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FDA Approves Pfizer Vaccine for COVID-19

Designated groups first, but approval is for all 16 years of age and older

By Gary Evans, Medical Writer

The Food and Drug Administration's (FDA) vaccine advisory committee has approved the use of the COVID-19 vaccine developed by Pfizer Inc. (NYC) and BioNTech (Mainz, DEU) in the United States for those ages 16 years and older. In a Dec. 10, 2020, vote, the FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) approved the broader population group, while acknowledging the first doses will go to healthcare workers, including those in long-term care, and long-term care residents.

Those priority groups were designated by the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP). (*See related story,* "Healthcare Workers Cleared for COVID-19 Shots, Long-Term Care Residents Raise Safety Concerns.") ACIP was expected to sign off on the action, and vaccine distribution and immunizations in the first groups were to follow in rapid fashion.

There was a matter of contention among FDA advisors about including those 16 and 17 years of age, with some citing insufficient data but others urging the committee to go forward and approve the resolutions as written. The resolution that passed to grant the vaccine an Emergency Use Authorization (EUA) was written as a question: "Based on the totality of scientific evidence available, do the benefits of the Pfizer BioNTech vaccine outweigh its risk for use for individuals 16 years of age and older?"

Paul Offit, MD, a pediatrician and VRBPAC member, said at the meeting, "I support this statement as written. It's never a question of when you know everything — it's a question of when you know enough. The fact of the matter is

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that 16- and 17-year-olds can get this infection. We have had children in our hospital who have had cardiac anomalies at 16 and 17 years old. We have such a [vaccine] benefit and all we have on the other side is a theoretical risk."

The resolution question was approved in the affirmative by the FDA committee, with 17 "yes" votes, four "no" votes, and one abstention. The record number of daily COVID-19 deaths in the United States and the high efficacy of the vaccine were common threads throughout the discussions.

"A Phase III randomized and placebo-controlled trial using BNT162b2 in approximately 44,000 participants is currently ongoing to evaluate the vaccine's safety and efficacy," Pfizer said in documents submitted to the FDA. "Vaccine efficacy for the primary endpoint against confirmed COVID-19 occurring at least seven days after the second dose was 95.0% with eight COVID-19 cases in the vaccine group compared to 162 COVID-19 cases in the placebo group."

Safety, Adverse Events

The frequency of serious adverse events was low (< 0.5%), without meaningful imbalances between study arms, Pfizer stated. There was a slight numerical imbalance of adverse events potentially representing allergic reactions, with more participants reporting hypersensitivity-related adverse events in the vaccine group (137 [0.63%]) compared with the placebo group (111 [0.51%]), Pfizer reported.

"Among non-serious unsolicited adverse events, there was a numerical imbalance of four cases of Bell's palsy in the vaccine group compared with no cases in the placebo group, though the four cases in the vaccine group do not represent a frequency above that expected in the general population," the company reported. Some of the palsy cases resolved naturally, but this condition will be tracked by the FDA.

Safety data presented to the FDA included approximately 38,000 participants ≥ 16 years of age randomized 1:1 to vaccine or placebo, with a median of two months of follow-up after the second dose. The findings suggest a favorable safety profile, with no specific safety concerns identified that would preclude issuance of an EUA. Participants enrolled through Nov. 14, 2020, brought the number of participants to 43,252, which was consistent with the safety profile, the company said.

"The most common solicited adverse reactions were injection site reactions (84.1%), fatigue (62.9%), headache (55.1%), muscle pain (38.3%), chills (31.9%), joint pain (23.6%), [and] fever (14.2%); severe adverse reactions occurred in 0.0% to 4.6% of participants, were more frequent after dose 2 than after dose 1, and were generally less frequent in participants ≥ 55 years of age (≤ 2.8%) as compared to younger participants (≤ 4.6%)," Pfizer reported.

There are unknown risks and safety issues that may not come to light until a larger number of people are vaccinated. "There are currently insufficient data to make conclusions about the safety of the vaccine in subpopulations, such as children less than 16 years of age, pregnant and lactating individuals, and immunocompromised individuals," Pfizer reported.

Serious side effects to vaccines almost invariably occur within six weeks of getting a dose, although long-term effects cannot be ruled out, Offit said in comments before the meeting.

"Usually, if you have a serious side effect, you will find it out very quickly," Offit said. "Now, that said, 20,000 people isn't 20 million people and you are only going to find out a rare, serious event post-approval. That has always

been true. But the good news is there are systems in place, like the vaccine safety [active systems] and the Vaccine Adverse Event Reporting System to pick that up."

With more than a quarter of a million people dead of coronavirus in the United States in a pandemic that continues to surge, the risk of not getting vaccinated has accumulated considerable weight. The United Kingdom has already approved the Pfizer vaccine and there was some pressure on the United States to get a vaccine on the market.

"There is another side to this – the choice not to get a vaccine is not a risk-free choice," Offit said in a live stream interview before the FDA meeting.[1] "It is a choice to take a different risk. The term 'safety' in the medical world means that benefits outweigh theoretical risks. It does not mean absolute safety. We may find that it causes a serious adverse event post-approval. I hope not, but we have to be open-minded to the fact that that might happen."

The question public health officials weighed then is, "Does the severity of the pandemic, its multiple societal repercussions, warrant a kind of leap of faith to vaccines?"

"I just think you have to be humble in all of this — there are things that I'm sure we don't know yet, so we have to be open to the fact that we don't know everything," Offit said. "But on its face we are dealing with a pandemic that has brought us to our knees. We have massive joblessness, homelessness, and food insecurity. If this vaccine in any way looks like the topline data looks, it's a lifesaver."

'Unprecedented'

The FDA panel was slated to meet again on Dec. 17, 2020, to consider a similar vaccine by Moderna Inc. (Cambridge, MA), which also uses a "messenger RNA" platform and has 95% efficacy. Offit said the development of these vaccines in less than a year is unprecedented.

"If you said to a thousand scientists when a paper was published [early in 2020] that reported the SARS-CoV-2 genome ... that in 11 months you are going to have two clinical trials with a novel vaccine strategy that is going to be studied in 44,000 and 30,000, respectively, using two different constructs of messenger RNA that will induce protection at least soon after the second dose of 95% in protecting against disease — including severe disease, including people greater than 65 years of age — no one would have thought it was possible," Offit said. "I certainly wouldn't have thought it was possible."

There is one caveat, however, as the incidence of disease in the placebo groups in the vaccine trials was unexpectedly low — in the 0.7% or 0.85% range, Offit said.

"You would expect something more like 3% to 3.5%," he said. "When you see it low like that you worry that you are seeing something called 'volunteer bias.' Who volunteers for these trials? It may be people who are attentive to their health, physical distancing, mask wearing, and therefore may be exposed to a lesser inoculum of virus. People who are exposed to a lower inoculum of virus are therefore less likely to suffer a moderate to severe disease."

In real world circumstances, that means the vaccine may not be quite as effective as the 95% levels that stunned the scientific community, he warned. Another factor common to all vaccines is that people may already be incubating illness unrelated to immunization, or they may suffer an unrelated medical emergency after taking the shots.

"What worries me about this is that the SARS-CoV-2 vaccines are only designed to prevent SARS-CoV-2 — not everything else that happens in life," Offit said. "And that is definitely going to happen, especially with people who are older and have more febrile conditions. They are going to get a vaccine, and a few days later they are going to have a stroke or a heart attack. We are going to have to do … epidemiology studies quickly to reassure people that it is occurring at the same rate as background."

That said, he played down the side effects after receiving the shot — particularly the second one, which can be followed by a day of relative misery.

"These messenger-RNA vaccines do induce an immune response," Offit said. "And when your immune response is activated, you have certain symptoms, which can be low-grade fever, headache, muscle ache, and fatigue. Enough so that you could miss a day of work — that's possible. But this is a natural consequence of having an activated immune system."

It remains unknown how long immunity induced by COVID-19 vaccines will last, he said. "These kinds of viruses, which do not have long incubation periods, where viremia is not part of pathogenesis, as a general rule, they induce immunity that is short-lived and incomplete," he said. "By short-lived I mean years, not decades. By incomplete I mean no sterilizing immunity — so protection against moderate or severe disease but not necessarily mild disease. That's OK — all you want to do is keep people out of the hospital and the morgue. I think [the vaccine] can certainly do that, even if there is some fading of immunity at six months, one year, or a two-year period." ■

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Healthcare Workers Cleared for COVID-19 Shots, Long-Term Care Residents Raise Safety Concerns

With one death per minute in United States, 'there comes a time to act'

A Centers for Disease Control and Prevention (CDC) advisory panel finalized COVID-19 vaccine priority for healthcare workers and long-term care residents, although the latter received the greenlight only after discussions of safety concerns that led to the one dissenting vote in a 13-1 approval.

At a Dec. 1, 2020 meeting, the CDC Advisory Committee on Immunization Practices (ACIP) approved the following recommendation: "When a COVID-19 vaccine is authorized by Food and Drug Administration (FDA) and recommended by ACIP, vaccination in the initial phase of the COVID-19 vaccination program (Phase 1a) should be offered to both 1) healthcare personnel and 2) residents of long-term care facilities."[1]

"We have spent eight months discussing and evaluating the data," said ACIP Chair **José Romero**, MD, FAAP, secretary of the Arkansas Department of Health. "Our discussions have been transparent and our motives have been clear. We are using the principles of maximizing benefits and minimizing harms, promoting justice, and mitigating health inequities. Those of us who are in public health see the growing number of cases before us. We see the growing number of healthcare providers that become infected and some of [whom], unfortunately, have passed away. We see that individuals living in long-term care facilities are at exceptional risk for mortality and morbidity due to this virus and disease."

Approved by the CDC director, the recommendation includes long-term care staff among its broad definition of healthcare workers, "as paid and unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials. Long-term care facility residents are defined as adults who reside in facilities that provide a variety of services, including medical and personal care, to persons who are unable to live independently."

These groups are at clear and present danger. As of Dec. 1, 2020, approximately 245,000 COVID-19 cases and 858 deaths had been reported among U.S. healthcare workers. Despite the concerns raised about the safety of immunizing long-term care residents, clearly they are at greatest risk of death if infected with SARS-CoV-2. Although they represent only 1% of the population, long-term care residents represent 6% of all COVID-19 cases and 40% of all deaths, the CDC reported. Approximately 21 million healthcare personnel work in settings such as hospitals, long-term care, outpatient clinics, home health care, public health clinical services, emergency medical services, and pharmacies. About 3 million people are residents of long-term care facilities.

ACIP member **Helen Talbot**, MD, MPH, an infectious disease physician at Vanderbilt University in Nashville, TN, cast the lone "no" vote. Talbot expressed concern about the lack of data on immunizing long-term care residents and whether there was a sufficient safety net in place to follow them for adverse effects. She strongly endorsed the recommendation to immunize healthcare workers, including long-term care staff.

"I have spent my career studying vaccines in older adults," she said. "We have traditionally tried a vaccine in a young, healthy population and then hope it works in our frail older adults. So, we enter this realm of 'we hope it works and we hope it's safe.' That concerns me on many levels, particularly for this vaccine."

There also is the historic background that the elderly typically have less immune response to vaccines, meaning there may be less benefit despite the risk of side effects and long-term problems associated with immunization.

"We know with flu there is little impact of vaccinating residents and a huge impact in vaccinating [long-term care] workers," Talbot said. "I'm [the] odd woman out I guess. I struggled with this — this was not an easy vote. I really hope this highlights that skilled nursing facilities are a population that needs lots of [better] vaccines — not just COVID. We really need to find ways to develop and test these vaccines to prolong quality of life for all long-term care facility residents."

As this report was filed, FDA advisors were weighing the approval of two COVID-19 vaccines in the United States, and the ACIP meeting was conducted with the general anticipation that at least one of them would be cleared for distribution. If the FDA approves a vaccine, ACIP will meet again to determine whether to formally recommend it for the identified 1a groups. The two vaccines under consideration are both "messenger RNA" platforms developed respectively by Pfizer Inc. (NYC) and BioNTech (Mainz, DEU), and Moderna, Inc.

(Cambridge, MA). Totaling more than 70,000 participants in Phase III trials, both vaccines report efficacy of 95%. (*See related story,* "FDA Approves Pfizer Vaccine for COVID-19.")

Hard Choices

The initial vaccine allotments are not expected to be in sufficient numbers to cover all targeted recipients, who must receive two doses several weeks apart to achieve immunity with either vaccine. Thus, initially there will be a need for some "subprioritization" among the targeted groups, an issue that was the subject of much ACIP discussion. The general consensus was that the vaccines should not be mandated because of their emergency use status and lack of long-term safety data.

"We anticipate having about 40 million doses — so, enough to cover some 15 to 20 million individuals … by the end of December," said ACIP Executive Secretary **Amanda Cohn**, MD, of the CDC National Center for Immunization and Respiratory Diseases (NCIRD). "After that, each week we anticipate somewhere between 5 and 10 million [more] doses."

Healthcare personnel comprise clinical staff members, including nursing or medical assistants and support staff members who work in food service, environmental, and administrative services. "Jurisdictions might consider first offering vaccine to healthcare personnel whose duties require proximity (within six feet) to other persons," the CDC stated. "If vaccine supply remains constrained, additional factors might be considered for subprioritization."

ACIP members warned that vaccine supplies could, at some point, be delayed by an unforeseen issue, leading to difficult decisions on who should receive the available vaccine among the designated groups. For example, should healthcare workers with underlying medical conditions, older age, or ethnicity risks be prioritized?

"Each individual healthcare system is going to need to figure out their additional subprioritizations based on doses and the staff that they have," said **Sara Oliver**, MD, MPH, an epidemiologist with the CDC NCIRD.

Patricia Stinchfield, RN, MS, CPNP, an ACIP liaison member representing the National Association of Pediatric Nurse Practitioners, said her hospital does not routinely keep medical and demographic information on many employees, particularly those not involved in direct patient care.

"We don't have birthdates of people in their files," she said. "We have their month and date but not the year, for age discrimination reasons. We may not have race and ethnicity, and we certainly don't have medical records — their own personal medical histories — in the occupational health setting."

Healthcare workers could be asked to disclose underlying risk factors, but that could lead to unintended consequences, warned ACIP member **Grace Lee**, MD, MPH, of Stanford University School of Medicine. "If we ask people to self-disclose, that may inherently create unintended inequities," Lee said. "I worry, by creating that as a construct, we might actually, unintentionally, create more inequity. Lower wage workers may not feel comfortable disclosing medical conditions, but may be faced with higher risk of infections in the community or workplace."

The CDC recommends staggering immunizations among groups of healthcare workers, since the initial side effects of the vaccine may require a sick day after shots are administered.

"The convenience of vaccinating unit-by-unit would be pretty high within a healthcare system, but that could wipe out that unit for a day if people have reactogenicity," said **Paul Hunter**, MD, of the Milwaukee Health Department.

Romero echoed this point. "It goes without saying that this applies to emergency personnel — if you have a mass vaccination of [emergency medical technicians] you could be extremely short of these individuals," he said.

That sounds good in principle, but the logistics are another matter, said **Marci Drees**, MD, MS, an ACIP liaison member representing the Society for Healthcare Epidemiology of America (SHEA).

"The logistics involved are kind of a disconnect," she said. "From a large healthcare system, I won't be able to manage which people on which unit get vaccinated on which days. We're just going to have to manage that on a unit level as much as possible. The smaller hospitals are going to have a really hard time. If they have a hundred-bed hospital, they don't have enough staff [for backup]."

Adequate Safety Net?

Although vaccine supplies are limited, skilled nursing homes with high resident acuity should be considered for vaccination priority in long-term care, the CDC recommended. Some of these decisions and allotments will come down to down to state and public health jurisdictions looking at their vaccine supply and populations at need. Regarding long-term care facilities, concerns were expressed that these sites have not routinely used the longstanding Vaccine Adverse Event Reporting System (VAERS), which is passive surveillance in that it relies on clinicians, manufacturers, and public reports.

"I have no concern about the healthcare personnel," said ACIP member **Robert Atmar**, MD, of the Baylor College of Medicine in Houston. "I remain a bit concerned about including residents of long-term care facilities in the 1a group because of a lack of both safety and efficacy data in that

patient population. I know that plans are in place to do the [safety] monitoring, but there is a potential for a lag of information arising. It will be particularly important to ask the long-term care facilities to vigorously participate in the VAERS program. Staffing to do that may be an issue. I am worried about this group, though I am leaning towards including it."

Indeed, Atmar did vote in favor of the motion after the CDC outlined the many passive and active surveillance systems that are being brought to bear to detect vaccine adverse events for COVID-19 immunizations.

"I want to reassure the ACIP, public health, healthcare providers, and the public that we have the systems in place to collect safety data," said **Tom Shimabukuro**, MD, MPH, MBA, of the CDC's COVID-19 Vaccine Safety Team. "We have validated methods to rapidly analyze the data. We have processes in place to respond to safety signals when we detect them. And we have trusted partners that we will depend on when we implement the vaccination program."

The CDC urged clinicians to help them in this effort through vigilant monitoring and rapid reporting of any COVID-19 vaccine side effects and adverse events.

"I want to reiterate the importance that CDC places on the safety of vaccines," added **Nancy Messonnier**, MD, director of the CDC NCIRD. "I know that the FDA will not authorize a vaccine and ACIP will not recommend a vaccine unless you are convinced based on the Phase III clinical trials that the vaccines are very safe. We know that vaccine safety doesn't stop there, especially for these vaccines. We are going to hold ourselves to an extremely high standard for safety monitoring after a vaccine is authorized and rolled out."

Ultimately, arguments in favor of the motion held the day, as ACIP members argued that they must act in the face of a devastating and expanding pandemic of the novel coronavirus.

"I strongly agree with the recommendations," said **Peter Szilagyi**, MD, MPH, a pediatrics professor at the University of California, Los Angeles. "With the assumption that FDA and ACIP will only recommend a vaccine if the best available evidence shows it is effective and safe. I want to emphasize that post-recommendation guidance and support for any implementation and safety monitoring is critical. As we heard today, that is being planned very well by the CDC."

To underscore the moral imperative, Szilagyi cited Mahatma Gandhi's observation that "a nation's greatness is measured by how it treats its weakest members."

ACIP member **Beth Bell**, MD, MPH, of the University of Washington, Seattle, noted that the United States was averaging one COVID-19 death a minute as the meeting was taking place. "In the time it takes us to have this ACIP meeting, 180 people will have died from COVID-19," Bell said. "We would all like to know more, but we go through a process — we evaluate carefully every bit of information that we have — and then it is time to act."

Pharmacy Partnership

To deliver the vaccine, the CDC is collaborating with the Pharmacy Partnership for Long-Term Care Program, which has enrolled more than 15,000 skilled nursing facilities across the country. "I would assume that most planning around long-term facilities would have them vaccinate both residents and [their] healthcare personnel at the same time," Cohn said. "But there will be some jurisdictions that will likely start with healthcare personnel and then vaccinate residents. It is very dependent on [vaccine] supply and local context."

Questions arose about staff and resident turnover during vaccinations, particularly in the lag period of several weeks after the first dose has been administered.

"It will be a challenge," said **Kathleen Dooling**, MD, MPH, a member of the ACIP vaccine work group and a medical officer in the CDC's division of viral diseases. "The pharmacies that have signed up for this program have agreed to make three separate visits to the facilities in order to vaccinate all persons who wish to be vaccinated. Again, when [the] vaccine is more available in the community this will less of an issue."

The CDC is planning to produce toolkits with information on vaccinating both healthcare workers and long-term care residents, with the latter being particularly important because a vaccine side effect could be taken for an underlying illness or infection.

"We will need to have a lot of guidance post-vaccination to evaluate symptoms, adverse events, or side effects," said ACIP member **Sharon Frey**, MD, of Saint Louis (MO) University Medical School. "Because when the elderly suffer from fatigue and a little fever, people worry about them having an underlying condition."

There also was discussion of a consent/assent process to be sure long-term care residents and their families understand the risks and benefits of the vaccine.

Concerning medical offices and outpatient practices, the CDC recommended public health authorities and healthcare systems work together to ensure COVID-19 vaccine access to healthcare personnel who are not affiliated with hospitals. However, some ACIP members were concerned that this may not take place, emphasizing the risk faced by small practice physicians and medical offices.

"The outpatient community physician in a small private practice

truly is the backbone of the healthcare system," said **Jason Goldman**, MD, FACP, a liaison ACIP member representing the American College of Physicians. "I'm pleased to see that it is considered in [the] healthcare first phase, but we really need to look at the outpatient offices at risk."

He cited a recent study that indicated small-community physicians may be at higher risk of death than their hospital counterparts. "General practitioners, family medicine, and primary care physicians account for 27% of physician deaths, while anesthesiologists, emergency medicine, and critical care physicians account for 7%," the authors found.[2]

"For example, an intensive care unit (ICU) physician, while seeing sicker patients, may have greater access to personal protective equipment (PPE) compared to small offices," Goldman said, adding that it is crucial to vaccinate office staff as well. "[We need to] make sure we are really getting the vaccine to the people on the frontlines who need it the most."

Other ACIP members seconded this concern, saying home health medical workers and first responders also are at heightened risk.

"On the science front, the transmission dynamics of COVID-19 suggest that those providers who care for patients earlier in their course of illness may be at higher risk," said **Jeffrey Duchin**, MD, an ACIP liaison member representing the National Association of County and City Health Officials. "This is supported by information CDC has recently published as well. That would include outpatient healthcare providers." ■

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CDC: COVID's Worst Is Yet to Come

But study shows masks work: 'We are not defenseless'

The COVID-19 pandemic is coming to a disastrous boiling point in the United States, with one of the nation's top public health officials predicting a high death toll as the pandemic surges nationwide over the winter months.

"The reality is, December, January, and February are going to be rough times," said **Robert Redfield**, MD, director of the Centers for Disease Control and Prevention (CDC). "I actually believe they are going to be the most difficult time in the public health history of this nation, largely because of the stress it is going to put on our healthcare system."

Redfield, whose tenure at the agency ends in January 2021 with the change of administrations, spoke Dec. 2, 2020, to the U.S. Chamber of Commerce.[1]

"We really have a very extensive pandemic now throughout the nation," he said. "In the month of November, unfortunately, we had over 1 million cases reported each week — 4 million cases were reported. Our hospitalization rates are going up. Whereas in the spring we were talking about 20,000 to 30,000 people in the hospital, now we are over 90,000 people in the hospital.

"One of the most concerning things about the impact of the pandemic right now is to recognize that 90% of our hospitals in this nation are actually in what we call one of the hot zones, in the red zones," Redfield said.

Underscoring a message that has fallen on too many deaf ears, Redfield emphasized that there now is scientific proof that masking prevents SARS-CoV-2 transmission. In a CDC study in Kansas, counties that adopted a mask mandate saw COVID-19 cases fall, while the disease continued to spread in counties that opted out and did not wear masks.[2]

"The time for debating whether masks work or not is over," he said. "We have scientific evidence."

When comparing counties that opted in, "they had about a 6% decrease in new cases per 100,000. Other counties [that] opted out of the mandate had over 100% increase in cases," Redfield said. "Couple that with social distancing, handwashing, being smart about crowds, doing things more outside than inside — these are critical mitigation steps. They have an enormous impact."

The mask issue was politicized early, going from a common-sense public health measure to a badge of partisanship.

"I am disappointed in one thing as CDC director, and that was that the inconsistency of the American public

embracing the message," Redfield said. "Mask wearing is not a political discussion. This is a powerful public health tool."

Without such measures, even if the vaccines begin to roll out to certain groups, the United States may see another 150,000 to 200,000 COVID-19 deaths by February 2021 — bringing the overall toll to 450,000 in the United States during the pandemic, he said.

"Mitigation works — we are not defenseless," he says. "The challenge with the virus is, it is not going to work if [only] half of us do what we need to do. It is not even going to work probably if three-quarters of us do what we need to do."

Home gatherings are driving some of the upsurge now, particularly since many infected people under age 40 years will have no symptoms.

"[They] don't recognize it until, unfortunately, the virus gets transmitted and somebody that is vulnerable, older, ends up developing symptomatic illness, and they end up in the hospital."

As one "example of hope," Redfield said many colleges have been able to reopen after taking mitigation measures, using widespread screening to identify asymptomatic cases and quarantine them. This "silent" aspect of the pandemic had the CDC back on its heels during the early days of the pandemic.

"One of the big challenges that hit us with this COVID-19 pandemic was we had modeled it like severe acute respiratory syndrome (SARS) or influenza. SARS and influenza make you sick. So, it is not that complicated for you to have a case identification program that says, let's look at people who are sick and [determine] if they have COVID-19 and then isolate, contact trace, and control the pandemic."

But COVID-19 was not like those other respiratory infections. It could spread in the absence of cases, particularly from younger people. "Therefore, we had to say, wait a minute — how do we then define the silent epidemic? How do we define asymptomatic transmission?" Redfield said. "We would argue going back to the college campuses. They figured out by doing regular weekly screenings of students, they are able to identify the asymptomatic infections and pull them out of the transmission cycle, isolate them, contact trace around them, and isolate those individuals, and control the output. There has to be a strategic use of testing."

MASK WEARING IS NOT A POLITICAL DISCUSSION. THIS IS A POWERFUL PUBLIC HEALTH TOOL.

Lessons Learned

No doubt there will be a series of after-action reports and postmortem analyses, but Redfield's immediate verdict is that the nation was "severely unprepared" for the pandemic.

"We have to call it like it is," he says. "I wasn't prepared to understand how little investment had been made in the capabilities of public health. And that is [for] the premier public health institution in our nation. We really have not invested where we need to be in day-to-day data analytics. We haven't invested in what I call laboratory resilience, to make sure our public health capacity has multiple platforms. There is a huge lack of investment, which I hope this pandemic will change."

The costs of the pandemic, including the economic implications, have been estimated in the range of $8 trillion to $20 trillion.

"It would seem wise for us to invest $100 billion across the nation," Redfield said. "Remember, most of our CDC funding actually goes to the local, state, territorial, tribal health departments. In most of the states, we are the dominant funder of the public health infrastructure of those state or local communities. It is time for this nation to have the public health system that we not only need, but we deserve."

Another "painful lesson" is how critical it is to have agreement and harmony in messaging.

"When you really want to get everybody on board, you have to have clear, unified, reinforced messaging," he said. "The fact that we were still arguing in the summer about whether or not masks work was a problem."

The closures of businesses and schools and the shutting down of many healthcare procedures went too far and should be rethought for the next pandemic, he said.

"What did we learn that works?" Redfield said. "What did we learn that didn't work? So, the next time this happens — and there will be a next time — this nation will be much more prepared." ■

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2. Van Dyke ME, Rogers TM, Pevzner E, et al. Trends in county-Level COVID-19 incidence in counties with and without a mask mandate — Kansas, June 1-August 23, 2020. *MMWR Morb Mortal Wkly Rep* 2020;69:1777-1781.

Coronavirus Vaccine Hesitancy in Black and Latinx Communities

Mistrust could undermine uptake in at-risk groups

"I am a Black man and sometimes I don't trust the government. Not in the times we live in now. Sorry."

This answer from a survey respondent on the COVID-19 vaccine underscores the considerable challenge to immunizing people of color and ethnic minorities, who generally are at risk of more serious outcomes if infected with SARS-CoV-2.

The survey by the COVID Collaborative was conducted in September 2020 and reflects attitudes about vaccine hesitancy and resistance in the Black and Latinx communities.[1] The survey collected responses from 1,050 Black adults and 258 Latinx adults.

There have been concerns about the speed of COVID-19 vaccine development and the possible politicization of the process. Historically, minority populations have been victimized in medical research, such as the Tuskegee syphilis experiments. In addition, the nation's vocal antivaccine movement has endangered routine immunization rates, as evidenced by measles outbreaks after the measles, mumps, and rubella vaccine was falsely linked to autism.

"Confirming previous findings, fewer than half of Black adults, 48%, say they probably or definitely would get a coronavirus vaccine if it were available for free — including just 18% who definitely would get vaccinated," the report states. "Among Latinx adults, interviewed for comparison, far more likely would get vaccinated, 66% percent, including 31% percent definitely."

Safety and trust concerns are pervasive in both groups — but their higher levels among Black people are key in these differing vaccination uptake intentions:

- Just 14% of Black adults completely or mostly trust that a vaccine will be safe, compared with 34% of Latinx people.
- Eighteen percent of Black people express trust in vaccine effectiveness, compared with 40% in the Latinx community.
- Black adults are nearly 20% more skeptical than Latinx people that a vaccine will be adequately tested for safety and effectiveness specifically in their own racial or ethnic group.

> HISTORICALLY, MINORITY POPULATIONS HAVE BEEN VICTIMIZED IN MEDICAL RESEARCH.

"The academic literature long has identified lower rates of vaccine uptake among Black people than other Americans," the report notes. "With respect to the seasonal flu, this disparity is connected to worries about vaccine safety, prevalent distrust, racial identities, and experiences of discrimination, among others. This survey builds upon these and other findings in the context of the coronavirus pandemic.

Just 26% of Black people would recommend the COVID-19 vaccine to friends and family. In contrast, 43% of Latinx people would recommend immunization.

"Crucially, messaging must be sensitive to the unique challenges and difficult history of Black Americans with respect to medical practices — and more broadly, experiences of discrimination and inequality," the report concludes. "Among other key results, those who don't think that the government can be trusted to look out for the interests of Black and Latinx people are less likely to trust that a coronavirus vaccine will be safe and less likely to trust the vaccine process. Any efforts to improve intended coronavirus vaccine uptake among Black Americans must address this challenging history and work to repair this trust."

Other comments by survey respondents included those expressing doubts about the development process and perceived political pressure to create a vaccine:

- "The development and trials appear to be rushed because of politics. I wouldn't trust a vaccine that hasn't been tested thoroughly. I don't want to be a victim of side effects that may have been identified if the vaccine were thoroughly tested."
- "Too much haste in developing this vaccine. Politics is being put before people's health and safety."
- "The speed to get a vaccine approved is scary. Until enough research and testing is done, I won't feel safe."
- "The rush to develop a vaccine by companies who have never even developed vaccines [leaves] room for errors and serious side effects."
- "It's a rush vaccination and not truly tested for Black lives."

• "The president has interfered too much, and I don't trust that he is not behind manipulating decisions about drugs safety and readiness."

• "It is too early and appropriate testing has not happened. I feel the vaccine is being rushed for political reasons and African Americans are especially vulnerable to abuses in the process. I am very pro-vaccination but the steps and protocols for approval must be followed." ■

REFERENCE

1. COVID Collaborative. *Coronavirus Vaccine Hesitancy in Black and Latinx Communities*. Nov. 23, 2021. https://www.covidcollaborative.us/content/vaccine-treatments/coronavirus-vaccine-hesitancy-in-black-and-latinx-communities

Are Healthcare Workers Exposing Colleagues to COVID-19?

PPE fatigue contributes

Healthcare workers may be vigilant with personal protective equipment (PPE) around COVID-19 patients, but inadvertently expose 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 at the IDWeek 2020 conference, held Oct. 21-25, 2020. "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 breakroom, 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."

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

"Our providers are tired," said Steed, president of the Association for Professionals in Infection Control and Epidemiology. "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 will help 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 breakrooms and during meals have 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 [United States], 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." ■

Novel COVID-19 Syndrome in Adults

Inflammatory syndrome first seen in children

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 infections 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 polymerase chain reaction 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 Infection Control & Prevention submitted questions to CDC investigators and received the following answers, which have been edited for clarity.

HIC: 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.

HIC: 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.

HIC: 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

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symptoms. Antibody testing might be needed to confirm previous infection, since these patients might not have positive test results from viral or antigen testing. ■

REFERENCE

1. Morris SB, Schwartz NG, Patel P, et al. Case series of multisystem Inflammatory syndrome in adults associated with SARS-CoV-2 infection — United Kingdom and United States, March-August 2020. *MMWR Morb Mortal Wkly Rep* 2020;69:1450-1456.

CME/CE OBJECTIVES

Upon completion of this educational activity, participants should be able to:

1. Identify the clinical, legal, or educational issues encountered by infection preventionists and epidemiologists;
2. Describe the effect of infection control and prevention issues on nurses, hospitals, or the healthcare industry in general;
3. Cite solutions to the problems encountered by infection preventionists based on guidelines from the relevant regulatory authorities, and/or independent recommendations from clinicians at individual institutions.

CME/CE QUESTIONS

1. **Although they represent only 1% of the population, long-term care residents represent what percentage of deaths in all COVID-19 cases?**

   a. 6%
   b. 18%
   c. 24%
   d. 40%

2. **Although vaccine supplies are limited, which type of long-term care facility should be considered for vaccination priority?**

   a. Memory care
   b. Skilled nursing facilities
   c. Assisted living
   d. Subacute

3. **According to Robert Redfield, MD, director of the Centers for Disease Control and Prevention, a study in Kansas showed that counties where residents did not wear masks increased new cases of COVID-19 by how much per 100,000 people?**

   a. 25%
   b. 50%
   c. 75%
   d. 100%

4. **What percent of Black respondents to a survey said they would "definitely" take the COVID-19 vaccine?**

   a. 10%
   b. 18%
   c. 27%
   d. 34%