relax a little bit when they're in the break room, even though the guidelines say they need to socially distance and keep their masks on unless they are eating or drinking. That, many times, does not occur. Therefore, they expose each other to a provider who is asymptomatic."

PPE Fatigue Contributes

Part of the problem is healthcare workers are experiencing PPE fatigue and may be tempted to removed gear for brief respites when possible.

"Our providers are tired," Steed noted. "In organizations across the country, there have been reports of significant outbreaks related to providers laxing off on PPE. Not necessarily on COVID-19 wards, but on the regular units where they take care of patients they don't suspect have [the virus]. We need to really pay attention to what our providers are doing, not only when they are in the room caring for the patient, but also outside of that environment when they take their mask down when they are talking to someone because their voices are muffled."

Steed's hospital has adopted a "200% accountability" campaign encouraging healthcare providers to be role models. "COVID-19 is a pandemic and it is still here," she said. "We have flu coming, and we need to clean our hands and wear our masks. We are going to be communicating in different ways — nonverbally — when we observe providers not following a rule. Hopefully, this useful help will mitigate some of their risk."

Collaboration between employee health and infection prevention is critical. "Make sure that your occupational health department and team have updated guidance," Steed said. "Make sure that when they see clustering of healthcare provider infections that they contact infection prevention and control so you can undertake an investigation and figure out what is going on. Assess your organization's exposure management process, and continue to alter it and change it as need arises."

PPE lapses in break rooms and during meals has been an ongoing issue, but leaders are using several tactics to address the problem. "What we have done that has probably had the biggest impact is actually go to the area and talk to the providers who are using the space," Steed said. "If they are not using it properly, help them change it. We have brought engineering in and removed chairs and moved things to socially distance them. Some of our facilities and departments have posted the maximum number of individuals who can take a break in that space, based on the size. That seems to have worked."

Intervention and observations must occur during all shifts if exposures are to be prevented. "We have found that after hours we need to have someone who goes around and observes," she explained. "We have also set up some locations where providers have a huge community room space. There are hand hygiene rubs on every table, and the limit is two people per table. We also have changed some of our waiting rooms throughout the organization, where they are closer to the unit so they can eat and drink. They are more apt to use those because it is closer to where the patients are. We have also set up areas outside. People enjoy going out to eat, and it gets them out in the fresh air and the risk is less."

With PPE fatigue and other issues undermining worker protections, facilities need to restore the sense of urgency that hit the healthcare system with the pandemic's emergence.

"From what I hear as I talk to people around the U.S., we have to ensure access to PPE and training," Steed said. "We need to make sure that the PPE denial or laxity we are seeing now is turned around."

New CDC Training

The Centers for Disease Control and Prevention (CDC) has launched on online, interactive training network on infection control aimed at both frontline healthcare workers and other personnel.

"Project Firstline [is] a comprehensive infection control program designed to help prevent the spread of infectious diseases in U.S. healthcare settings," the CDC states. "Project Firstline will reach healthcare workers in all healthcare settings, including hospitals, outpatient clinics, dialysis centers, and nursing homes. Core training is posted to address immediate workforce infection control training needs, delivered via short and accessible training videos. The site also includes practical tools to support everyone working in a healthcare facility as they implement infection control protocols and procedures throughout their workday."[1]

The training should help clarify and reinforce CDC guidelines on COVID-19 and other infectious threats. "Their focus is on frontline providers and staff, and I think that this is long overdue," Steed noted. "It's hard and challenging many times to grasp the rationale of basic IP prevention practices."

The educational materials include concise 10-minute videos that do not require a certain level of training or educational background to understand. They offer interactive features through periodic "knowledge checks" during training.

"If you look at what they have online, they have a general one on hand hygiene, and then their focus right now is long-term care and dialysis," says Steed. "I think that in the future they will get into some other topics. Right now, their focus is on COVID, the basics of hand hygiene, and things like that."

Steed has shared the training on long-term care and dialysis with staff in her facility. "I see them using it as support and validation for what needs to be done," she said. "These short videos are excellent. They can be used at a staff meeting and are accessible from any computer."

Regarding PPE, **Michael Bell**, MD, deputy director of the CDC's Division of Healthcare Quality Promotion, recently gave an overview in a webinar hosted by one of the project's sponsors, the American Medical Association. There are some questions and confusion regarding masks, N95 respirators, or the lack thereof.[2]

"Full disclosure: We are painfully aware of the supply chain challenges that many of the facilities are experiencing," Bell said. "It is a very frustrating situation in the context of something like the COVID-19 pandemic."

Given the supply limitations, particularly of N95s, Bell said the CDC resorted to crisis standards.

"There are certain things where you should always be using an N95, assuming you have them," he explained. "There are currently recommendations that say if, for any reason you are not able to use respirators in a single-use disposal kind of way, we have available crisis standards that are not intended to be normal practice.[3,4] But if you are up against the wall and you are needing to do something, we have suggestions for how to extend the use of respirators. In other words, keep them on and going from patient to patient, or, if you are absolutely out, using surgical masks as a temporary alternative. They are not as good, but they are definitely better than nothing." ■

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With Political Change, OSHA Infectious Disease Standard Appears Back in Play

Standard would protect healthcare workers from infectious disease

In acknowledged underestimates, the Centers for Disease Control and Prevention (CDC) reports tens of thousands of healthcare workers have acquired COVID-19 and hundreds have died. With CDC guidelines nonregulatory, politicized, and too often ignored during the pandemic, the question arises: Could an enforceable infectious disease standard by the Occupational Safety and Health Administration (OSHA) have saved lives during the pandemic?

David Michaels, PhD, former OSHA chief during the Obama administration, told *Hospital Employee Health*, "There is no question that an OSHA infectious disease standard would prevent illnesses and deaths among healthcare workers."[1]

Michaels moved the standard forward to the rulemaking agenda by the end of his tenure. OSHA's infectious disease standard was in the legislative pipeline, but it fell into political limbo after the 2016 presidential election led to a new antiregulatory environment. The recently proposed Heroes Act (H.R. 6800) would require OSHA to issue an emergency temporary standard to protect workers in hospitals, meatpacking plants, retail stores, and other workplaces during the pandemic. Although stuck in the Senate, the proposed law also would prohibit employers from retaliating against workers for sounding the alarm about unsafe conditions.[2]

As originally proposed, the standard would include a Worker Infection Control Plan (WICP). Employers would have been required to create a WICP for those at risk of occupational exposures to infectious diseases during patient care and other duties. In a provision that seems particularly germane to the situation, the standard called for worker protections to be reviewed and updated to meet the threat of new and emerging infectious diseases.

With President-elect Joe Biden emphasizing unions and worker safety during his campaign, labor advocates anticipate the OSHA standard and other occupational protections will be priorities under the new administration. Hospital groups have opposed OSHA regulations as burdensome, and the agency itself has said in recent congressional testimony that it currently has sufficient regulatory authority under its general duty clause to protect healthcare workers from COVID-19.[3]

In that regard, OSHA recently announced $2.8 million in fines have been levied based on 179 inspections for violations relating to coronavirus as of Nov. 5, 2020.[4] OSHA inspections have resulted in the agency citing employers for violations, including failures to:

- Create a written respiratory protection program;
- Provide respirator fit-testing, medical evaluations, and training on the proper use of PPE and respirators;
- Report an injury, illness, or fatality;
- Record an injury or illness on OSHA recordkeeping forms.[4]

Nevertheless, the Washington State Nurses Association and several other labor unions recently sued OSHA, demanding an infectious disease standard to protect healthcare workers.

"OSHA lacks a standard addressing occupational exposure to infectious diseases transmitted by contact (such as MRSA or norovirus), droplets (such as H1N1 and SARS-CoV-2), or the air (such as measles)," the lawsuit alleges. "In fact, OSHA currently has only one standard that directly addresses workplace infectious diseases: the Bloodborne Pathogens standard (29 CFR § 1910.1030), which covers only infectious diseases transmitted by blood. … OSHA has a duty to issue a safety and health standard to protect healthcare workers from the significant risk of harm from infectious diseases. The record of the risk to public health from HAIs [healthcare-acquired infections], even in ordinary times, is clear. The risks are especially high during pandemics like H1N1 in 2009 and now COVID-19."[5] ■

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15 Minutes of Infamy? CDC Warns of Cumulative Exposures

The Centers for Disease Control and Prevention (CDC) raised questions after the agency said clinically significant COVID-19 close-contact exposures could occur in intervals over time. For example, three five-minute exposures over a 24-hour period would roughly equal a 15-minute exposure for that day.

Data are limited, making it difficult to precisely define "close contact," the CDC stated. "However, 15 cumulative minutes of exposure at a distance of six feet or less can be used as an operational definition for contact investigation."[1]

Factors to consider when defining close contact include proximity, the duration of exposure, and whether the infected individual is exhibiting symptoms. The situation is further aggravated if the source case generates respiratory aerosols by coughing, singing, or shouting. Indoor crowding with poor ventilation would likely worsen these effects as opposed to an outdoor gathering with spacing.

Michael Bell, MD, deputy director of the CDC's Division of Healthcare Quality Promotion, recently addressed this issue in some detail in a webinar by the American Medical Association.[2] Bell's comments have been edited for length and clarity:

Bell: The risk of infection is a combination of how much infectious material is being generated. This is a reflection of whether the individual who is ill is manifesting symptoms. We have data some people generate a lot more droplets and aerosols even when they are speaking quietly — not even from coughing. We have all seen the range of sneeze and cough behaviors. That's one factor — people generating a lot of [viral] material. Related to that is the pathophysiology of the infected individual themselves. Is there a large enough infectious virus being generated? Are they making a lot and projecting a lot? That's the source piece.

The environment piece is the second step. Are you in a very ventilated outdoor location, or are you in a small space with very little air exchange? Those are the two extremes. In the former, the risk is much lower; in the latter category, the risk is much higher. What we are seeing is that in enclosed places with poor air exchange, we are much more likely to see transmission from cases to multiple individuals.

The examples we have seen so far include exercise classes that were in small, not well-ventilated locations, where one person who was shouting and breathing hard during exercise managed to infect a large proportion of people in that small space. We don't see that systematically, but we do when the conditions are right. Similarly, in a choir practice — we have seen this in a couple of examples now — in places without great air exchange, somebody who is aggressively generating aerosols by singing was able to infect a large number [of people] who were nearby.

The third factor is: What sort of mitigation actions are being taken? If the patient who is the source is wearing a mask, that vastly reduces the efficiency of [viral] release. Also, if you are wearing a mask — even if it is not a fit-tested N95 respirator — there is some effect.

We are starting to see data that goes from really great [protection] with a respirator to something like 40% to 50% with surgical masks. There is some benefit to wearing protection as well as keeping from exposing others to your own secretions. There are other factors, like inherent susceptibility based on your genetic makeup, but those are the factors that I think about.

With these in mind, the time that you spend in that context also is related to your likelihood of receiving enough of a dose to initiate an infection. The longer you are in that exposed setting, the more likely you are to be infected. We use the number 15 minutes, and this was originally proposed as a 15-minute [exposure] time. There is this question now — and we will be saying more about

this in the coming weeks — that is related to an outbreak that occurred at a prison setting. What we saw there was a relationship with time, but it wasn't just once — it was cumulative. It makes sense that cumulative series of exposures to shorter periods would add up to be a greater risk. It's not as if you breathe for 14.99 minutes and only once you cross that threshold you become infected — that's not how it works. Basically, if you think about it from a probability perspective, if you are spending two minutes with eight patients, there is a possibility that one of those people are going to be shedding coronavirus and you might be unlucky enough to be infected in that two-minute segment. A lot of segments are probably as bad as having one big one.[2] ■

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COVID-19 Inflammatory Syndrome Emerging in Adults

The pathophysiology of MIS in both children and adults is unknown

Healthcare workers could be at risk of multisystem inflammatory syndrome (MIS) linked to COVID-19, as the poorly understood condition first seen in children now is emerging in adults.

Findings indicate adult patients of all ages with current or previous SARS-CoV-2 infection can develop a hyperinflammatory syndrome resembling MIS-C, the Centers for Disease Control and Prevention (CDC) reported.

"Although hyperinflammation and extrapulmonary organ dysfunction have been described in hospitalized adults with severe COVID-19, these conditions are generally accompanied by respiratory failure," the CDC states. "In contrast, the patients described here had minimal respiratory symptoms, hypoxemia, or radiographic abnormalities in accordance with the working case definition, which was meant to distinguish MIS-A from severe COVID-19; only eight of 16 patients had any documented respiratory symptoms before onset of MIS-A."[1]

The pathophysiology of MIS in children and adults is unknown. "Eight of 27 (30%) adults described in this report and 45% of 440 children with MIS-C reported to CDC through July 29, 2020, had negative PCR and positive SARS-CoV-2 antibody test results, suggesting MIS-A and MIS-C might represent postinfectious processes," the CDC noted. "All but one of the patients with MIS-A described in this report belonged to racial or ethnic minority groups."

Hospital Employee Health submitted questions to CDC investigators and received the following answers, which have been edited for clarity:

HEH: Can you describe what differences, if any, you are seeing in this syndrome in adults compared to children?

CDC: Researchers have described MIS in children since April 2020. This review describes nine adult patients reported to CDC, seven published case reports, and summarizes the findings in 11 adult patients described in three published case series. Children are more likely to contract asymptomatic or mildly symptomatic COVID-19 than adults. In this case report, the patients had less dermatologic and gastrointestinal involvement than the numbers reported in children.

HEH: Can you provide more detail on the adult patients?

CDC: These 27 patients with MIS-A exhibited signs and symptoms in various parts of the body (such as the heart, digestive tract, nervous system, or skin) and didn't have severe respiratory illness. Although some patients had positive viral tests, antibody testing was required to identify SARS-CoV-2 infection in approximately one-third of the 27 cases. A positive antibody test indicates previous infection. In the working case definition used in this description, the lack of respiratory symptoms at presentation represents the main distinction between patients with severe COVID-19 and MIS-A. Patients may present with multiorgan dysfunction without history of

symptomatic SARS-CoV-2 infection or acute COVID-19, thus requiring an antibody test to confirm the diagnosis.

HEH: What were the morbidity and mortality outcomes for these patients?

CDC: The 16 patients reported to CDC and in published case reports ranged in age from 21-50 years and included seven men and nine women. Nine patients had no reported underlying medical conditions; six had obesity, one had poorly controlled type 2 diabetes, two had hypertension, and one had sleep apnea. Six patients were initially evaluated for possible heart trouble symptoms, such as chest pain or palpitations; all 16 had evidence of dysfunction related to the heart. All patients had evidence of laboratory evidence of inflammation. Ten patients tested positive for SARS-CoV-2 at their initial assessment. Among seven patients with negative viral test results, five had positive antibody test results when first evaluated. Ten patients required intensive care, including three who required mechanical ventilation, and two who died.

As the COVID-19 pandemic continues, clinicians and health departments should consider MIS-A in adults with compatible signs and symptoms. Antibody testing might be needed to confirm previous infection, as these patients might not have positive test results from viral or antigen testing. ■

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Will COVID-19 Establish an Animal Reservoir?

Minks farmed for their fur are acquiring SARS-CoV-2 from humans and transmitting it back, a classic scenario for a possible genetic mutation that could create a mismatch with some vaccines under development, the World Health Organization (WHO) reported.

"Since June 2020, 214 human cases of COVID-19 have been identified in Denmark with SARS-CoV-2 variants associated with farmed minks, including 12 cases with a unique variant, reported on 5 November," WHO stated. "All 12 cases were identified in September 2020 in North Jutland, Denmark. The cases ranged in age from 7 to 79 years, and eight had a link to the mink farming industry, and four cases were from the local community."[1]

While the clinical presentation in humans was similar to other COVID-19 infections, WHO reported a so-called "cluster 5" variant with a combination of previously unobserved mutations.

"Preliminary findings indicate that this particular mink-associated variant identified in both minks and the 12 human cases has moderately decreased sensitivity to neutralizing antibodies," WHO reported. "Further scientific and laboratory-based studies are required to verify preliminary findings reported and to understand any potential implications of this finding in terms of diagnostics, therapeutics, and vaccines in development."

To head off the threat, Danish officials are culling more than 17 million farmed minks and will conduct mass PCR testing of the human population in the Jutland area. They are increasing surveillance of the local population to detect all COVID-19 cases, including through population-wide mass PCR testing for the region of North Jutland. Officials also will conduct genetic sequencing of human and mink SARS-CoV-2 to identify the mutated strain. Mitigation efforts include limiting transportation and movement between Jutland and other cities.

"Minks were infected following exposure from infected humans," WHO reported. "Minks can act as a reservoir of SARS-CoV-2, passing the virus between them, and pose a risk for virus spillover from mink to humans. People can then transmit this virus within the human population. Additionally, spillback (human-to-mink transmission) can occur."

At the time of this report, Denmark, the Netherlands, Spain, Sweden, Italy, and the United States have reported SARS-CoV-2 in farmed minks.

While the general scientific consensus is epidemic coronaviruses arise from bats, the original severe acute respiratory syndrome (SARS) in 2002 found an intermediate host in palm civets sold at Chinese wet markets.[2] Similarly, Middle East respiratory syndrome (MERS) has established a reservoir in camels. Palm civets were aggressively culled, and SARS disappeared. The first MERS cases emerged in 2012, and the link to dromedary camels is now

well-established. Due to their central cultural role in the region, camels have not been culled, and MERS still sporadically spread.[3]

Finding SARS-CoV-2 in minks and, to a lesser extent, other animals, raises the possibility that coronavirus will eventually become endemic through an animal reservoir.

Research on Animals and COVID-19

In addition to minks, the CDC reports ongoing research on a variety of other animals and COVID-19.

"These findings were based on a small number of animals, and do not show whether animals can spread infection to people," the CDC stated.[4]

The studies thus far reveal:

• Cats, dogs, ferrets, fruit bats, hamsters, and tree shrews can become infected. They can spread the infection to other animals of the same species in laboratory settings.

• Data suggest dogs can become infected but might not spread the virus to other dogs as easily as cats and ferrets can spread it to other animals of the same species.

• Researchers have studied nonhuman primates as models for human infection. Rhesus macaques, cynomolgus macaques, Grivets, and common marmosets can become infected and sick in lab settings.

• Lab mice, pigs, chickens, and ducks do not appear to catch or spread infection.

• The CDC, the U.S. Department of Agriculture, state public health and animal health officials, and academic partners are working to conduct active surveillance of SARS-CoV-2 in pets, including cats, dogs, and other small mammals, that had contact with a person with COVID-19. The animals are tested for infection and to see whether the pet develops antibodies.

The WHO recommended detailed analyses and scientific studies to better understand the reported mutations. Other key points recommendations in the report:

• "The sharing of full genome sequences of human and animal strains will continue to facilitate detailed analyses by partners.

• "This event highlights the important role that farmed mink populations can play in the ongoing transmission of SARS-CoV-2 and the critical role of strong surveillance, sampling, and sequencing SARS-CoV-2, especially around areas where such animal reservoirs are identified.

• "The preliminary findings by Denmark are globally relevant, and WHO recognizes the importance of sharing epidemiological, virological, and full genome sequence information with other countries and research teams, including through open-source platforms.

• "All countries should enhance surveillance for COVID-19 at the animal-human interface where susceptible animal reservoirs are identified, including mink farms.

• "Strengthen farming biosafety and biosecurity measures around known animal reservoirs to limit the risk of zoonotic events associated with SARS-CoV-2. This includes infection prevention and control measures for animal workers, farm visitors, and those who may be involved in animal husbandry or culling.

• "WHO advises against the application of any travel or trade restrictions for Denmark based on the information currently available on this event."[1] ■

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HOSPITAL EMPLOYEE HEALTH

CE INSTRUCTIONS

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CE QUESTIONS

1. **Of the new investigational Moderna and Pfizer COVID-19 vaccines, which requires two separate doses?**

   a. Both
   b. Moderna only
   c. Pfizer only
   d. Neither

2. **The Washington State Nurses Association and several other labor unions recently sued OSHA, demanding:**

   a. patient lift equipment be required by hospitals.
   b. an infectious disease standard.
   c. an ergonomics standard.
   d. nurse-patient ratios.

3. **According to the Centers for Disease Control and Prevention, how many "cumulative" minutes at a distance of six feet or less from a COVID-19 case could trigger a contact investigation?**

   a. 10
   b. 15
   c. 20
   d. 30

4. **Of 95 infections in the Moderna study, how many were in the vaccine group?**

   a. None
   b. Two
   c. Four
   d. Five

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 healthcare 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.