



HOSPITAL EMPLOYEE HEALTH



THE PRACTICAL GUIDE TO KEEPING HEALTHCARE WORKERS HEALTHY



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FDA Approval of Pfizer Shot Opens Floodgates for Mandates

'People who are unvaccinated are like a drunk driver out there'

By Gary Evans, Medical Writer

Many hospitals and healthcare facilities are expected to mandate COVID-19 vaccination for healthcare workers now that the FDA has removed the emergency use authorization (EUA) label and fully licensed the Pfizer-BioNTech vaccine.

"I think full FDA licensure will open the floodgates for vaccine mandates in hospitals and nursing homes," says **Lawrence Gostin**, JD, a law professor at Georgetown University in Washington, DC. "Although these facilities could legally mandate vaccines under an EUA, many have been waiting for full FDA approval. Now that it has

come, it would be almost negligent not to require vaccines. Hospitals and long-term care facilities are very high-risk environments. Having

a fully vaccinated workforce is vital to keeping patients or residents safe."

"MANY [FACILITIES] HAVE BEEN WAITING FOR FULL FDA APPROVAL. NOW THAT IT HAS COME, IT WOULD BE ALMOST NEGLIGENT NOT TO REQUIRE VACCINES."

Although some early adopters of mandates were successful in legal challenges, many healthcare facilities said they would move the day a vaccine received final approval. That day came Aug. 23 for the Pfizer mRNA vaccine, which will now be marketed

as Comirnaty for the prevention of COVID-19 disease in individuals 16 years of age and older, the FDA reported.¹

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"The vaccine also continues to be available under EUA, including for individuals 12 through 15 years of age and for the administration of a third dose in certain immunocompromised individuals," the FDA stated.

The FDA did not mention the booster shots that have been announced by the Biden administration to begin Sept. 20, but the landmark vaccine approval should give the booster effort more legitimacy and momentum.

Indeed, it is expected the full licensure will now encourage vaccine mandates and requirements beyond healthcare settings, says **William Schaffner**, MD, a professor of healthcare policy at Vanderbilt University, which previously mandated vaccination for all employees.

"I will think this will eliminate that [EUA] barrier to more institutions, healthcare facilities, colleges, [business] employers, entertainment venues — you name it," he says. "Governmental agencies will be able to implement requirements for vaccination. I certainly think that healthcare workers, wherever they are located — including nursing homes — have a professional and ethical obligation to be vaccinated."

Many hospitals waited for the EUA to be lifted so they could avoid legal challenges, but those who went ahead saw court rulings go in their favor. Now, it is a fait accompli that many healthcare workers will be mandated to take the COVID-19 vaccine or agree to frequent testing or other measures if their employers permit.

With the delta variant spreading all over the country and 90 million people unvaccinated but eligible, the real question is whether the FDA approval will convince some of the

skeptics and anti-vaxxers to take the vaccine. Certainly a hardcore group will remain, but the full licensure and the call for booster shots might be persuasive to some of the vaccine-hesitant.

"The public can be very confident that this vaccine meets the high standards for safety, effectiveness, and manufacturing quality the FDA requires of an approved product," said Acting FDA Commissioner **Janet Woodcock**, MD.¹

Under the Vanderbilt mandatory COVID-19 program, those who claim medical or religious exemptions must appear before a panel and make their case. Those who are approved under this system must agree to a frequent COVID-19 testing protocol to work.

"I am a strong advocate of mandates," Schaffner says. "The analogy is that we are in a war with the coronavirus, particularly with this delta variant. So far, we have relied on a volunteer army. It is not sufficient. Now, we have to institute a draft."

Monica Gandhi, MD, MPH, professor of medicine at the University of California, San Francisco, says her hospital waited a long time for the EUA to be lifted, intending to mandate the vaccine to healthcare workers. However, FDA approval was not immediately forthcoming as many expected, and the hospital proceeded with a mandate several weeks before the agency's action.

"Yes, our hospital is now mandating the vaccine, but I am delighted the FDA at long last approved the Pfizer/BioNTech vaccine for other workplace settings," Gandhi says. "This will go a long way in getting those who are hesitant to take the vaccine as well as allowing employers to issue vaccine mandates

with limited exceptions. There is a Supreme Court ruling on the books in the U.S. since 1905 making compulsory vaccination legal and ethical.”

The 1905 case of *Jacobson v. Massachusetts* upheld the right of states to require smallpox vaccination for school attendance, setting a precedent that, with other case law, has seen hospital vaccine mandates upheld in court.²

Mandates for Nursing Home Staff

Citing the highly transmissible delta variant, President Biden ordered the Department of Health and Human Services (HHS) to mandate COVID-19 vaccinations for long-term care staff on Aug. 18. As a result, the Centers for Medicare & Medicaid Services (CMS) is moving to make nursing homes require all workers to be fully vaccinated against COVID-19 or risk losing federal reimbursement. The new requirements would apply to nearly 15,000 nursing home facilities, which employ approximately 1.6 million workers and serve approximately 1.3 million nursing home residents, the White House announced.³

“It is unclear if HHS needs to go through rule-making,” Gostin says. “I wholeheartedly support President Biden’s push for vaccine mandates. Nursing homes are extraordinarily high-risk settings with highly vulnerable residents. But it is on the edge of his authority. Congress can set conditions for receipt of federal funding, but not the president. Biden will likely rely on the flexibility in funding that Congress granted to HHS in the Medicaid and Medicare legislation. I believe he will act rapidly without a long rule-making process.”

Initially, long-term care companies said they would lose workers to other healthcare settings that do not mandate the vaccines, but with the FDA’s full licensure of Pfizer, that argument is becoming largely moot.

“I think they have to look reality right in the face,” Schaffner says. “Many healthcare workers and attendants at nursing homes come from minority and ethnic communities. They have a built-in reluctance — for a variety of reasons — to be vaccinated. I think the nursing home directors were very concerned that if they moved before full licensure, they would lose employees. I can understand that. Now that [the vaccine] is licensed, everybody who works in a nursing home is going to have to be vaccinated, or they can’t move from one [facility] to another. Also, I certainly expect every healthcare worker in the community would be vaccinated, and that includes doctor’s offices.”

CMS recently announced that, in conjunction with the CDC, it is developing an “emergency regulation” requiring staff vaccinations in nursing homes.

“Today’s action is in keeping with CMS’s authority to establish requirements to ensure the health and safety of individuals receiving care from all providers and suppliers participating in the Medicare and Medicaid programs,” CMS stated.³

As of Aug. 8, 62% of nursing home staff are vaccinated nationally, and vaccination among staff at the state level ranges from a high of 88% to a low of 44%. The emergence of the delta variant has driven a rise in cases among nursing home residents from a low of 319 cases on June 27, to 2,696 cases on Aug. 8. Many of the recent outbreaks occurred in facilities with the lowest staff vaccination rates.³

That is almost a ninefold increase in resident infections in 10 days, a staggering jump that will make it hard to argue against mandating the vaccine. Indeed, the combination of the delta variant and the FDA ruling means healthcare workers who refuse vaccines are “reckless,” Gostin says.

“We were already seeing the federal government mandating vaccine for federal workers and contractors,” he says. “California has done it and New York City has done it. More and more businesses are doing it every day, from Facebook and Google to Microsoft.”

The lack of a national identification system to verify vaccination status is a sore point with Gostin, who thinks the Biden administration should have moved on this issue long ago.

“You can’t set a guideline that sharply distinguishes between the vaccinated and unvaccinated and then give cities and states no guidance on how to make that differentiation,” he argues.

The HHS paper vaccine cards “are being procured, forged, and stolen,” Gostin adds. “It is not a credential within a system in any sense of the word. It should be reliable and confidential. A lot of countries have done this — Israel, France. Resisting it [in the United States] has no scientific or public health reason — it is purely political.”

Nurses, Vaccine, and Fertility

Although only 58% of nurses in a recent American Nurses Association (ANA) survey supported mandating the vaccine, the association signed off on a statement supporting the requirement.^{4,5} According to the survey’s findings, 90% of nurses

said they are immunized against COVID-19 or plan to be. They also reported they are comfortable recommending COVID-19 vaccines.

"We signed on to a clinician statement with about 57 other organizations," says ANA President **Ernest Grant**, PhD, RN, FAAN. "The reason being the safety of the public is at stake. Nurses are expected — from an ethical and professional standpoint — to model the safe behavior that we are expecting the public to do. People who are unvaccinated are like a drunk driver out there. You may think that you have the right to drive drunk, but when you injure someone else, you put that person or their family at risk. We are trying to minimize the risk of the delta variant."

According to the survey results, about 10% of nurses are holding out. They are not immunized and have no plans to take the vaccine.

"We are finding that those nurses are on the fence, based on things that they have heard or read on social media," Grant says. "We are answering their questions and concerns. A lot of the young, female nurses are clinging to the rumors that the vaccines affect their fertility. There is nothing — no research — that says that. But, unfortunately, they read something on social media without looking to see if it was in a peer-reviewed journal."

According to the CDC, "No evidence shows that any vaccines, including COVID-19 vaccines,

cause fertility problems in women or men. ... Many people have become pregnant after receiving a COVID-19 vaccine, including some who got vaccinated during COVID-19 vaccine clinical trials. In addition, a recent report using the v-safe safety monitoring system data showed that 4,800 people had a positive pregnancy test after receiving a first dose of an mRNA COVID-19 vaccine."⁶

On the other hand, COVID-19 infection is a serious threat to an unvaccinated pregnant woman, and the CDC recommends vaccination of this population. "If you get pregnant after receiving your first shot of a COVID-19 vaccine that requires two doses, you should get your second shot to get as much protection as possible," the CDC stated.

In terms of male fertility, persistent misinformation on social media claims unvaccinated sperm is somehow pure and will be extremely valuable. The claim is the COVID-19 vaccine will ruin the sperm of immunized males. The truth is quite the opposite, with no reported detrimental effects on sperm count or quality in tested, vaccinated men in a recent study.⁷ On the other hand, an unvaccinated man who acquires COVID-19 is at risk of detrimental effects to his reproductive system, with researchers concluding "the male reproductive tract, specifically the testes, may be targets of COVID-19 infection."⁸ ■

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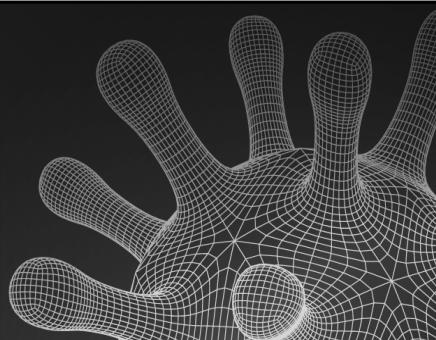
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Fauci: Vaccine Booster Should Spark Strong Immune Response

Will it stop the rise of COVID-19 delta variant?

Healthcare workers are expected to be a priority for COVID-19 vaccine booster shots this fall, providing more protection against the highly transmissible delta variant and likely reducing breakthrough infections.

"Healthcare workers were among the very first group prioritized to receive the vaccine. If we look at the eight-month interval, which is now being discussed, they would be among the early recipients of the booster," says **William Schaffner**, MD, professor of health policy at Vanderbilt University. "Obviously, they are also considered to be at high risk."

The plan, as this report was filed, was to begin booster doses on Sept. 20 to those who received at least one dose of an mRNA vaccine at least eight months prior, the Department of Health and Human Services (HHS) announced in a joint statement representing its leading medical personnel in all agencies.¹

"At that time, the individuals who were fully vaccinated earliest in the vaccination rollout, including many healthcare providers, nursing home residents, and other seniors, will likely be eligible for a booster," the statement said.

Final approval is contingent on an FDA safety and effectiveness review, and the CDC's Advisory Committee on Immunization Practices (ACIP) "issuing booster dose recommendations based on a thorough review of the evidence," HHS stated. "We also anticipate booster shots will likely be needed for people who received the Johnson & Johnson (J&J) vaccine.

Administration of the J&J vaccine did not begin in the U.S. until March 2021, and we expect more data on J&J in the next few weeks."

As medical director of the National Foundation of Infectious Diseases, Schaffner is liaison member of ACIP, which scheduled a meeting for Aug. 30. Booster shots are likely to come up for discussion.

"I wouldn't be surprised if there is a vote," Schaffner said. "The President's Task Force has said sometime in September we will start boosting, and people really need to plan for that."

Approval would appear to be little more than a formality, particularly since the FDA recently approved full licensure for the Pfizer mRNA shot. (*See related story in this issue.*) It seems unlikely ACIP would want to get bogged down in booster data for the same vaccine, particularly since the panel recently approved a third shot for the immune-compromised with either mRNA vaccine (Pfizer or Moderna). Adding considerable pressure to the public health response is the delta variant, the most formidable and successful version of SARS-CoV-2 to arise since the pandemic began.

In the meeting slides from an internal discussion, the CDC said the delta variant has an R naught — the number of susceptible people who will be infected by one case — between 5 and 8. The R naught for SARS-CoV-1 in 2002-2003 was thought to be little more than one. The CDC estimates the SARS-CoV-2 delta variant is as transmissible as chickenpox, and more transmissible

than Middle East respiratory syndrome, SARS, Ebola, seasonal flu, the 1918 pandemic flu, and the common cold.

Given this threat, the American College of Emergency Physicians (ACEP) is urging booster shots for their members as a top priority. "As emergency beds continue to fill up in hospitals across the country, we cannot afford to lose physicians on the frontlines," ACEP President **Mark Rosenberg**, DO, MBA, FACEP, said in a statement.²

New details about the delta variant eluding vaccines makes highly exposed emergency workers vulnerable, Rosenberg stressed.

The American Nurses Association (ANA) also urged its members to get the booster. In a recent survey, 85% of nurses responding said they intended to.³

"We realize the only way we are going to get this delta strain under control is if we all get vaccinated," says ANA President **Ernest Grant**, PhD, RN, FAAN. "That is evidence-based science. And now science is pointing to the fact that we need this booster. We will continue to encourage that. We want to protect the nurses, their families, their patients. There are multiple reasons we are in support of the booster, particularly because the delta variant is a huge game-changer."

Indeed, preliminary data through Aug. 6 from two CDC vaccine effectiveness cohort studies — which included 4,000 vaccinated healthcare personnel, first responders, and other frontline workers in eight national locations — show waning

effectiveness against symptomatic and asymptomatic infection with the delta variant, **Rochelle Walensky**, MD, director of the CDC, said at an Aug. 18 White House briefing.⁴ In the healthcare workers, vaccine efficacy dropped from 92% before delta to 64% after delta, she added.

The vaccines remain strongly protective against hospitalization and death, but nobody wants to wait until that mortal efficacy starts eroding. “We are concerned this pattern of decline we are seeing will continue in the months ahead, which could lead to reduced protection against severe disease, hospitalization, and death,” U.S. Surgeon General **Vivek Murthy**, MD, MBA, said at the briefing.

The Big Boost

Rather than simply a third shot that will wane in eight months, the booster should produce a multiplier effect on the immune system, said **Anthony Fauci**, MD, director of the National Center for Allergy and Infectious Diseases.

“The booster mRNA immunization increases antibody titers by at least tenfold,” Fauci noted at the briefing. “You get a dramatic increase in antibody titers when you do a third immunization dose.”

The booster could imprint longer-lasting immunity, refreshing the memory of B cells and T cells in the immune system while greatly increasing neutralizing antibodies.

“Part of the biology of boosting is that it really gives you a faster antibody response, and one that is higher than the initial series provided,” Schaffner explains. “There are data to support that it will provide long-term protection.”

The booster will be the same mRNA vaccine with which people

were inoculated originally. Thus, this booster will not be tailored against the delta variant, but there is ongoing research in that regard, Schaffner says. Still, the real-world effect of the booster remains relatively unknown, though theoretically by increasing antibody titers it could reduce the level of SARS-CoV-2 breakthrough infections.

“We hope with a higher serum antibody level you would get more antibody at the surface of mucous membranes, thus preventing the initial infection, making it less likely that a person who is vaccinated could be a transmitter of the infection,” Schaffner says.

That is what happened this summer in a large SARS-CoV-2 outbreak in Barnstable County, MA.

“During July 2021, 469 cases of COVID-19 associated with multiple summer events and large public gatherings in [Barnstable County] were identified,” the CDC reported.⁵ “Approximately three-quarters (346; 74%) of cases occurred in fully vaccinated persons.”

The outbreak prompted the CDC to call for a return to indoor masking among the vaccinated and raise a warning that even vaccinated people can transmit SARS-CoV-2 if they are shedding sufficient virus for transmission.

“[On] rare occasions, some vaccinated people infected with the delta variant after vaccination may be contagious and spread the virus to others,” Walensky said at a press conference. “This new science is worrisome and, unfortunately, warrants us to update our recommendations. Vaccinated individuals continue to represent a very small amount of transmission occurring around the country.”

In investigating the Barnstable County outbreak, the CDC found

“cycle threshold values” of SARS-CoV-2 viral loads were similar among specimens from patients who were fully vaccinated and from those who were not vaccinated.

“High viral loads suggest an increased risk of transmission and raise concern that, unlike with other variants, vaccinated people infected with delta can transmit the virus,” Walensky said.

A study in preprint revealed delta replicates to viral loads a thousand times higher than the original SARS-CoV-2 strain.⁶ That could partially explain its shorter incubation period, high transmissibility, and greater ability to cause breakthrough infections in the vaccinated. Another study in Singapore documented breakthrough infections, but encouragingly found less serious infections and saw viral titers drop faster in vaccinated people.⁷

“The delta variant seems to produce the same high amount of virus in both unvaccinated and fully vaccinated people,” the CDC reported in an update.⁸ “However, like other variants, the amount of virus produced by delta breakthrough infections in fully vaccinated people also goes down faster than infections in unvaccinated people. This means fully vaccinated people are likely infectious for less time than unvaccinated people.”

COVID-19's Long Shadow

This viral decline phenomenon has caused some hope and speculation the delta variant might be less likely to cause long COVID than the alpha variant, particularly in those who are vaccinated. We will know soon enough. The alpha variant, which can linger in the body, has heretofore

caused most of the long COVID cases, a malingering condition that besets patients with fatigue, brain fog, neurological, and sensory symptoms that can go on for weeks and months. A recently published Israeli study revealed 19% of fully vaccinated healthcare workers experienced long COVID for more than six weeks after breakthrough infections with the alpha variant.⁹

"Generally speaking, because delta does not last in the body the way alpha strain does — we are thinking, anecdotally, that perhaps long COVID may not be as dramatic in these individuals," says

Sharagim Kemp, DO, a primary care physician and the coordinator of Nuvance Health's COVID-19 Recovery Program at two facilities in New York and Connecticut.

"The preliminary data that 85% of [long COVID] we are dealing with is from the alpha variant. The majority of the long-haulers [are alpha]. [With] community infections, the majority are delta. Remember, time is of the essence and this data is emerging. We are not seeing long COVID in delta yet, but remember by definition it has to cause symptoms more than four weeks out."

However, long COVID in the unvaccinated could be a much different story. Kemp is trying to secure equipment to begin distinguishing between different variants of coronavirus. Vaccination improved symptoms for those who developed long COVID after acquiring the alpha variant — before the delta variant began.

"In the unified data we have seen, individuals who get vaccinated are actually having some resolution of their symptoms," Kemp says. "Can we explain why? Not with certainty. It could have to do with the immune

response in general — maybe a different immune response that overrides what is already occurring. Of the patients I see in New York, approximately 75% have noted some improvement in their symptoms after vaccination. Not complete resolution, but improvement. People who had severe disease, with lung scarring and organ damage — the vaccine isn't going to do a lot for them."

More data are forthcoming because it appears the unvaccinated are acquiring delta in the community and then coming to Nuvance facilities with symptoms of long COVID.

"The important thing is that the majority of people who have been long-haulers are in the unvaccinated population," Kemp says. "That is exactly what we are seeing now — the community population is getting the delta, including children. We are seeing this rise in child cases, which we didn't necessarily have with the alpha strains."

Thus, in a maddening nutshell, those who refuse vaccination are at higher risk of exposing family, friends, and co-workers, of hospitalization and death, and possibly long COVID if they survive to discharge.

Although Kemp is hopeful about delta clearing the body quickly, it remains unknown whether it will cause long COVID after breakthrough infections in vaccinated healthcare workers, or allow them to transmit the virus. That said, the vaccine improves the symptoms in many long-haulers. Those vaccinated will certainly be offered the booster shot, Kemp says.

Given the projected power of the booster, Fauci noted it might stop transmission after breakthrough infections.

"Transmissibility is a bit

trickier than looking at a clinical phenomenon such as infection, seriousness of disease, and hospitalization," he said.⁴ "The increase with a boost is really quite striking — multiple-fold increase — [so] it is conceivable that that would be important in lowering the level of virus in the nasopharynx, which could have an impact on transmission."

The question of enhanced virulence remains unanswered, but the CDC noted it is "likely more severe."¹⁰ The CDC cited three studies in meeting materials that report indicators of increased virulence, with one from Canada revealing higher odds of hospitalization, ICU admission, and death.¹¹ Researchers in Singapore cited higher odds of oxygen requirements, ICU admission, pneumonia, and death.¹² Finally, investigators in Scotland reported higher odds of hospitalization with the delta variant.¹³ ■

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Inadequate Staffing Caused Nurse Burnout Before Pandemic

Nurses already experienced high levels of burnout before the pandemic, primarily because of chronic understaffing. A regression to the mean in the coronavirus aftermath would greatly hurt the profession and the patients they protect, emphasizes **Linda Aiken**, PhD, RN, FAAN, professor of nursing and sociology and the founding director of the Center for Health Outcomes and Policy Research at the University of Pennsylvania School of Nursing.

Recently, Aiken wrote an op-ed in *The New York Times*, where she described the futile effort to improve patient-nurse staffing ratios, even though it improves patient safety and saves no small amount of money.

"If we value their sacrifices and want them to be there when we need them, we must prevent a return to the poor prepandemic working

conditions that led to high nurse burnout and turnover rates even before COVID," she wrote.¹ "States should set meaningful safe nurse staffing standards, following the example of California, where hospital nurses cannot care for more than five adult patients at a time outside of intensive care."

The public strongly agrees in polls that hospitals and nursing homes should be required to meet safe nurse staffing standards, she notes.

"But powerful industry stakeholders — such as hospital and nursing home organizations and, often, medical societies — are strongly opposed and usually defeat legislation," Aiken wrote. "The New York State Legislature is the first in the postpandemic era to fail to approve proposed safe nurse staffing standards for hospitals. The legislature passed a bill that did not require safe

nursing ratios, opting instead for internal committees at hospitals to oversee nursing and patient safety."

Hospital Employee Health spoke to Aiken about this issue in the following interview, which has been lightly edited for length and clarity.

HEH: We know patient safety has been linked to inadequate nurse staffing, but how much do nurses suffer due to poor staffing?

Aiken: Burnout has been higher for nurses than in any other occupation for a long time. We were doing a big study that turned out to be immediately before COVID. We studied all the nurses and all the hospitals in New York and Illinois. We found that before COVID, 46% of all the nurses scored in the high burnout range. We just resurveyed, while COVID is still going on, and the rate has increased to 50%. The point being, nurses are more stressed now than they were,

but the problem was there before COVID even started. We know that those high burnout rates are associated with understaffing. That is the biggest reason why nurses are burned out. There are not enough nurses, and they each have too many patients to safely take care of.

HEH: Were you surprised the high burnout rate only went up four percentage points?

Aiken: Yes, but when you look at some of the subgroups, as you might imagine, burnout has increased more among ICU nurses. ICU nurses went from 47% being highly burnt out before COVID, to 62% now. That's consistent with where all these critically ill patients are. But the point is the same — more than 45% of them were already burnt out before COVID. Yes, we should thank nurses for their sacrifices, but the reason that they're making so many sacrifices now is that conditions were so bad before COVID. If we go back to those bad conditions before COVID [after the pandemic] we're not giving any gratitude to nurses whatsoever or helping [patients] because the care is unsafe.

HEH: In another study, you found that with adequate nurse staffing, New York state could prevent 4,370 patient deaths and save \$720 million over a two-year period.²

Aiken: Can you believe the legislature didn't pass the legislation after we showed them that? It shows how strong the interests are that are against doing these things, because they presume it would cost so much more money. But they're really not open to the idea that science is pointing out that it's not as expensive as you think it is. In fact, they're wasting money now by not having enough nurses, because the length of stay is longer than it needs to be, which they're not being reimbursed for. Their readmis-

sion rates are higher than they need to be, for which they're being penalized financially by Medicare. They're just not being knowledgeable in how they look at nursing. They look at it as a cost and not as a revenue. I mean, it could really produce revenues for hospitals and save them a lot of money — which would offset the costs of employing more nurses. The stakeholders greatly overestimate what it would cost to improve nurse staffing, and that scares the public and the legislators, so they don't pass it.

HEH: California remains the one state that passed a nurse staffing law.

Aiken: It's the only successful one that's passed — and that was 20 years ago. It's been very successful, and there are plenty of studies that show it's been successful. But the special interests mobilize and the public's not paying attention. I think what's going to happen with more publications like mine in *The New York Times* is the public's going to realize that their own representatives are not acting in their interests by improving nurse staffing. I think this is a matter of educating the public to educate their legislators.

HEH: You call for more transparency on hospital nurse-patient ratios, which are not often reported in public-facing data.

Aiken: Right. There really isn't any way for the public to figure out what the staffing is in hospitals or nursing homes so they could choose one that has good staffing. I've recommended that the federal government add mandated reporting of hospital patient-to-nurse staffing on the existing Hospital Compare website. That website allows any consumer to go in and evaluate any hospital on things like mortality rates, but there's not a word on there about nursing [levels]. The public just has no idea if nursing is either good or really horrible in their local hospital, where

they're thinking about going to for serious surgery.

HEH: This is a speculative question, but what difference would it have made to have adequately staffed hospitals during the pandemic? From your research, it sounds like the effect could have been profound.

Aiken: I think it would have been. One of the ways we tried to get at that was to look at another mortality problem that is similar in some respects to COVID, which is sepsis. Sepsis is an infection that sometimes starts out innocently, but that can escalate very rapidly and kill people that normally are in good health. We chose that because there's a great focus on hospitals implementing standardized protocols to save people's lives who have sepsis, and these have been tested by the National Institutes of Health and shown to be effective.

The New York State Legislature — the same one that turned down nurse staffing [legislation] — passed a requirement that New York hospitals had to adhere to this protocol. We looked at that as an example of what would happen if we tried to improve COVID outcomes without changing nursing staffing. What happened with sepsis — despite [the legislature] mandating that hospitals had to follow the protocols — is they couldn't. They didn't have enough nurses. We put all the data together and estimated that they could have saved more lives by requiring an improvement in nurse staffing instead of mandating that protocol.³ All these things are out there in the scientific literature. We informed the state legislature of that. I think it's a very good example that you can't save really sick people by mandating a committee or a process if the cause of excess mortality has to do with not enough nurses. ■

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Before the COVID-19 Vaccine, Most HCWs Infected in Community

Taking on a contentious issue with a thorough analysis, researchers found during the pre-vaccine pandemic in 2020 that 11.5% of healthcare workers who acquired COVID-19 in their hospital were occupationally infected. Thus, as has often been observed by employee health professionals, the lion's share of exposures and SARS-CoV-2 infections in hospital staff have occurred in the community.¹

"Recommendations were changing constantly, at least in the beginning," said **Aimee Russell**, MLS(ASCP), CIC, an infection preventionist at St. Luke's Health System in Boise, ID. "There were PPE [personal protective equipment] shortages, and we were making decisions that were completely unheard of in infection prevention, like reusing PPE. Things were uncertain. For our staff, it was kind of scary at times. Our staff needed to know that the decisions we were making were keeping them safe, and we needed to know that we were making the right decisions."

Russell and her colleague, Jessi Bond, MPH, CIC, recently presented the findings at the Association of Professionals in Infection Control and Epidemiology 2021 virtual conference.

Russell and Bond used a communicable disease reporting process through workers' compensation between March 1, 2020, and Aug.

31, 2020, to determine workplace exposure and transmission. The number of COVID-19-positive patients was extracted from employee health laboratory reports.¹

They found 693 COVID-19-related exposures for the period, with 85 of those testing positive. Fifty-one employees acquired SARS-CoV-2 from a workplace exposure, including 26 patient exposures, 14 co-worker exposures, six patient and co-worker exposures, and five unknown exposures. A total of 441 positive cases were found, with workplace acquisition accounting for 11.6% of the employee cases.

"We felt the best way to track this was to look at our workplace acquisitions, because in the end, keeping people safe is our ultimate concern, but we needed a way to be able to do it," Russell said. "After the first couple of discussions with [the infection control committee], we recognized we actually had an existing infectious disease reporting process through our employee safety and our workers' compensation program that would fit the need. We actually had no idea this program existed. That was a really good reminder for us that if we can get out of our silos that occur in large organizations, we can find resources we didn't even know existed, and we can save ourselves from reinventing all kinds of wheels."

Thus, workplace exposure and transmission of COVID-19 were determined in part using this established process, which directs employees to use an incident reporting system for occupational injury and illness. Employees also were asked to report possible exposures.

"Information then was gathered directly from the employee regarding their potential work and non-work exposure sources, and that was then provided to the occupational health physician," Russell said. "The physician would review the information and then advise the workers' compensation department if the information available supports that the employee contracted COVID-19 in the course of their work duties at St. Luke's."

Of course, reliance on self-reporting was a limitation of the study, as was the lack of information on compliance with PPE.

"I would say anecdotally during this time, infection prevention was also doing patient exposure contact tracing and that also involved interviewing of staff directly," Russell said. "What we were seeing matched very closely with the data that we were collecting from the workers' compensation process. For the most part, what we found is staff had a really good idea of where they got COVID-19. They knew what their exposure source was."

The level of COVID-19 in the community also was factored in. These numbers fluctuated, but could be an indicator of enhanced risk of exposure and infection beyond work.

"When our community levels rose, so did our employee cases," she says. "However, our workplace exposures stayed low and sporadic. But sometimes our staff tend to forget that COVID actually spreads quite well in a break room. That

[realization] helped us identify if clusters were occurring."

During the study period, there were no known exposure sources for five infected healthcare workers. Ultimately, these were determined to be occupational cases, contributing to the higher percentage of 11.6% out of the larger total of 441 positive cases.

"It was determined that it was more likely these employees acquired the virus from some type of exposure

in the workplace," Bond says. "[Still], we have concluded that the vast majority of employees acquired COVID-19 from exposures outside of work." ■

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1. Bond JM, Russell A. Utilizing worker's compensation claims to assess SARS-CoV-2 transmission in healthcare workers at a large health system. *Am J Infect Control* 2021;49:S10.

Pediatricians Urge FDA to Approve Shots for Kids

The American Academy of Pediatrics (AAP) is urging the FDA to work aggressively to authorize a safe and effective COVID-19 vaccine for children younger than 12 years of age as soon as possible.

"Pediatricians and the families they care for have been anxiously awaiting a vaccine that can be used in children 11 years of age and younger, and especially so now given the rise of the hyperinfectious delta variant," AAP wrote in the Aug. 15 letter.¹ "The delta variant is surging at extremely alarming rates in every region of America. This surge is seriously impacting all populations, including children."

The AAP and the Children's Hospital Association have been tracking COVID-19 cases in children since the start of the pandemic. "Last week saw the largest week-over-week percentage increase in pediatric COVID-19 cases since the start of the pandemic," AAP noted. "The data show 71,726 COVID cases in children reported last week, almost double the 38,654 reported in the previous week. Simply stated, the delta variant has created a new and pressing

risk to children and adolescents across this country."

Since the pandemic began, children have represented 14.3% of total cumulated cases. However, for the week ending July 29, children represented 19% of reported weekly cases.

"The higher proportion of cases in this population means this age group could be contributing in driving continued spread of COVID-19," AAP wrote. "Sadly, over 350 children have died of COVID since the start of pandemic and millions of children have been negatively impacted by missed schooling, social isolation, and in too many cases, the death of parents and other caregivers."

The FDA has worked with Pfizer and Moderna to double the number of children ages 5-11 years included in clinical trials. However, AAP noted, things have changed and children are in immediate danger.

"In our view, the rise of the delta variant changes the risk-benefit analysis for authorizing vaccines in children," AAP stated. "FDA should strongly consider authorizing these vaccines for children ages 5-11 years based on data from the initial enrolled

cohort, which are already available, while continuing to follow safety data from the expanded cohort [of those younger] in the post-market setting."

The FDA also is continuing to evaluate clinical trial requirements for children younger than 5 years of age.

"We similarly urge FDA to carefully consider the impact of its regulatory decisions on further delays in the availability of vaccines for this age group," AAP stated. "Based on scientific data currently available on COVID-19 vaccines, as well as on 70 years of vaccinology knowledge in the pediatric population, the academy believes that clinical trials in these children can be safely conducted with a two-month safety follow-up for participants. Assuming that the two-month safety data does not raise any new safety concerns and that immunogenicity data are supportive of use, we believe that this is sufficient for authorization in this and any other age group." ■

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1. American Academy of Pediatrics. Letter to the FDA. Aug. 5, 2021. <https://bit.ly/3zu2Dj3>



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CE QUESTIONS

- 1. Under Vanderbilt's mandatory COVID-19 program, those who claim medical or religious exemptions must argue their case before a panel. Those who are approved under this system must agree to:**
 - a. wear a surgical mask at all times during work.
 - b. return to the panel annually to update their status.
 - c. undergo frequent COVID-19 testing.
 - d. work in non-patient care.
- 3. As of Aug. 8, the average vaccination rates for nursing home workers was:**
 - a. 62%.
 - b. 44%.
 - c. 88%.
 - d. 36%.
- 4. Linda Aiken, PhD, RN, says hospitals are losing money by not hiring an adequate number of nurses due to longer lengths of patient stay. What other cost factor increases with an insufficiently staffed nursing department?**
 - a. Violence against staff
 - b. Liability risk
 - c. Readmission rates
 - d. Patient satisfaction scores drop
- 2. According to ANA President Ernest Grant, PhD, RN, what is the most cited reason for the 10% of nurses who decline vaccination?**
 - a. Growing stigmatization by their family and friends
 - b. Growing evidence suggesting the vaccines are ineffective
 - c. They are boosting their immunity with natural foods and supplements

CE OBJECTIVES

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

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