



# HOSPITAL INFECTION CONTROL & PREVENTION

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## INSIDE

### Immune-Compromised Can Be

**Vaccinated:** Adults of any age with an underlying medical condition that puts them at increased risk for severe illness from COVID-19 can be considered for immunization. . . . . 15

### IPs See 'Hope' in Vaccine:

Connie Steed, MSN, RN, CIC, APIC president, said getting the COVID-19 vaccine is 'step toward the solution'. . . . . 16

### Emerging SARS-CoV-2 Variants: A

highly transmissible variant of the SARS-CoV-2 virus originally from the United Kingdom is emerging rapidly in the United States. . . . . 19

### Half of COVID-19 Spread by

**Asymptomatic Cases:** SARS-CoV-2 can spread from people showing no symptoms. . . . . 20

### Allergic Reactions: COVID-19

shots causing anaphylactic shock at 10 times the rate of vaccines historically. . . . . 21

### Squeezing the Balloon: As focus

shifts to COVID-19, other healthcare infections are on the rise. . . . . 22

### COVID-19 Survey: New questions,

issues in CMS "Focused Infection Control Survey Tool". . . . . 23



From Relias

## HHS, CDC Open COVID-19 Vaccination to All Age 65 Years and Older

*Those younger than 65 years of age with high-risk conditions also green-lit for shots*

*By Gary Evans, Medical Writer*

Public health officials, saying that the COVID-19 vaccine supply now exceeds demand from healthcare workers and long-term care residents — the first 1a immunization priority groups — are opening up vaccine eligibility to a broad swath of society. This includes those 65 years of age and older and those under age 65 years with high-risk medical conditions.

The Pfizer vaccine can be given to those as young as 16 years of age, while the Moderna vaccine is approved for those age 18 years and older.

“Every vaccine dose that is sitting in a warehouse rather than going into an arm could mean one more life lost or one more hospital bed occupied,” **Alexander Azar Jr.**, secretary of Health and Human Services (HHS), said at a Jan. 12, 2020, press conference. “We are expanding the groups getting vaccinated because state restrictions

on eligibility have obstructed speed and accessibility of administration,” he said.

One issue has been the reluctance of healthcare workers to be immunized, which has created a bottleneck as some states tried to finish vaccination of this group before moving forward. There are reports of vaccine reluctance and refusal in the Los Angeles area, with reports of from 20% to 40% of frontline nurses and doctors declining an initial offer of vaccine in L.A. County.<sup>1</sup>

Vanderbilt University realized it had a problem when it did a survey of healthcare workers in anticipation of receiving the vaccine, finding a surprising level of reluctance and hesitancy, says **William Schaffner**, MD, professor of health policy.

“One of the reasons these [public health] jurisdictions are now opening up is that people in 1a are not completely accepting the vaccine,” he says. “There is

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a fair amount of skepticism among healthcare providers.”

Finding this in their own staff, Vanderbilt ramped up educational activities and question-and-answer sessions to assure healthcare workers that the two available vaccines are safe and effective.

“It has helped move the needle,” Schaffner says. “More and more of our colleagues, employees, and staff are receiving the vaccine. We are not exactly where we want to be yet, but we keep working on that and going back to groups that are lagging. We’re making progress, but the lesson there is if it took that much work for healthcare workers, we have a lot of persuasion to do [in the community].”

## Wide Variations in Practice

There has been much confusion and chaos about prioritizing the groups, with some states and localities ignoring Centers for Disease Control and Prevention (CDC) guidelines and vaccinating those perceived at highest risk in their area.

“As I talk to colleagues around the country and my state health department, they all say the same thing — there is extraordinary heterogeneity out there,” Schaffner says, adding that there are different policies within states, sometimes from institution to institution within the same county, between counties, and between states.

In that same vein, as this issue went to press, there were concerns and questions about whether the HHS has sufficient vaccine supplies to fulfill the deliveries described by Azar. If not, the critical question of whether there is a clear national distribution plan will again come to the fore.

Another point of contention is what happens to the carefully deliberated

plans of the CDC Advisory Committee on Immunization Practices (ACIP). At a Dec. 20, 2020, meeting, ACIP voted to continue the rationing process while vaccine stocks are insufficient. 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, for example, first responders, firefighters, police, teachers, food and agriculture workers, manufacturing workers, corrections workers, postal workers, public transit workers, and grocery store workers.

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

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. Now, the HHS has broadened that move to include all those with high-risk medical conditions. Part of this change hinged on securing an ongoing vaccine supply, but the result appears to drop frontline essential workers down the priority list for the time being.

About 38 million total doses of vaccine — including 25 million first doses — have been made available for states, and more are on the way, Azar said.

“The doses allocated exceeds the priority populations in group 1a —

including frontline health workers and seniors living in long-term care facilities — which means supply exceeds demand from those groups,” Azar said. “Over the last several days, we have averaged around 700,000 reported vaccinations each day and we are on track to hit 1 million per day in a week to 10 days’ time.”

Approximately 95% of long-term care facilities have had their first vaccination visit, he said.

“We are telling states they should open vaccinations to all people 65 and older and all people under age 65 with a comorbidity with some form of medical documentation as defined by governors,” Azar said. “This is the fastest way to protect the vulnerable and it is easier to allocate vaccines to people 65 and older and has enabled states to use much more diverse administration channels.”

With healthcare worker vaccine hesitancy and logistics an issue, some states have been holding back doses to complete the 1a group before proceeding.

“There was never a reason that states needed to vaccinate all healthcare providers before opening it up to older populations,” he said. “States should not be waiting to complete 1a priorities before proceeding to broader categories of eligibility. Think of it like boarding an airplane. You might have an order to board people, but you don’t wait [until] everyone from a group is boarded. You have to keep the process moving.”

## Shift to Community Settings

Hospitals have been the primary early vaccination sites, but outreach to broader populations means there will be more pharmacy involvement.

In addition, community health centers have more than 13,000 delivery sites across America, and they

# CDC: Immune-Compromised Can Be Vaccinated for COVID-19

*People with Bell’s palsy also can be immunized*

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,” the Centers for Disease Control and Prevention (CDC) reports.

These include those with human immunodeficiency virus (HIV) and those who have weakened immunity as a result of 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 previously have had 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 risks and benefits.

“Cases of Bell’s palsy were reported in participants in the mRNA COVID-19 vaccine clinical trials,” the CDC noted. “However, the (Food and Drug Administration) 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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have convenient locations and strong connections in low-income and minority communities.

“We are making the full reserve of doses available” Azar said. “We are 100% committed to ensuring a second dose is available for every American who receives a first dose. Because we now have a consistent pace of production, we can now ship all of the doses that have been held in physical reserve, with second doses being supplied by doses coming off of manufacturing lines with quality control. Going forward, each week, doses available will be released to first cover the needed second doses and then cover additional first vaccinations.”

Effective Jan. 26, 2020, federal allocation to states will be based on their success in getting the vaccine to the most vulnerable, he said.

“We will be allocating based on the pace of administration as reported by states and by the size of the 65 and over population in each state,” Azar said. “We are giving states two weeks’ notice of this shift to give them the time necessary to plan and improve their reporting if they think their data is faulty. This new system gives states the incentive to ensure that vaccinations are being reported and ensure that doses are going to work to protect people rather than sitting on shelves or freezers.”

**Robert Redfield**, MD, director of the CDC, said the agency is asking governors to “recommend the vaccination now be expanded to those individuals 65 and over and those individuals between 16-18 — depending on the vaccine — to 64 with a comorbidity with documentation. We clearly have enough vaccine to expand and get more and more of the vulnerable individuals vaccinated.”

This is particularly important right now, since we are seeing the post-holiday surge and there is the possibility of pushing hospital capacity to the breaking point, he noted.

“It is critically important to get those most vulnerable people, as quickly as we can, into vaccination programs as a key strategy to maintain hospital resilience,” he said. “Using the approved antibodies for those that develop symptoms prior to hospitalization is a second important intervention to maintain hospital resilience.”

As the pandemic surges and frequently sets daily records for cases and deaths, masking and other mitigation strategies remain critical.

“Most of the transmission that is occurring in our nation is not occurring in the public square, but one household to one household to one household,” Redfield said. “Wear a mask. They work. Social distance, it works. Staying away and being smart about crowds, washing your hands, they work. We need to work all together now. It’s going to be a difficult January and probably February,

but with the vaccine and the new therapeutics we have, there is a strong light [at the end of the tunnel].

## FDA Discourages Novel Vaccination Strategies

In a related development, the Food and Drug Administration (FDA) recently emphasized the importance of using the vaccines in a manner consistent with their clinical trials.

“We have been following the discussions and news reports about reducing the number of doses, extending the length of time between doses, changing the dose (half-dose), or mixing and matching vaccines in order to immunize more people against COVID-19,” the FDA stated in a letter.<sup>2</sup>

Although these are reasonable questions to consider and evaluate in clinical trials, “at this time, suggesting changes to the FDA-authorized dosing or schedules of these vaccines is premature and not rooted solidly in the available evidence,” the agency stated. “Without appropriate data supporting such changes in vaccine administration, we run a significant risk of placing public health at risk, undermining the historic vaccination efforts to protect the population from COVID-19.”

The available data continue to support the use of two specified doses of each authorized vaccine at specified intervals. For the Pfizer-BioNTech COVID-19 vaccine, the interval is

21 days between the first and second dose. For the Moderna COVID-19 vaccine, the interval is 28 days between the first and second dose.

“Using a single dose regimen and/or administering less than the dose studied in the clinical trials without understanding the nature of the depth and duration of protection that it provides is concerning, as there is some indication that the depth of the immune response is associated with the duration of protection provided,” the FDA states. “If people do not truly know how protective a vaccine is, there is the potential for harm because they may assume that they are fully protected when they are not, and accordingly, alter their behavior to take unnecessary risks.” ■

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# IPs See ‘Hope’ in COVID-19 Vaccine

*Dearth of data for healthcare workers on pregnancy*

The day *Hospital Infection Control & Prevention (HIC)* talked to **Connie Steed**, MSN, RN, CIC, FAPIC, president of the Association for Professionals in Infection Control and

Epidemiology, she had just received her second and final dose of COVID-19 vaccine.

“I’m ecstatic,” she said. “In talking to infection preventionists (IPs) around the

country who are being vaccinated — it is like hope. It is a positive step forward. It is a step towards the solution. Of course, we need to continue to mask and clean hands.”

Steed had only minimal side effects after the shots.

“If I compare it to the flu shot, my sore arm was pretty bad. With this vaccine, it was slight but insignificant,” she says. “The [overall] side effects — we’ve only had a couple of moderate ones. One person had hives and another one had some shortage of breath because of asthma. They used their inhaler and were fine.”

## Pregnant Pause

Some young female healthcare providers are holding off on vaccination because of pregnancy or conception concerns, she said.

“They didn’t trial this vaccine in the pregnant,” Steed says. “One of our OB/GYN physicians has done some sessions to talk them through the pros and cons of taking the vaccine.”

Currently, the Centers for Disease Control and Prevention (CDC) is equivocal on the issue, saying pregnant healthcare workers “may choose to be vaccinated.”<sup>1</sup> However, COVID-19 infection during pregnancy can have serious sequelae.

“Observational data demonstrate that, while the chances for these severe health effects are low, pregnant people with COVID-19 have an increased risk of severe illness, including illness that results in ICU (intensive care unit) admission, mechanical ventilation, and death compared with nonpregnant women of reproductive age,” the CDC states. “Additionally, pregnant people with COVID-19 might be at increased risk of adverse pregnancy outcomes, such as preterm birth, compared with pregnant women without COVID-19.”

On the other hand, there are limited data about COVID-19 vaccination during pregnancy, although animal studies have revealed no safety concerns. The Food and Drug Administration (FDA) approved two “messenger RNA”

vaccines for COVID-19, both having an efficacy of about 95%. One was developed by Pfizer Inc. (NYC) and BioNTech (Mainz, DEU), and the other by Moderna Inc. (Cambridge, MA).

“Limited data are currently available from animal developmental and reproductive toxicity studies,” the CDC said. “No safety concerns were demonstrated in rats that received the Moderna COVID-19 vaccine before or during pregnancy. Studies of the Pfizer-BioNTech vaccine are ongoing.”

Both vaccine manufacturers also are following participants in the clinical trials who became pregnant.

**Arnold Monto**, MD, acting chair of the FDA’s Vaccines and Related Biological Products Advisory Committee, recently weighed in on this topic in an interview.<sup>2</sup>

“I think a pregnant woman should look at her risk group and get vaccinated as she would if she were not pregnant,” he said. “By that I mean that if somebody has underlying conditions I would have no doubt that she should be vaccinated. There is always theoretical risk — especially during the first trimester. Looking at the flu story, we have come from most pregnant women not being vaccinated to pregnant women being the highest priority by the (World Health Organization) to be vaccinated.”

Beyond the issue of pregnancy, there is some hesitation among healthcare workers in general.

“Our chief medical officer said our staff vaccination rate of people who have been offered is about 70% right now,” says **Tiffany Horsley**, BSN, RN, CIC, an IP at the University of Kansas Hospital. “So that is kind of average. The data he had showed it ranges nationally from about 50% to 90%.”

Having received one dose of vaccine and awaiting her second, Horsley says they give healthcare workers all the information on COVID-19 immunization, but it is strictly voluntary.

“We share the accurate information, but some of those people may have valid reasons for not [being vaccinated],” she says. “Maybe they are pregnant, nursing, or had a previous allergic reaction or are under treatment by a physician for some other reason. Our healthcare teams are really educated, and they make the decision that is really best for them.”

CDC officials are emphasizing that healthcare workers should not decline the vaccine because of some of the circulating myths and misconceptions about the shots.

“I am definitely concerned that healthcare workers are electing to wait to get vaccinated,” **Nancy Messonnier**, MD, director of CDC’s national center for immunization and respiratory diseases said at a recent press conference. “It really makes it exceedingly important that we get correct information to healthcare workers and that we quickly dispense with myths and misinformation.”

For example, the CDC states that “none of the authorized and recommended COVID-19 vaccines or COVID-19 vaccines currently in development in the United States contain the live virus that causes COVID-19. This means that a COVID-19 vaccine cannot make you sick with COVID-19.”<sup>3</sup>

Addressing another myth, the CDC states that “COVID-19 mRNA vaccines do not change or interact with your DNA in any way.”

“We want [healthcare workers] not only to protect themselves, but we also want them to be educating their patients,” Messonnier said. “We are working in any way that we can to try to reach healthcare workers with this correct information. I think that if healthcare workers could really hear the data and see the information, it would help them make the decision to go ahead and get vaccinated.”

## 'No Rhyme or Reason'

Both vaccines were developed at record pace — less than one year. That raised suspicions that the production had been politicized during an election year, and some distrust set in about the safety and efficacy of a vaccine produced at “warp speed.”

“I’ll be honest with you, at the very beginning I was one of those that was absolutely not going to do it,” says **Courtney Paschal**, ADN, RN, an emergency nurse at a Veterans Administration hospital in Augusta, GA.

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

“I’m 32 and I work with two other nurses my same age with no comorbidities,” she says. “They have both gone to the ICU. It doesn’t discriminate. There is no rhyme or reason of who gets it 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 that 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.”

Overall, healthcare workers — some of whom initially were hesitant to take one of the rapidly developed COVID-19 vaccines — are being immunized in an uneven national rollout marked by delays, chaos, and disruptions. “For me, at the end of the day, it came down to, ‘Somebody’s got to get it,’” she says. “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 that I care about in the future. That is a small price to pay for me.”

The vaccination program at her facility was just getting underway when *HIC* talked to Paschal, and she was on the list to be immunized.

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

## PPE Fatigue

An element of personal protective equipment (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 all the time for all patients.

He may revert to a surgical mask after being fully immunized, Husainy says.

“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 that I don’t need to be as protected [with PPE] because I have had the vaccination.”

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

“Systemic signs and symptoms, such as fever, fatigue, headache, chills, myalgia, and arthralgia, can occur

following COVID-19 vaccination,” the CDC states.<sup>4</sup> “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 on the day of vaccination 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 healthcare personnel,” the CDC said.

The idea is to avoid unnecessarily excluding HCP with only post-vaccination signs and symptoms from work, while detecting those who may have SARS-CoV-2 or other infections. Ideally, workers could be immunized prior to having one or two 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 this is the approach at his hospital and he also has scheduled days off after his vaccination — which at one point he questioned taking.

“I was very skeptical for a while,” he says. “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 front lines, 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 of 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." ■

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# Emerging Coronavirus Variants Narrow the Margin for Error

*Highly transmissible strains raise the stakes on every exposure*

A highly transmissible variant of the SARS-CoV-2 virus originally from the United Kingdom is emerging rapidly in the United States, with 76 cases detected in 12 states when 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 in the community and healthcare settings.

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

"Health officials in the United Kingdom and South Africa recently reported two new variants of the SARS-CoV-2 virus," 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."

The B117 UK variant has undergone multiple changes, including "a mutation in the receptor binding domain (RBD)

of the spike protein," the CDC reports. This mutation apparently allows the spike protein of the virus to bind more easily to cells to enhance transmission.

"Currently there is no evidence to suggest that the variant has any impact on the severity of disease or vaccine efficacy," the CDC emphasized.

## Thirty-Two Cases in California

Cases of the U.K. variant have been reported in California (32), Colorado (4), Connecticut (2), Florida (22), Georgia (1), Indiana (1), Maryland (2), Minnesota (5), New York (4), Pennsylvania (1), Texas (1), and Wisconsin (1). The South African variant had not been detected in the United States when this report was filed.

"Because the variants spread more rapidly, they could lead to more cases and put even more strain on our heavily burdened healthcare systems," Walke said. The variant first seen in the United Kingdom — which is now spreading among people with no travel history

in the United States — is 56% more transmissible than the original pandemic coronavirus, researchers report in a paper under review.<sup>1</sup>

"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," they 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."

A lot remains unknown, including whether the variant in South Africa is spreading within the United States. "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."

**Greg 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,” he 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.”

The CDC is rapidly expanding a national surveillance system to collect and genetically sequence SARS-CoV-2 strains in the United States 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 (United States) that are doing sequencing. It includes public health, academia, nongovernmental organizations, and industry.”

The virus likely would need to accumulate multiple mutations in the spike protein to evade immunity induced by vaccines or by natural infection, the CDC states.<sup>2</sup>

“Among these possibilities, the last — the ability to evade vaccine-induced immunity — would likely be the most concerning because once a large proportion of the population is vaccinated, there will be immune pressure that could favor and accelerate emergence of such variants by selecting for ‘escape mutants,’” the CDC concludes. “There is no evidence that this is occurring, and most experts

believe escape mutants are unlikely to emerge because of the nature of the virus.” ■

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# CDC: At Least 50% of COVID-19 Spread by Asymptomatic Cases

*A key distinction from the original SARS in 2002*

**S**ARS-CoV-2 is one of the most insidious viruses because it can spread from people showing no symptoms.

Consider this: The United States has had about 23 million cases of COVID-19 as of Jan. 13, 2021. According to the Centers for Disease Control and Prevention (CDC), at least 11.5 million of those cases were transmitted by someone without symptoms. The estimate is based on models and statistical assumptions in a new paper by CDC authors.<sup>1</sup>

“The findings presented here complement an earlier assessment and reinforce the importance of asymptomatic transmission: Across a range of plausible scenarios, at least

50% of transmission was estimated to have occurred from persons without symptoms,” the authors found. “In the absence of effective and widespread use of therapeutics or vaccines that can shorten or eliminate infectivity, successful control of SARS-CoV-2 cannot rely solely on identifying and isolating symptomatic cases; even if implemented effectively, this strategy would be insufficient.”

Of course, this is further evidence that wearing masks and social distancing is all the more critical.

Veteran epidemiologist **Arnold Monto**, MD, of the University of Michigan said in a recent interview that asymptomatic transmission was a key distinction between the pandemic virus

and the original severe acute respiratory syndrome (SARS) coronavirus that emerged in 2002.<sup>2</sup>

“Asymptomatic and pre-symptomatic spread were a real surprise — the magnitude of it,” he said. “You have to remember we didn’t really have a diagnostic test for SARS. (Polymerase chain reaction) was in its infancy at that point. Most of the cases were clinical cases that were recognized.

“Even so, SARS could not have been controlled the way it was if asymptomatic infection and transmission were as common as it is with this virus,” Monto added. “This was a real change from the SARS virus. This may have been something that evolved.” ■

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# COVID-19 Shots Causing Anaphylactic Shock at 10 Times Rate of Other Vaccines

*At least 29 cases of life-threatening allergic reaction*

With millions more healthcare workers and the general public slated to be immunized for COVID-19, researchers report that the Pfizer SARS-CoV-2 mRNA vaccine is causing anaphylactic shock reactions at 10 times the rate of typical vaccines.

In a published review of the issue, researchers reported that “in the United States after vaccination of almost 2 million healthcare workers ... the incidence of anaphylaxis associated with the Pfizer SARS-CoV-2 mRNA vaccine appears to be approximately 10 times as high as the incidence reported with all previous vaccines, at approximately one in 100,000, as compared to one in 1,000,000.”<sup>1</sup>

With many more vaccines expected to come on the market in 2021, there are open questions whether such severe reactions will occur with other formulations.

“Acute allergic reactions after vaccination might be caused by the vaccine antigen, residual nonhuman protein, or preservatives and stabilizers in the vaccine formulation, also known as excipients,” the authors noted.

As of a Jan. 6, 2021, the Centers for Disease Control and Prevention (CDC) reported a total of 29 cases of anaphylactic shock following vaccination, but had detailed information and total immunization numbers on only 21 of those. No deaths

were reported, but four patients were hospitalized, including three in intensive care. Another 17 were treated in an emergency department.

From Dec. 14 to Dec. 23, 2020, vaccine surveillance systems picked up 21 cases of anaphylaxis after administration of a reported 1,893,360 first doses of the Pfizer-BioNTech COVID-19 vaccine, the CDC reports.<sup>2</sup> That comes to an allergic shock rate of 11.1 cases per million doses. Overall, 71% of the reactions occurred within 15 minutes of vaccination.

“The rate of anaphylaxis for flu vaccine is 1.3 per one million doses administered,” Nancy Messonnier, MD, director of CDC’s national center for immunization and respiratory diseases, said at a Jan. 6, 2021, press conference. “The anaphylaxis rate for COVID-19 vaccines may seem high compared to flu vaccines, but I want to reassure you this is still a rare outcome. This means that right now the known and potential benefits of the current COVID-19 vaccines outweigh the known and potential risks of getting COVID-19.”

The median age of persons with anaphylaxis was 40 years, with a range of 27 to 60 years of age. Nineteen (90%) of the cases occurred in females. “In 19 of 21 reports, patients were treated with epinephrine as part of therapy; one patient received subcutaneous epinephrine and the remaining 18 were

confirmed or presumed to have received intramuscular epinephrine,” the CDC reported.

Overall, 17 patients had a documented history of allergies or allergic reactions, including to drugs or medical products, foods, and insect stings, he said. No geographic clusters of anaphylaxis cases were observed, and the cases occurred after receipt of doses from multiple vaccine lots, Messonnier said.

“Anyone who has an immediate or allergic reaction to the first dose should not receive the second dose,” she said. “Anyone with a history of an immediate allergic reaction to injectable vaccine and people with a history of anaphylaxis due to any cause should be observed for 30 minutes after vaccination.”

All COVID-19 vaccine recipients should be observed for 15 minutes, regardless of history. The Food and Drug Administration has approved two messenger RNA vaccines for COVID-19, both having an efficacy of about 95%: one developed by Pfizer Inc. (NYC) and BioNTech (Mainz, DEU), and the other by Moderna Inc. (Cambridge, MA).

“At this point, we think that it [anaphylactic shock] is something that is seen with both vaccines and, therefore, our recommendations apply to both vaccines,” Messonnier said. “As you can imagine, there are tremendous efforts

underway right now to try to understand what the cause of these severe allergic reaction with both vaccines might be.”

In interim clinical guidance on anaphylaxis, the CDC goes into more detail, including these specific contraindications for both vaccines.<sup>3</sup>

The CDC considers a history of the following to be a contraindication to vaccination with both the Pfizer-BioNTech and Moderna COVID-19 vaccines:

- 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]). 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.

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

The 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 — as a precaution but not a contraindication to vaccination for COVID-19.

“We want to be sure that any administration site that is any place that is administering the vaccine is prepared to treat somebody if they had a severe allergic reaction,” Messonnier said. “Again, these events are rare. But immunization sites need to be prepared. Their staff need to be trained, and they need to know what to do if a patient has anaphylaxis.” ■

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## With Focus on COVID-19, Other HAIs Increase

*Efforts against pandemic virus lead to increase in other infections*

Infection preventionists are reporting increasing outbreaks of healthcare associated infections (HAIs) as the COVID-19 pandemic demands outsized efforts by overworked caregivers.

A survey by the Association for Professionals in Infection Control and Epidemiology (APIC) found that respondents reported a 27.8% increase in central line-associated bloodstream infections (CLABSIs); a 21.4% jump in catheter-associated urinary tract infections (CAUTIs); and a 17.6% climb in ventilator-associated pneumonia (VAPs) or ventilator-associated events (VAEs).<sup>1</sup>

For example, in July 2020, the Florida Department of Health

was alerted to three *Candida auris* bloodstream infections and one urinary tract infection in four patients with coronavirus disease 2019 (COVID-19) who received care in the same dedicated COVID-19 unit of an acute care hospital (hospital A), the Centers for Disease Control and Prevention (CDC) reports.<sup>2</sup>

A multidrug-resistant yeast that can cause invasive infections, *C. auris* has been described as spreading more like bacteria and is notoriously difficult to remove from the environment. Accordingly, before the pandemic, the hospital screened on admission for *C. auris*, admitting colonized patients to a dedicated ward.

“Hospital A’s COVID-19 unit spanned five wings on four floors, with 12 to 20 private, intensive care-capable rooms per wing,” the CDC stated. “Only patients with positive test results for SARS-CoV-2 ... at the time of admission were admitted to this unit. After patient discharge, room turnover procedures included thorough cleaning of all surfaces and floor, and ultraviolet disinfection.”

Among 67 patients admitted to the COVID-19 unit and screened during point prevalence surveys, 35 (52%) were positive for *C. auris*. Of those, six had clinical cultures that grew the fungus.

Healthcare workers in the COVID-19 unit had a practice of

wearing multiple layers of gowns and gloves during care of pandemic patients.

“A second, disposable isolation gown and pair of gloves were donned before entering individual patient rooms, then doffed and discarded upon exit,” the CDC noted. “Alcohol-based hand sanitizer was used on gloved hands after doffing outer gloves. HCP (healthcare professionals) removed all PPE (personal protective equipment) and performed hand hygiene before exiting the unit.”

Computers and medical equipment were not always disinfected between uses, and medical supplies (e.g., oxygen tubing

and gauze) were stored in open bins in hallways. “A combination of factors that included HCP using multiple gown and glove layers in the COVID-19 unit, extended use of the underlayer of PPE, lapses in cleaning and disinfection of shared medical equipment, and lapses in adherence to hand hygiene likely contributed to widespread *C. auris* transmission,” the CDC concluded. “After hospital A removed supplies from hallways, enhanced cleaning and disinfection practices, and ceased base PPE layer practices, no further *C. auris* transmission was detected.” ■

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# CMS Updates COVID-19 Infection Control Survey

## *New questions on dialysis infection control*

The Centers for Medicare & Medicaid Services (CMS) revised its “COVID-19 Focused Infection Control Survey Tool: Acute and Continuing Care” recently.

“CMS is making revisions to the non-long-term care (NLTC) focused infection control survey tool for acute and continuing care providers to reflect COVID-19 guidance updates, provide clarifications to existing information, and update the appropriate CMS regulatory tag considerations if a citation is warranted,” the agency states.<sup>1</sup>

Effective Dec. 30, 2020, some of the revisions and additional questions for CMS inspectors include the following:

- Does the facility have a screening process for those entering the facility (patients and visitors) to mitigate the risk of COVID-19 exposure (for example, exposure to COVID-19 screening questions and assessment of symptoms/illness)?

- Are visitors, if permitted on the premises based on state or federal guidance (e.g., reopening recommendations), instructed to

frequently perform hand hygiene; limit their interactions with others in the facility; and restrict their visit to the room of the patient they are visiting or other location designated by the facility?

- Appropriate hand hygiene practices (e.g., alcohol-based hand rub [ABHR] or soap and water) are followed. Unless hands are visibly soiled, an alcohol-based hand rub is preferred over soap and water in most clinical situations.

- Appropriate mouth, nose, and eye protection (e.g., face masks or respirator with goggles or face shield) along with isolation gowns are worn for patient care activities or procedures that are likely to contaminate mucous membranes, or generate splashes or sprays of blood, body fluids, secretions, or excretions.

- Unless additional source control is needed, face masks are worn by all staff while they are in the healthcare facility.

## Dialysis Facilities

- Hands should be washed with soap and water if visibly soiled. If not visibly soiled, hand hygiene with ABHR may

be used. Handwashing sinks should be dedicated only for handwashing purposes and should remain clean.

- The facility’s usual practice for cleaning and disinfection of external surfaces and the internal circuits of hemodialysis machines, including those used for COVID-19 patients, continue to be appropriate. Facilities should ensure cleaning and disinfection procedures are consistent with the manufacturer’s instructions for use and any cleaning agents used for surface disinfection is active against SARS-CoV-2. Healthcare settings should refer to List N2 for Environmental Protection Agency-registered disinfectants qualified for use against COVID-19.<sup>2</sup>

- Any surfaces, supplies, or equipment (such as dialysis machines) located within six feet of symptomatic patients should be cleaned and disinfected or discarded, as appropriate.

- Items taken into the dialysis station should either be disposed of, dedicated for use only on a single patient, or cleaned and disinfected before being taken to a common clean area or used on



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another patient. Waiting areas should be organized to separate patients with symptoms from patients without symptoms.

- Patients with confirmed or suspected SARS-CoV-2 infection should maintain at least six feet of separation from other patients at all times in the dialysis facility, e.g., waiting area, treatment area.

- Patients with confirmed or suspected COVID-19 should be dialyzed in a separate room or area. If a separate room or area is not available, patients with confirmed or suspected COVID-19 may be dialyzed in the general treatment area; however, they should be separated by at least six feet from the nearest patient (in all directions).

- A negative COVID-19 test result is not a requirement for discontinuing

isolation precautions. Surveyors should verify that facilities are adhering to the Centers for Disease Control and Prevention's most recent guidance for discontinuing transmission-based precautions. ■

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**CME/CE QUESTIONS**

**1. Which of the following statements about cases of Bell's palsy reported in participants in the mRNA COVID-19 vaccine clinical trials is false?**

- a. The Food and Drug Administration does not consider these cases to be above the rate expected in the general population.
- b. The mRNA COVID-19 vaccine definitely has been linked to onset of Bell's palsy.
- c. People who previously have had Bell's palsy may be vaccinated.
- d. Investigators have not concluded the Bell's palsy cases were caused by mRNA COVID-19 vaccination.

**2. Tiffany Horsley, BSN, RN, CIC, said the immunization rate of healthcare workers who have been offered the COVID-19 vaccine in her facility is about:**

- a. 40%.
- b. 50%.
- c. 70%.
- d. 90%.

**3. Arnold Monto, MD, said that asymptomatic transmission of SARS-CoV-2:**

- a. was occurring rarely.
- b. was also seen widely with the original severe acute respiratory syndrome (SARS) virus in 2002.
- c. diminishes its virulence.
- d. is a key difference between the current pandemic virus and the original SARS coronavirus that emerged in 2002.

**4. What is the rate of anaphylactic shock researchers found among recipients of the COVID-19 vaccine?**

- a. 1 in 50,000
- b. 1 in 100,000
- c. 1 in 500,000
- d. 1 in 1,000,000