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INSIDE

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CDC Quickly Reverses ACIP's Vote Against Booster Shots for HCWs

FDA nixes Biden plan of boosters for all vaccinated

By Gary Evans, Medical Writer

In a highly unusual move, CDC Director **Rochelle Walensky**, MD, MPH, overruled her own vaccine advisory committee when they became mired in a far-ranging debate about COVID-19 booster shots that led to an end-of-the day vote not to recommend them for healthcare workers (HCWs).

The surprising 9-6 "no" vote by the Advisory Committee on Immunization Practices (ACIP) rejected a generally worded "occupational" risk recommendation for many reasons, including the fact that many HCWs actually acquire SARS-CoV-2 in the community. That would seem to be supported in part by the breakthrough infections after the CDC temporarily canceled mask recommendations for the vaccinated.

A KEY DIFFERENCE IS THE WORD "RECOMMENDED" IS DELETED IN THE FINAL CDC VERSION, WHICH INSTEAD EMPHASIZES THOSE IN THE CATEGORY "MAY" GET THE BOOSTER.

The contentious meeting was held Sept. 23. Walensky overruled the panel on the occupational booster question in an email statement sent at 12:27 a.m. Sept. 24. The rapidity and decisiveness of that revocation has been rarely seen between the CDC and its advisory committees.

The occupational rationale is not supported by evidence as HCWs are protecting themselves with personal protective equipment (PPE) and other measures

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MEDICAL WRITER: Gary Evans
EDITOR: Jill Drachenberg
EDITOR: Jonathan Springston
EDITORIAL GROUP MANAGER: Leslie Coplin
ACCREDITATIONS DIRECTOR: Amy M. Johnson, MSN, RN, CPN

at work, noted ACIP member **Beth Bell**, MD, MPH, clinical professor of global health at the University of Washington.

"I don't believe [the recommendation] is scientifically correct," Bell said at the meeting. "Perhaps a case could be made for healthcare workers to reduce the incidence of infections they get because of exposure in the community, and therefore reduce absenteeism among vaccinated healthcare workers."

That might be strictly true given the protective measures taken in hospitals, but there always is the risk of a breach in protocol, an unanticipated direct exposure, or something potentially more widespread like not using a negative pressure room to perform an aerosol-generating procedure on a COVID-19 patient.

ACIP members also argued vaccinated workers would remain protected against serious infection, which was the original intent of the vaccines. This raises a question that demands a coherent answer and some consensus from public health officials: Does immunity to the delta variant wane after two doses of mRNA vaccine? A recent CDC study of HCWs — which has not been highly touted and was advised to be "interpreted with caution" — offered this relatively straightforward conclusion: "The vaccine efficacy point estimates declined from 91% before predominance of the SARS-CoV-2 delta variant to 66% since the SARS-CoV-2 delta variant became predominant."[1]

The vaccines were thought to be waning when the Biden administration announced an ambitious plan to boost the public at large in August. In contrast, ACIP members expressed concern about loose wording in the "occupational" recommendation that would negate the purpose of designating groups and let everybody receive a booster pell-mell.

"We might as well as just say, 'Give it to everybody 18 and over," said ACIP member **Pablo Sanchez**, MD, principal investigator in the Center for Perinatal Research at The Research Institute and a professor of pediatrics at The Ohio State University. "We have a really effective vaccine, and this is like saying it is not working — and it is working. Certainly, some high-risk individuals do have waning immunity with time, but I am concerned about this."

At this point, the narrative was going off track, particularly since the FDA approved a similar recommendation only a day before the ACIP meeting.

ACIP chair **Grace Lee**, MD, MPH, professor of pediatrics at Stanford University School of Medicine, was cool under pressure, reminding the committee the risk-benefit calculation for the recommendation is "individualized," meaning those at risk of occupational exposures who are fully vaccinated can choose to get the booster — or not. It is a choice. On the other hand, the benefit in passing the recommendation would be providing greater "access" to the booster, which in turn opens a wider path to equity, she emphasized.

Although CDC officials reminded ACIP the recommendation will be accompanied by education and close follow-up for myocarditis — a rare side effect seen primarily in young men — one ACIP member said the effect of the booster could actually increase risk for this population by prompting a strong antibody response.

"If an 18-year-old is anxious about myocarditis, we are not providing anything in the benefit

department, but we are providing risk," said ACIP member **Sarah Long**, MD, professor of pediatrics at Drexel University College of Medicine.

In any case, many ACIP members thought the original occupational recommendation was written too broadly, open-ended, and would be difficult to explain. Other members argued it was necessary to maintain the healthcare workforce and preserve morale amid massive burnout and a national nursing shortage.

Still, many ACIP members seemed unenthusiastic about the boosters, citing competing pandemic priorities — including immunizing children — and frustration at focusing on those already vaccinated when so many are not. The tipping point probably came when one member called the recommendation a "solution looking for a problem."

The meeting ended shortly after the measure was rejected, but the CDC moved quickly to head off a public relations debacle that could have read something like this: "Healthcare workers, who held the line when there was no vaccine, have been denied the full measure of immunity amid a nursing shortage, chronic burnout, and the highly transmissible delta variant." Not a good look, and the reversal happened quickly.

CDC, FDA Booster Recommendations

Here is the CDC occupational recommendation as reissued and approved by Walensky:

"People aged 18-64 years who are at increased risk for COVID-19 exposure and transmission because of occupational or institutional setting may receive a booster shot of Pfizer-BioNTech's COVID-19 vaccine at least six months after their Pfizer-BioNTech primary series, based on their individual benefits and risks."[2]

This is the original wording of the measure voted down by ACIP:

"A single Pfizer-BioNTech COVID-19 vaccine booster dose is recommended based on individual benefit and risk for persons age 18-64 who are in an occupational or institutional setting where the burden of COVID-19 infection and risk of transmission are high, at least six months after the primary the series under the FDA's emergency authorization act."

A LACK OF OVERALL DATA AND THE CONCERN FOR MYOCARDITIS SIDE EFFECTS IN YOUNG PEOPLE WERE AMONG THE REASONS CITED BEFORE THE 16-2 VOTE AGAINST BROAD BOOSTER SHOTS.

A key difference is the word "recommended" is deleted in the final CDC version, which instead emphasizes those in the category "may" get the booster. Still, Lee was right: It was a choice based on individual benefit-risk, and the revision made that point clearer.

The other recommendations approved by ACIP are as follows:

• People age 65 years and older and residents in long-term care settings should receive a booster shot of Pfizer-BioNTech vaccine six months after completion of the first series;

• People age 50-64 years with underlying medical conditions should receive a Pfizer-BioNTech booster shot at least six months after completion of the first series;

• People age 18-49 years with underlying medical conditions may receive a Pfizer-BioNTech booster shot at least six months after completion of the first series, based on their individual benefits and risks.[2]

The FDA finalized similar recommendations after its Sept. 17 meeting of the Vaccines and Related Biological Products Advisory Committee. One exception is the ACIP panel lowered the age range for those at high risk to age 50 years, in a nod to health disparities among minorities and ethnic populations. Walensky's statement said the agencies are in alignment, but there is much more to be done because the FDA only issued an emergency use authorization (EUA) for a Pfizer-BioNTech booster.

The FDA recommended boosters for individuals:

• age 65 years and older;

• age 18-64 years of age at high risk of severe COVID-19 infection;

• age 18-64 years whose frequent institutional or occupational exposure to SARS-CoV-2 places them at high risk of serious complications of COVID-19.[3]

In an initial vote, the FDA decided vaccine efficacy was still sufficient in immune-competent people in the general population, dashing President Biden's hopes of a large national rollout of booster shots. A lack of overall data and the concern for myocarditis side effects in young people were among the reasons cited before the 16-2 vote against broad booster shots.

In comments to fellow FDA committee members, **Paul Offit**, MD, a vaccine expert at the Children's Hospital of Philadelphia, summed up the situation this way: "The stated goal of this vaccine for people like Rochelle Walensky and others has been to protect against serious illness," he said. "The data presented show that the vaccine still does exactly that. It is also clear, however, that the third dose of mRNA vaccine increases the titer of virus-specific neutralizing antibodies and will likely decrease the incidence of asymptomatic or symptomatic infection, which is associated with contagiousness. So then the question becomes, 'What will the impact of that be on the arc of the pandemic?' It may not be all that much. Certainly, we all agree that if we really want to impact this pandemic, we need to vaccinate the unvaccinated."

The FDA said the most common booster side effects among clinical trial participants were pain, redness, and swelling at the injection site. Also reported were fatigue, headache, muscle or joint pain, and chills. "Of note, swollen lymph nodes in the underarm were observed more frequently following the booster dose than after the primary two-dose series," the FDA reported.[3]

In terms of efficacy, the FDA studied real-world data from the United States and international sources, including the United Kingdom and Israel. "The immune responses of approximately 200 participants 18 through 55 years of age who received a single booster dose approximately six months after their second dose … demonstrated a booster response," the FDA said.[3]

A Voice in the Wilderness

The FDA did not detail the degree of that response, but it was previously described in enthusiastic terms by **Anthony Fauci**, MD, director of the NIH's National Institute for Allergy and Infectious Diseases. This is what makes the ACIP vote and reversal one of the more surprising glitches that have occurred throughout the pandemic response.

Only a month or so before the ACIP vote on occupational boosters, Fauci said at a White House briefing that "the booster mRNA immunization increases antibody titers by at least tenfold." He also emphasized evidence of waning immunity of the vaccines to the SARS-CoV-2 delta variant.[4] Who would not want a super-boost of immunity, HCW or not? But that message did not seem to resonate in any significant way in the ACIP meeting, and certainly was not presented as a compelling argument to protect HCWs in the final, controversial vote.

In making the claim, Fauci cited a study in preprint. "Two weeks after the booster vaccinations, titers against the wild-type original strain, B.1.351, and P.1 variants increased to levels similar to or higher than peak titers after the primary series vaccinations," the researchers concluded.[5] The research did not appear to test against the delta variant, but Fauci found the findings compelling, citing data from a Pfizer-BioNTech booster study that showed a dramatic increase in antibody titer to delta.[6]

Although his was a voice in the wilderness during the ACIP discussions, Fauci's contention was recently vindicated by an Israeli study. In a large study involving more than 2 million patients, researchers found the booster dose after the initial two-shot series reduced the incidence of COVID-19 infection more than tenfold compared to those who were vaccinated at least five months previously but not boosted.

"Our findings can be understood through the following example," the authors explained.[7] "Suppose, first, that the combined effect of waning immunity and the increased prevalence of the delta variant decreases the efficacy of a vaccine that had been administered six months earlier to approximately 50% relative to the susceptibility in an unvaccinated person, as recent reports have suggested. Then, suppose that, as suggested by our results,

the booster dose reduces the rate of infection for such vaccine recipients by a factor of 10. This would mean that the susceptibility of a person who receives a booster dose would decrease to approximately 5% (i.e., 50% divided by 10) relative to that in an unvaccinated person and would bring the vaccine efficacy among booster recipients to approximately 95%, a value similar to the original vaccine efficacy reported against the alpha variant."

In retrospect, it appears there was a major disconnect between the Biden administration and the CDC and FDA on boosters. The Biden plan was to begin Sept. 20. The Department of Health and Human Services issued an announcement supporting the plan, specifically stating those who were vaccinated earliest — "including many healthcare workers"[8] — would be eligible for boosters.

However, this was before the FDA and CDC held meetings on boosters. The president seemed to concede in a Sept. 9 speech on vaccine mandates that the administration got out ahead of the federal agencies.

"The decision of which booster shots to give, when to start them, and who will give them, will be left completely to the scientists at the FDA and the CDC," Biden said in his address.[9]

They did, but to what effect? Was it politics trumped by science, some bruised egos whose input was ignored, or just another day in chaotic pandemic response, with too few singing from the same hymnal? If more non-boosted vaccinated people start experiencing breakthrough infections, particularly if they are serious, there may be some hastily called meetings at these federal agencies. ■

REFERENCES

1. Fowlkes A, Gaglani M, Groover K, et al. Effectiveness of COVID-19 vaccines in preventing SARS-CoV-2 infection among frontline workers before and during B.1.617.2 (delta) variant predominance — eight U.S. locations, December 2020-August 2021. *MMWR Morb Mortal Wkly Rep* 2021;70:1167-1169.
2. Centers for Disease Control and Prevention. Who is eligible for a COVID-19 vaccine booster shot? Sept. 30, 2021. https://bit.ly/39Nqm2u
3. Food and Drug Administration. FDA authorizes booster dose of Pfizer-BioNTech COVID-19 vaccine for certain populations. Sept. 22, 2021. https://bit.ly/3zSQ0gT
4. The White House. Press briefing by White House COVID-19 Response Team and public health officials. Aug. 18, 2021. https://bit.ly/3EWFVn3
5. Wu K, Choi A, Koch M, et al. Preliminary analysis on the safety and immunogenicity of a SARS-COV-2 variant booster. medRxiv 2021.05.05.21256716. doi: 10.1101/2021.05.05.21256716. [Preprint].
6. Watch Dr. Fauci reveal reasons for Covid-19 Booster (W.H. press briefing). CNET Highlights. Aug 18, 2021. https://bit.ly/3F5zOwz
7. Bar-on YM, Goldberg Y, Mandel M, et al. Protection of BNT162b2 vaccine booster against COVID-19 in Israel. *N Engl J Med* 2021 Sep 15;NEJMoa2114255. doi: 10.1056/NEJMoa2114255. [Online ahead of print].
8. Department of Health and Human Services. Joint statement from HHS public health and medical experts on COVID-19 booster shots. Aug.18, 2021. https://bit.ly/3kSN5R8
9. Weise E. Who will be able to get a COVID-19 booster shot and when? That's still in limbo. *USA Today*. Sept. 13, 2021. https://bit.ly/3idoS6r

ANA: Nursing Shortage Is at Crisis Point

Biden administration urged to declare emergency

With federal COVID-19 vaccine mandates looming, burnout at record levels, and many baby boomers nearing retirement age, a national nursing shortage is approaching that could shut down critically needed care.

"This is getting serious," say **Ann Marie Pettis**, RN, an infection preventionist at University of Rochester (NY) Medicine and president of the Association for Professionals in Infection Control and Epidemiology. "In my own organization it's frightening. We are having to shut down beds. We don't have some ICU beds staffed."

Given the situation, the American Nurses Association (ANA) recently sent a letter to the Department of Health and Human Services (HHS) calling for the Biden administration "to declare a national nurse staffing crisis and take immediate steps to develop and implement both short- and long-term solutions."[1]

"We need to realize there has been a shortage for decades. The situation now is that it has reached crisis proportions," says ANA President **Ernest Grant**, PhD, RN, FAAN.

The Biden administration has confirmed they received the letter and will issue a formal response.

"I think there are a couple of things the federal government could do," Grant says. "First, take the lead to get all of the [stakeholders] in the room so we can get this problem fixed once and for all — for the short term and long term. Call in the players like the insurance companies, the lawmakers, the nurses, and regulatory agencies to address this problem. We realize that there is not one size that will fit all."

Pay, Burnout Are Issues

Indeed, one proposal listed in the ANA letter is "work with the Centers for Medicare & Medicaid Services (CMS) on methodologies and approaches to promote payment equity for nursing service." This might prove a shrewd approach, as President Biden has mobilized CMS to leverage compliance with his recently ordered healthcare vaccine mandates.

"CMS is so important because they are responsible for a lot of different costs," says **Julie Swann**, PhD, department head and A. Doug Allison Distinguished Professor of the Fitts Department of Industrial and Systems Engineering at North Carolina State University. "Even though they don't directly set salaries, they push the costs down so much. Other payers should be at the table as well. I understand that insurance companies had a great year last year because there were much fewer elective surgeries. They didn't have as many costs on that side as they normally would have. Should we be putting in place hazard pay [for nurses]?"

This is the crux of the issue, with too many hospitals trying to get by on the cheap despite the dire working conditions during the pandemic, says **Linda Aiken**, PhD, RN, FAAN, FRCN, 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.

"The country does not have a shortage of nurses, and I want to go on record with that," she tells *Hospital Employee Health*. "We graduate 175,000 new nurses every year. People don't want to work under these circumstances. [Hospitals] are not really offering the kind of financial incentives that would be reasonable in a national emergency. A lot of hospitals are not offering hiring bonuses. More importantly, they are not offering retention bonuses to the people who are there."

Burnout is at record highs — which was a longstanding problem even before the pandemic.

"We are studying this — 62% of ICU nurses are experiencing burnout, but it is because it was already so high before COVID," Aiken says.

States Move on Mandates

As this report was filed, New York was not backing down from a requirement for all healthcare workers (HCWs) to be vaccinated for COVID-19. Gov. Kathy Hochul signed an executive order on Sept. 28, declaring a statewide emergency due to healthcare staffing shortages. The emergency order coincides with an expired deadline that HCWs must be vaccinated for COVID-19. Some refused or resigned. The emergency declaration allows New York to temporarily suspend state requirements and allow HCWs from other states and countries to practice in the state.

A court also ruled that a group of workers claiming religious exemption could not be fired pending further review. Amid the chaos, some have floated the idea, particularly in other states, of letting unvaccinated nurses keep working temporarily to buy some time. "I think the mandate for vaccination of everyone in healthcare should hold under any circumstances," Aiken says. "It's totally science-based. There are plenty of nurses in the country, but it is a question of whether they are willing to work under the conditions that are being offered."

Normally, the market forces of supply and demand would drive nursing wages up, but Aiken alleges groups of hospitals have "colluded" to keep these forces at bay. Nurses who are finding a way around this — putting themselves in a competitive hiring position — are making as much as $100 an hour, she says.

"One important factor is that nurses and doctors have been responding to this for about a year and a half," Swann says. "That is a long-sustained time period for anything – certainly a pandemic. There is a concern that some nurses will decide to quit rather than to be vaccinated. It's unclear how large that problem is going to be. Across the United States, we have an age distribution with a lot of people close to retirement age. If they are not happy in their job, then they are a little more likely to retire."

Do Not Let Unvaccinated Nurses Slide

Swann concurs with Aiken that unvaccinated workers should not be given a reprieve due to the staff

shortage. "People in healthcare and other first responder jobs could directly impact someone else if they are not vaccinated," she said. "There are a number of other vaccines and other healthcare measures that someone in healthcare would generally take. They have to be up to date on all kinds of vaccinations. I am not comfortable with unvaccinated workers continuing [working]. Another thing people do in an emergency is that they [will have more nurses] working across state borders than they would normally allow. And they bring back people who are retired. We've got to get some relief for nurses and first responders to give them the ability to care for patients and the community."

In in a time of crisis, consider which tasks can be performed by people without nursing degrees. That would give nurses time to focus on important things where their skill set is needed, Swann says.

Aiken supports the idea of federal intervention as long as it brings more resources for hospitals to employ more nurses or to bring in agency nurses and use other ways to staff up.

"I would hope that if the [nursing emergency] is granted, the focus would be put on permanent changes in hospitals that would prevent this from ever happening again," she says. "That is desperately needed. It's not that we just need to plug holes in staffing — we need to put in place some requirements. The main thing to be considered is that the federal government should pass safe staffing mandates in all hospitals that participate in Medicare. It's long past time for that to happen, and the states are not going to do it."

However, as a policy matter, the ANA does not support setting nurse-patient ratios for different types of care.

"This is not just a numbers thing." Grant says. "We feel you also have to take into account the expertise or the experience that that nurse has. Is it a nurse who has been on the floor six months, or one that has been there 10 years? Also, are there other members of the healthcare team that may be there, including nursing assistants? Do you have the ability to flex [staffing] up and flex down? ANA has always advocated that staffing should be done in conjunction with hospital administration on individual floors."

> "THERE ARE PLENTY OF NURSES IN THE COUNTRY, BUT IT IS A QUESTION OF WHETHER THEY ARE WILLING TO WORK UNDER THE CONDITIONS THAT ARE BEING OFFERED."

While Aiken believes that approach has failed, it could give Grant some negotiating room if he can sit at the table with the powers that be.

"We have to ensure that we have a valued nursing workforce and an environment that is safe and addresses the physical and mental fatigue that nurses are experiencing right now," Grant says. "We have been carrying this burden for quite some time. It's obvious that we need federal leadership to address this problem."

In the ANA letter, Grant emphasized that "this severe shortage of nurses, especially in areas experiencing high numbers of COVID-19 cases, will have long-term repercussions for the profession, the entire healthcare delivery system, and, ultimately, on the health of the nation."

The ANA cited several national examples of the crisis, with many hospitals losing nurses and demand exceeding staffing needs. Thousands of nursing positions are unfilled. Some hospitals requested support from the National Guard, the ANA emphasized.

Remove Practice Barriers

In addition to more staff, Grant urged HHS to remove practice barriers for nurses and increase the annual number of qualified students educated in the field. Moreover, nurses need help and techniques to address fatigue and mental well-being to maintain a resilient workforce, the ANA letter stated.

There also is a clear patient safety issue since staffing has been cited as one of the problems in a dramatic increase in healthcare-associated infections (HAIs) in 2020. Too few nurses translate to too little time.

"We know from studies that short staffing is associated with higher incidence of HAIs," says **Mary Hayden**, MD, chief of infectious diseases at Rush University Medical Center in Chicago. "You have to have enough staff so they have enough time to practice hand hygiene at every point they are supposed to, change dressings, and monitor devices." ■

REFERENCE

1. American Nurses Association. ANA urges U.S. Department of Health and Human Services to declare nurse staffing shortage a national crisis. Sept. 1, 2021. https://bit.ly/3olxMmj

CMS to Issue Rule Mandating Vaccines for Healthcare Workers

Healthcare mandates on solid legal footing

President Biden has dropped the carrot and picked up a stick, ordering healthcare workers (HCWs) — all 17 million — to receive the COVID-19 vaccine, or Medicare money may be withheld from their employers.

This is something of an unfolding situation, as many hospitals have already set deadlines, but CMS said it would issue an interim final rule — including a comment period — as early as Oct. 2. "Facilities across the country should make efforts now to get healthcare staff vaccinated to make sure they are in compliance when the rule takes effect," CMS stated. "Nursing homes with an overall staff vaccination rate of 75% or lower experience higher rates of preventable COVID infection. In CMS's review of available data, the agency is seeing lower staff vaccination rates among hospital and end-stage renal disease facilities. To combat this issue, CMS is using its authority to establish vaccine requirements for all [participating] providers and suppliers."[1]

Ties to Reimbursement

Biden announced the vaccination requirements on Sept. 9, expanding on his idea of leveraging CMS reimbursements to require all HCWs to take the vaccine. "Already, I've announced we'll be requiring vaccinations for all nursing home workers who treat patients on Medicare and Medicaid because I have that federal authority," Biden said. "I'm using that same authority to expand that to cover those who work in hospitals, home healthcare facilities, or other medical facilities — a total of 17 million healthcare workers. If you're seeking care at a health facility, you should be able to know that the people treating you are vaccinated. Simple. Straightforward. Period."[2]

Citing the highly transmissible delta variant and continuing nursing home outbreaks, President Biden ordered HHS to mandate COVID-19 vaccinations for long-term care staff on Aug. 18. As a result, CMS already was moving to require all nursing home workers to take the vaccine or risk losing federal funding. After Biden's announcement of the expanded mandates in healthcare, CMS followed suit, saying that in collaboration with the CDC, "emergency regulations requiring vaccinations for nursing home workers will be expanded to include hospitals, dialysis facilities, ambulatory surgical settings, and home health agencies, among others, as a condition for participating in the Medicare and Medicaid programs."[1]

Legal Questions

Using the reimbursement powers of CMS to affect and enforce healthcare policy should hold up in court, says **Lawrence Gostin**, JD, a law professor at Georgetown University. More specifically, the president has the power to use government agencies to enforce vaccine mandates in healthcare and places of work.

"I think he is on strong legal ground there," Gostin says. "The federal government can set conditions on the receipt of Medicare and Medicaid funding as long as they are reasonable. These mandates are evidence-based and logical because healthcare settings [are treating] some of most vulnerable people in the country. Healthcare workers and establishments have the strongest ethical duty to protect their patients. That is on firm legal ground."

In another mandate that could face many legal challenges, President Biden ordered the Department of Labor to develop an emergency rule to require all employers with 100 or more employees — an estimated 80 million people — to ensure their workforces are fully vaccinated or show a negative test at least once a week.

"There will be challenges, but again, the president is on strong legal footing," Gostin says. "He is acting under the Occupational Health and Safety Act, which allows the president to set standards for workplace health and safety. The threat of an infectious disease in the workplace — with a highly infectious variant that could cause hospitalization or death — is at least as hazardous as a workplace injury. We are currently in a public health emergency."

Countering some circulating disinformation, Gostin clarified that a president does not have the power to simply mandate vaccination for all citizens. Only cities and states can legally require those kinds of mandates.

That said, the Biden administration still has some powers it can deploy for vaccines, including requirements for air travel subject to federal oversight. The federal response is a mix of public health and political consequences, as Biden holds back some actions and pushes forward on others. For example, in the mandate speech, he again urged sports and entertainment venues to require proof of vaccination or a negative test for entry. Even if these venues tried to enforce such measures, the CDC vaccination cards are woefully short of a true national vaccination registry system that cannot be easily gamed, Gostin says. The Biden administration has resisted creating such a system, which could be branded as government overreach by political opponents. ■

REFERENCES

1. Centers for Medicare & Medicaid Services. Biden-Harris administration to expand vaccination requirements for health care settings. Sept. 9, 2021. https://go.cms.gov/3zXJKo0
2. The White House. Remarks by President Biden on fighting the COVID-19 pandemic. Sept. 9, 2021. https://bit.ly/3B0ub0h

A History of Violence: Leaders Must Stand Up for Nurses

Violence prevention is not a program to set up, walk away from

Two veteran occupational health nurses described their experiences with workplace violence over the years, emphasizing this chronic situation can be stopped if individual hospital leaders set a tone that enough is enough. If they are to succeed, they must address all facets of a comprehensive violence prevention program, the nurses said at a Caring for Healthcare Professionals podcast by the Association for Occupational Health Professionals in Healthcare (AOHP).[1]

Donna Zankowski, MPH, RN, FAAOHN, an occupational health nurse consultant in Maryland, started focusing on workplace violence in 2014.

"I was a graduate nurse intern at OSHA in the office of Occupational Medicine and Nursing," she said. "I did a research project for them looking at the contents of these commercially available workplace violence prevention programs that hospitals were buying to train their employees with. And that project really encouraged me to want to get more involved from an advocacy perspective."

It has been delayed and blocked for years, but OSHA proposed a violence prevention as the Obama administration came to an end in 2016. Such regulations were a nonstarter in the succeeding Trump administration.

"There is federal legislation right now on workplace violence prevention that would basically mandate OSHA to hurry up and issue that workplace violence standard," Zankowski said. "That particular legislation is the Workplace Violence Prevention for Health Care and Social Service Workers Act. It has passed the House."

A career nurse, Zankowski said violence against healthcare workers has always been more the rule than the exception in the facilities she has worked at over 35 years.

"I've seen workplace violence in every single facility I've ever worked at," she said. "I was an ICU nurse, a case manager, a discharge planner, and I did home care — and, of course, then, occupational health. But I've seen it in every possible setting. A lot of the workplace violence is coming from patients; it's patients on staff. But as you know, we have the other types as well."

The violence appears in myriad forms, from someone coming in to commit a crime (often with a weapon) to domestic situations that have spilled over into the workplace.

"You've got violence between co-workers — I've seen that as well. Sometimes, it's physical; sometimes, it's verbal abuse and bullying," Zankowski noted.

Mental Health in Teens

Amy Straight, RN, MBA, interim director for occupational health and safety at Seattle Children's Hospital, said she is seeing a mental health crisis in youth that results in violence in the ED and psychiatric units.

"These behaviors are really aggressive in terms of what we've seen in the past," Straight noted. "More biting, more hitting, more punching and kicking vs. the verbal types of assaults we're normally used to seeing. Sadly, through the pandemic, we've also noticed an increase in racial violence and discrimination and microaggressions in the workplace that are starting to play out as people

are experiencing racism in the community."

Zankowski stressed the importance of violence prevention programs requiring reporting of all incidents.

"We all know that workplace violence is really underreported — severely underreported," she said. "I've seen a lot of nurses don't want to report when they get hit, bit, or punched. They make excuses: 'Well, the person was just upset, in pain, [or] a little confused because the room was dark.' To my mind, none of those things actually matter in terms of creating your workplace violence prevention program. [You must] account for the numbers and report the workplace violence. Because regardless of why it's happening, we still need to have an accurate picture of how much it's happening."

Even if initially reported, breakdowns in the communication chain leave islands of data here and there, unknown to all the principals in the program.

"Many times, people will report [violence] to their direct supervisor, but they don't report that to employee health," Zankowski said. "It's a major issue because sometimes reports go to security, and then it 'lives' there. Then, sometimes it goes to employee health if the worker is injured. Facilities that find a way to integrate all the reporting do much better with their workplace violence prevention."

Leadership or Leaderless?

A fully functioning program that expects and receives compliance from workers requires leadership that sets the tone of the institutional culture.

"I think the facilities that have really involved leaders that care deeply about the workplace violence program do better, because management is completely on board with making sure that the program is successful and the numbers go down," Zankowski said.

More leadership involvement should be forthcoming, as The Joint Commission's new violence prevention requirements become effective Jan. 1, 2022.

"It has it has to start with culture," Straight emphasized. "You have to have a culture of safety for any policy or program to be effective when implemented. You can have all the technologies, tools, and resources and everything at your disposal, but if you don't have a culture that is committed to it, you're not going to be [successful]."

Violence prevention is not a program to set up and walk away from, intending to check the data occasionally but perhaps getting lost in the day-to-day crises in healthcare.

"This program that really requires constant eyes on it, constant auditing of your strategies," Straight said. "[Use] metrics to start looking at where you're making those positive changes, then you can start to use that data to drive forward other strategic initiatives with workplace violence."

Look for the root cause of incidents, which will help prevent recurrence. "It's not just saying, 'Well, the nurse didn't do this or we were short-staffed.' I mean, that's not good enough," Zankowski said. "We really need to get down to the root causes so we can make things better."

Another longstanding problem is the policy and legal inconsistencies between some states and individual

hospitals. In some states, attacking a healthcare worker is a felony. Similarly, in some hospitals, management encourages workers not to file charges against the patient who attacked them. Sometimes, employees are afraid to file criminal charges for their reasons of their own.

"Even if you do file criminal charges, or you try to, if your local state attorneys are not inclined to prosecute it, it really doesn't matter," Zankowski lamented. "We have found in Maryland that you really need to do education with your state's attorneys to have them understand the nature of the violence, that this is not part of our job, and that, yes, these really are crimes when they escalate to that level. They should be prosecuted to the fullest extent of the law."

Patients should understand healthcare workers are valued and protected when they enter the hospital.

"When they walk through your doors, is there an exception that's made for them to act that way?" Straight asked. "If so, we should not be accepting that as normal behavior. There should never be allowance for any of that."

One facility reinforced this by requiring patients to sign a behavior contract, explaining that if they become violent or disruptive, they could be discharged from care.

"They would still be allowed to be admitted to the facility for an emergency," Zankowski explained. "If they came to the ER, they'd be accepted, but they couldn't come back for elective procedures if they weren't willing to abide by the behavioral expectations."

On the other hand, hospitals are a business that need high patient satisfaction scores for marketing and to secure return customers.

"The staff is feeling like, 'We can't win here,'" Zankowski said. "Because if we get bad satisfaction scores, then they come down hard on us for not making the patients happier. But we also have to make patients be accountable for their behavior." ■

REFERENCE

1. Association for Occupational Health Professionals in Healthcare. AOHP Caring for Healthcare Professionals podcast, episode 14: Workplace violence prevention in healthcare. July 22, 2021. https://bit.ly/2Wr0PsT

CE OBJECTIVES

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

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

CE QUESTIONS

1. **A CDC vaccine efficacy (VE) study of healthcare workers revealed VE declined from 91% before the delta strain of COVID-19 emerged to what percentage after it became the predominant variant?**

   a. 86%
   b. 79%
   c. 66%
   d. 49%

2. **New York Gov. Kathy Hochul signed an executive order declaring a statewide emergency due to nurse staffing shortages. This declaration will:**

   a. allow licensed nurses from other states and countries to work in New York.
   b. assign mandatory overtime.
   c. restore licenses to nurses who have been successfully treated for substance abuse.
   d. divert patients to other states with adequate staffing.

3. **As part of a violence prevention program, a healthcare facility required patients to sign a "behavior contract," which explained that if they became violent or disruptive, they could be:**

   a. admitted to the psychiatric unit.
   b. discharged from care.
   c. given sedatives for the remainder of their stay.
   d. charged with endangering healthcare workers and patients.

4. **According to the FDA, which side effect is observed more frequently after booster shots than after the standard two-dose regimen?**

   a. Fatigue
   b. Severe headache
   c. Joint pain in the knees
   d. Swollen lymph nodes in the underarm

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