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IPs at a Crossroads: Change Is Coming in Pandemic Aftermath

'I don't think we solve [this] without growing our profession'

By Gary Evans, Medical Writer

Infection prevention — already hard-tasked before a 100-year pandemic hit — faces a reckoning that will determine the future of the field.

Will an aging and potentially burned-out workforce be able to retain and recruit infection preventionists (IPs), capitalizing on the value they have demonstrated during the COVID-19 pandemic? The betting money says yes, but there are many critical issues to resolve. The larger question is if IPs can go beyond the hospital, bringing their expertise into many vulnerable areas exposed by the pandemic.

Sarah Smathers, MPH, CIC, FAPIC, director of infection prevention and control at Children's Hospital of Philadelphia, delivered a plenary address recently at the spring 2021 conference of the Society for Healthcare Epidemiology of America (SHEA).

"We have been going through a pandemic where the spotlight has been on our departments in a way that it has never been before," Smathers said. "We have proven our worth and our value to our organizations. We should leverage that to ask our leadership for what we need to recover and rebuild our departments."

The pressures on IPs were many before an all-hands-on-deck SARS-CoV-2 pandemic compounded them immeasurably. These included device-related outbreaks, including infections with some reprocessed endoscopes and unusual, potentially fatal infections traced back to heater-cooler units in operating rooms.

"Things like multidrug-resistant organisms and *Candida auris* have been emerging, and we have been dealing with vaccine-preventable diseases like measles," she said. "Whether they have impacted you directly, you have had to prepare and respond to these a long time before COVID-19."

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To that point, all of these problems remain, and many, such as vaccine-preventable diseases, likely will be worsened in the absence of school attendance. Yet, regardless of circumstance, the core tenet of the IP mission is patient safety, which is something of a double-edged responsibility.

"Over the last decade, there has been increased transparency around patient safety, including ways to prevent healthcare-associated infections," Smathers said. "This has led to mandatory reporting requirements, which, again, are good for patient safety and core to the work that we do, but we need to acknowledge that this has increased our workload and burnout. [We] both track these infections and then are tasked with developing the programs to prevent them."

Again, these were the challenges IPs faced before the pandemic, which immediately demanded more of their time and aggravated the ongoing staffing issues amid demographic change in an aging workforce.

"You put a pandemic on top of that — it's been a real recipe for burnout and exhaustion," Smathers said. "It's [something] I don't think we solve without growing our profession and advocating for our departments. I want us to all be thinking about that as we emerge from this pandemic. It is really an opportunity for us to not go back to the old way of doing things. Reimagine what our work could look like, and how we can support it and structure it in the future."

Future Pathways

It may seem counterintuitive to see growth as a solution to exhaustion, but the Association for Professionals in Infection Control and Epidemiology (APIC) also sees these factors as critically related. There are questions about the levels of burnout and stress the pandemic is exacting on IPs as well as on the healthcare workforce overall.

"We are concerned about whether we will see that," says **Ann Marie Pettis**, RN, BSN, CIC, president of APIC. "We know we have an aging-out group of IPs and nurses. Will [the pandemic] accelerate that? What it brings to mind is that one of our most important initiatives right now is the IP Academic Pathways. We have a task force working very rapidly on that — we can't do that too soon."

Moving away from the traditional IP coming into the role by serendipity or happenstance from another medical career, APIC is creating an infection prevention curriculum for colleges and universities based on the competencies outlined by the Certification Board of Infection Control and Epidemiology. (*See "In a Time of Sea Change, Devin Jopp Takes APIC Helm."*)

The pandemic also has revealed the need for IP knowledge in non-traditional settings, such as entertainment, hospitality, sports, and school reopening strategies. "We recently had an important role in a school reopening document," Pettis says.[1] In addition, APIC conducted an "IP Recharge" series to help the profession with mental health needs and overall well-being.[2]

"Hopefully, one of the lessons learned will be when situations like this happen — or even in normal circumstances — we need resources to address the well-being of our healthcare workers," Pettis says.

An obvious key to individual well-being is working in an adequately staffed department, which appears to

be both an immediate and a long-term challenge.

"We have had a lot of retirements in the last five years," Smathers says. "We also anticipate that we are going to see more retirements. A study that we did found that 52% of hiring managers were anticipating that they were going to have an IP retire in the next one to two years."[3]

These retirements create vacancies that can take three to six months to fill. "Some places are taking up to a year to find a replacement," Smathers said they found in the study. "That creates a huge burden on the staff that is left behind."

IPs are needed but already understaffed or working in diluted roles in ambulatory care and long-term care.

"Our IPs are wearing multiple hats in these non-acute care settings," she says. "They are in nurse management, quality specialists as well as infection preventionists. [Overall,] 58% report infection prevention is less than half their job."[4,5]

Offering one novel solution to this problem, Smathers proposes a "plus one" initiative, where a highly experienced, well-paid IP trains two novice IPs to replace her or him upon retirement. Another option would be to hire a new IP as well as, for example, a data analyst who could help crunch healthcare-associated infection numbers and assist with antibiotic stewardship.

"That is a creative approach," Pettis says. "And I do think we are we going to have to get really creative about this."

The old formulas on how many IPs are needed for so many hospital beds are increasingly outdated by healthcare delivery changes. The ratio in the landmark SENIC study in 1980 was one IP per 250 beds, which has been updated over the years to one IP per 100 beds, and most recently to one IP per 69 beds.[6,7]

The authors of that last study concluded, "Size, scope, services offered, populations cared for, and type of care settings all impact the actual need for IP coverage, making the survey benchmarks available in the literature invalid."[7]

Smathers said a key part of that study is "that they were not only looking at the things IPs do every day, but asking the chief stakeholders what is it that you want from us? What are the needs of the organization? Using that to assess what their program should look like."

A finding that will surprise no one is that most IPs spend more than half their time doing surveillance, but only about one hour per week on professional development. This is one of the key reasons IPs leave the field, so Smathers created three levels of advancement and seeks diverse backgrounds in her program. The levels are Novice IP Level 1; Proficient IP Level 2; and Expert IP Level 3. She uses APIC competency levels to establish where the IPs should be placed.[8]

"We also have a nurse fellowship program where a nurse spends one day a week with us for 12 months," she said. "They spend the rest of the time with their own unit. What was really great during the pandemic is that we were able to call back some of these fellowship graduates to support our department and our activities in infection prevention."

Regarding educational diversity, Smathers recommended a study that sees benefits in adding IPs with different backgrounds than nursing, noting that "laboratory scientists and public health professionals are bringing knowledge attained through advanced degrees and diverse skillsets to infection control departments."[9]

Noting that it is less like a ladder than a jungle gym, Smathers said diversity "has really strengthened our program and allowed us to bring a lot of different aspects to the table."

Making the point that asking is not the same as receiving, Smathers encouraged IPs to emphasize the bottom-line savings and to be persistent.

"We are not revenue-generating and it is hard for us to make our business cases," she said. "If you are told 'no,' don't give up. Ask for feedback on what you can do to improve your presentation and pitch. Talk to people in your organization who have been successful at growing their departments."

As disastrous as it has been, the pandemic and its aftermath will open a way for a new breed of IP.

"Now is our time," she said. ■

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CDC: Vaccinated Healthcare Workers Can Take Breaks Together Without Masks

A welcome relief, but is it too soon?

At this point in a prolonged pandemic, many healthcare workers are suffering personal protective equipment (PPE) fatigue, burnout, and some level of exhaustion. Certainly, many may welcome new guidelines by the Centers for Disease Control and Prevention (CDC) that fully vaccinated staff can gather maskless in break rooms and dining areas to converse and eat.

"In general, fully vaccinated healthcare personnel (HCP) should continue to wear source control while at work," the CDC states.[1] "However, fully vaccinated HCP could dine and socialize together in break rooms and conduct in-person meetings without source control or physical distancing. If unvaccinated HCP are present, everyone should wear source control and unvaccinated HCP should physically distance from others."

According to anecdotal reports, these maskless interactions already were occurring before the vaccines were available, and some have speculated they could have been one of the primary sources of infection in healthcare workers. (*See* Hospital Infection Control & Prevention, *January 2021*.) Although the vaccines are proving extremely effective, sanctioning these practices now still raises questions because of issues such as breakthrough infections, variant strains that may elude immunization, and whether asymptomatic, vaccinated people can transmit the virus.

"A growing body of evidence suggests that fully vaccinated people are less likely to have asymptomatic infection and potentially less likely to transmit SARS-CoV-2 to others," the CDC states.[2] "However, further investigation is ongoing."

Remember, these are CDC recommendations – not required regulations, says **Ann Marie Pettis**, RN, BSN, CIC, president of the Association for Professionals in Infection Control and Epidemiology (APIC).

"We know that one size is not going to fit all with these recommendations," she says. " So, it is up to each organization, community, and each state. Often the states make mandates that you have to follow. Sometimes they go along with the CDC, sometimes they do not. We're still sort of sitting tight, as I am sure a lot of states are." A key indicator for such a policy is the level of SARS-CoV-2 in the surrounding community, she says.

"As with so many things, the devil is in the details," Pettis says. "So, IPs [infection preventionists] all over the country are looking at these guidelines, adjusting them, talking to their organization leaders, and interacting with their states. IPs are very good at implementation – that's our wheelhouse – implementing recommendations, regulations, guidelines."

Importantly, vaccine breakthrough infections are occurring at a lower rate than would be expected for the two RNA-messenger vaccines.

"The true numbers that we are seeing locally, and even nationally, are less than their 95% efficacy would indicate, where there would be a 5% breakthrough," she says. "We are seeing about a 1% [breakthrough]. So that's good news, and I think that may have influenced the CDC coming out with these guidelines."

If breakthrough infections rose as a result of variants, the CDC likely would revert to their previous, more conservative guidelines. "I think the CDC and the WHO [World Health Organization] are trying very hard to stay on top of that," she says.

Still, if these policies are enacted, it raises the immediate question of which healthcare workers have been vaccinated and which have declined. That sounds straightforward enough, but it may be easier for some IPs than others.

"In New York state, there is a regulation that keeps track of that, but I don't think that every state has mandated that," says Pettis, director of infection prevention at University of Rochester (NY) Medicine.

Human behavior comes into play, as well as the age-old unpopular role of being the infection control police.

"We have lists of who is and who isn't vaccinated," she says. "But when you think about 24/7 looking into the break rooms – which I will say is where most transmission has occurred in healthcare workers – how do you police who is vaccinated and who isn't?"

Another issue goes back to COVID-19 vaccination, which was approved for emergency use as a choice.

"We have also already heard from our unvaccinated staff that they are feeling unfairly singled out," Pettis says. "We have to be very conscious of that. Messaging is extremely important in terms of how you would implement that. We're really examining it closely."

Although seemingly straightforward, the CDC recommendations could open a can of worms. No one can afford to be cavalier about it because, ultimately, patients' lives are at stake. Cases of breakthrough infections in vaccinated healthcare workers that involve patient exposures can be very sensitive and time-consuming, she says.

"Even though it is only 1%, it does happen, and IPs do contact tracing," Pettis says. "In infection prevention, we may be over-careful because we have seen the worst-case scenarios occur. We are the ones on the frontline dealing with these things, so you can be sure that we will be very careful about which [of these guidelines] we are able to implement. We all want to go there [and remove PPE], but we need to do it very carefully, with safety being our number one concern."

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Airborne Transmission

In another recent CDC update, the agency said emerging science shows transmission of SARS-CoV-2 airborne viral particles can occur beyond six feet, particularly in enclosed, poorly ventilated spaces. IPs may want to check whether any of their break rooms and patient areas meet these conditions and may present an increased risk.

This has been something of a contentious issue, but the CDC acknowledges that under certain circumstances, the coronavirus can linger in the air and travel beyond the traditional six-foot droplet range. According to the CDC, factors that increase this risk include:

- enclosed spaces with inadequate ventilation or air handling within which the concentration of exhaled respiratory fluids, especially very fine droplets and aerosol particles, can build up in the air space;
- increased exhalation of respiratory fluids if the infectious person is engaged in physical exertion or raises their voice (e.g., exercising, shouting, singing);
- prolonged exposure to these conditions, typically more than 15 minutes. ■

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OSHA COVID-19 Standard Under Review

The agency has considerable political momentum

As this story was filed, the Occupational Safety and Health Administration (OSHA) had completed a proposed emergency temporary standard to protect healthcare workers and other employees from SARS-CoV-2 occupational infections. The standard is under further government review, and the specific regulatory requirements have not been revealed in any detail.

"In response to the [pandemic] devastation, President Biden issued an executive order that directed the Department of Labor to consider whether any emergency temporary standards were necessary to keep workers safe from the hazard created by COVID-19," OSHA stated in announcing the action.[1] "On Monday, April 26, OSHA sent draft standards to the Office of Management and Budget's Office of Information and Regulatory Affairs for review after working with its science-agency partners, economic agencies, and others in the U.S. government to get the proposed emergency standard right."

OSHA further stated that $100 million in additional funding granted under the American Rescue Plan of 2021 will be used, in part, to hire more than 160 new critical personnel, including compliance safety and health inspectors.

"The health and safety movement has been fighting for mandatory COVID rules in the workplace since this pandemic started," said **Jessica Martinez**, co-executive director of the National Council for Occupational Safety and Health. "There is no public agency that is tracking the number of workers who have died from workplace exposure to COVID."

Martinez urged rapid implementation of the measure in a recent national commemoration for workers. "We are hopeful that it is comprehensive and provides sufficient protections," she said. "At the very minimum, we are aware that the standard mandates that employers must have a [COVID-19] prevention program in place that allows for workers to provide input."

Lost Battles and Beyond

Broadly speaking, infection preventionists traditionally have preferred Centers for Disease Control and Prevention (CDC) voluntary guidelines rather than rigid OSHA regulations. Perhaps the most memorable example was when the Association for Professionals in Infection Control and Epidemiology (APIC) got into a prolonged battle with OSHA over a proposed tuberculosis (TB) standard about two decades ago. After outbreaks in the 1990s, TB was in a national decline that has continued in the United States. Thus, APIC argued the respiratory fit-testing and other regulations for a plummeting disease was a wasteful use of healthcare resources. It appeared APIC's arguments had won the day, but OSHA pulled a now infamous 11th hour move by adding some of the controversial TB provisions into its existing respiratory protections standard on New Year's Eve 2003.

"The TB standard was not as scientifically driven as we would have liked," says **Ann Marie Pettis**, RN, BSN, CIC, current president of APIC. "Hopefully, this one will be. The problem, though, in my mind is that so much of the science still isn't worked out for [COVID-19]. If [the standard] comes out and it is all evidence-based — and it gives support to the fact that the powers that be need to make sure that the [2020] PPE [personal protective equipment] supply debacle doesn't happen again — I would agree with that."

An argument still could be made against mandates seen as draconian, as more and more workers are vaccinated. Even if they are not vaccinated, some have argued workers are at more risk in the community than in the controlled healthcare environment. However, OSHA has considerable political momentum, not the least of which is President Biden's working-class roots. The Biden Administration certainly could argue that a standard now would protect workers in the next pandemic.

Then there are the personal stories from workers who lost coworkers. **Pascaline Muhindura**, RN, a critical care nurse at a hospital in Kansas City, MO, and a member of National Nurses United (NNU), spoke at the national commemoration for workers.

"I am here today to remember my colleagues and all the nurses and frontline workers who have lost their lives because our employers did not give us the protections we needed for the COVID pandemic," she said. "In January 2020, nurses urged our employers to prepare for COVID. They didn't."

Muhindura blames the lack of readily available N95 respirators for a

COVID-19 exposure from a patient, which led to the fatal infection of her coworker, Celia Yap Banago, in April 2020. "Despite Celia's death, the hospital continues to ration N95s," she says. "Management is still forcing us to unsafely reuse the same N95 for our entire shift."

Nurses need mandatory rules, not voluntary guidelines, she said. ■

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Clusters of Post-Vaccine Anxiety and Fainting

Fear of needles may have set off psychological chain reaction

Mass vaccination sites in five different states reported clusters of people stricken with anxiety and fainting after receiving the Janssen COVID-19 vaccine April 7-9, 2021, the Centers for Disease Control and Prevention (CDC) reports.[1]

The reactions appear to be psychological, since nothing was wrong with the lots of vaccine, and all of the people examined had no clinical medical problems. The incidents occurred before the national pause on Janssen immunization as a result of rare blood clot reactions. Immunization with the vaccine has resumed, and the pause is over.

However, women younger than age 50 years should be aware that they are at risk of the rare but real side effect of blood clots.

Overall, 15 women have had the reaction and three have died, the CDC reports. The reaction has not been observed with the other two vaccines approved for use in the United States, and the Pfizer and Moderna vaccines have continued to be administered.

The lead CDC investigator of the anxiety reaction clusters hypothesizes that those with an acute fear of needles sought out the Janssen vaccine, since it is a one-dose shot that requires no second vaccination. It is possible that a chain reaction of hysteria occurred in some people, after seeing other vaccinees faint. Overall, among 8,624 Janssen COVID-19 vaccine recipients, 64 people had the anxiety reactions.

The most commonly reported signs and symptoms were light-headedness or dizziness (56%), pallor or excessive sweating (31%), fainting (27%), nausea or vomiting (25%), and hypotension (16%).

The CDC interviewed vaccination site staff members to gather additional information about the reported events and vaccination site practices. Four of the five sites closed temporarily while an investigation took place.

"Thirteen (20%) of the affected patients informed staff members of a history of fainting associated with receiving injections or needle aversion," the CDC reported. "Among the 64 total cases, 39 (61%) occurred in women. Median patient age was 36 years (range 18-77 years). Most events resolved within 15 minutes with supportive care. Thirteen (20%) patients were transported to an emergency department for further medical evaluation. Among these, five for whom follow-up information was available were released from medical care on the same day."

Hospital Infection Control and Prevention (*HIC*) spoke to the lead author of the report, **Allison Hause**, PhD, an epidemiologist in the CDC immunization branch. The following interview has been edited for length and content.

HIC: Just to reiterate, these clusters occurred before the Janssen vaccine was paused. Have there been any more reports since the resumption of vaccinations?

Hause: These clusters of anxiety-related events were reported to CDC before Janssen COVID-19 vaccine was paused. No additional reports have been reported to CDC.

HIC: The fact that these were in clusters suggests that these patients could have triggered others to have the same reaction. Can you comment on this theory or why you think they would occur in clusters rather than random individual cases?

Hause: At some sites, some events did occur within a close window of time. A person who witnesses an adverse event may become nervous and experience an anxiety-related event themselves, especially if that person is needle-phobic. When this occurs at mass vaccination sites, it can cause a chain reaction.

HIC: Have these reactions been seen to this degree with the other two approved vaccines in the United States?

Hause: We have not received reports of similar clusters following the mRNA COVID-19 vaccines.

HIC: At this point, are these considered primarily psychological (fear) reactions or is there any concern that the vaccine could cause this side effect? Were the lots involved in these clusters inspected?

Hause: The events described in this report are consistent with the definition of anxiety-related events following vaccination. It's possible that individuals with a fear of needles have sought out the Janssen COVID-19 vaccine because it is a single dose. We do not consider these events to be a safety concern associated with Janssen COVID-19 vaccine. We performed a vaccine lot analysis for the vaccine used at each site to determine if a particular vaccine lot was associated with these events. No safety issues or clustering of adverse events indicated a product quality problem.

HIC: Was this phenomenon reported in the clinical trials?

Hause: In the Phase III trial, syncope [fainting] was reported for one person (of 21,895) who received Janssen COVID-19 vaccine. Of the 21,888 persons who received placebo, none experienced syncope. ■

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In a Time of Sea Change, Devin Jopp Takes APIC Helm

'We need to start thinking about how we make sure this never happens again'

It may tell you everything you need to know about **Devin Jopp**, EdD, MS, that amid the worst pandemic in a century he became the CEO of the Association for Professionals in Infection Control and Epidemiology (APIC).

"I saw APIC as a wonderful opportunity in an amazing organization that is doing work in numerous settings, both acute and non-acute," he tells *Hospital Infection Control & Prevention* (*HIC*). "Infection preventionists (IPs) are truly heroes through normal times, let alone during COVID."

Jopp has more than two decades of leadership experience working with non-profits and healthcare associations.

His immediate past job was CEO of the American College Health Association (ACHA), where he advocated for the health and well-being of some 20 million college students on the nation's campuses. Of course, that meant dealing with COVID-19, so perhaps the move to APIC leadership is not that surprising.

"We [at ACHA] formed our initial work groups [in] January 2020," he says. "So, we were very early and wrote the guidelines about college reopenings. I was very involved early on in some of the policy recommendations. It was an opportunity to bring my skills to bear and help further the mission."

Jopp does have an interesting skillset, one that embraces both technology and human learning. His education includes a master's degree in computer and information sciences and a doctorate in human and organization learning. Jopp lives in Vienna, VA, with his wife and their three children.

HIC spoke to him further in the following interview, which has been edited for length and clarity.

HIC: You picked a heck of a time to take the helm at APIC.

Jopp: This has been more than a year and, really, we are not done with COVID, so a critical priority is to help our members navigate this. There have been lots of issues and confusion along the way, but APIC is trying to be there, take the guidance as we learn about this virus, and help our members be responsive.

HIC: IPs sometimes struggle to get their programs resourced and supported. Are you interested in taking this pandemic moment to raise their profile?

Jopp: One hundred percent. It has been a struggle in some cases, but I think the organizations that have responded well are ones that really embrace infection prevention in their culture. It comes down to baking it in — how they talk about and demonstrate infection prevention, and how they staff it. Even, frankly, how it is led. This is a senior-level position that can provide guidance and influence.

HIC: Nursing homes were devastated by the pandemic. It raises the question of what a difference an IP presence could have made in those settings.

Jopp: I agree with you. What we saw was a wholesale lack of infection prevention. Not taking the opportunities to adequately staff and put in those processes led to needless, really tragic deaths.

I think one of the lessons that we learned — and, hopefully, we are going to see some state and federal action around — is requiring IPs in these institutions, just as we have done in acute care. Build on that model to protect patients and residents of those communities as well.

HIC: It looks like you are starting this campaign by calling for a state law in New York. Will you lobby other states to take similar action?

Jopp: That is a focus for us, and we are working right now in the state of New York to hopefully introduce some legislation. I think there needs to be national attention right now on setting staffing and certification requirements, as well as establishing surveillance in nursing homes. All of that needs to be in place and that is a big policy fight for us.

The other piece that is important for us is really trying to grow the profession at a time when we are in a real crisis. We are finding that there is huge need for IPs, and we don't have a bucket big enough to fill it.

There hasn't been a clear pathway on how to become an IP, so we are launching the IP Academic Pathway. We are really excited about that and are partnering with universities and trying to create some bachelor- and master-level certificate programs. We are really trying to spark our profession. We are also trying to elevate infection prevention training, not just for our IPs, but really for other healthcare workers in various settings. It's a little bit like taking a sip from a fire hose, but we have to get this right. We are still in response mode, but we need to start thinking about how we make sure this never happens again. There are policies and changes that we are going over now that we want to make sure get implemented. ■

NIOSH, FDA Cracking Down on N95s

Time to begin phasing out N95 reprocessing

The National Institute for Occupational Safety and Health (NIOSH) has revoked the public health emergency approval of an N95 respirator manufacturer after sample products failed filtering tests, according to a recent agency announcement.

"As of April 8, 2021, Plastikon Industries, Inc. respirator model PLASMA N95-01 N95 filtering facepiece respirator is no longer NIOSH-approved," NIOSH stated.[1] "Revocation also means that respirators bearing NIOSH approval numbers TC-84A-PH19 may no longer be manufactured, assembled, sold, or distributed."

NIOSH conducted a product audit of Plastikon's PLASMA N95-01 N95 respirator and found the mask failed to meet filter efficiency standards. "The Institute reserves the right to revoke, for cause, any certificate of approval issued pursuant to the provisions of this part," NIOSH stated. "Such causes include, but are not limited to, misuse of approval labels and markings, misleading advertising, and failure to maintain or cause to be maintained the quality control requirements of the certificate of approval."

Based in Hayward, CA, Plastikon Inc. had not replied to a request for comment as this story was filed.

In related regulatory action, hospitals should begin phasing out reprocessing systems for single-use N95 respirators, since national supplies have been replenished and it is time to end the temporary crisis response to the pandemic, the Food and Drug Administration (FDA) stated in a letter to the healthcare industry.

"We have stated all along that this is an extreme measure to be utilized when there are simply not adequate respirators available," says **Suzanne Schwartz**, MD, MBA, director of the FDA office of strategic partnerships and technology innovation. "We authorized these under an appropriate benefit-risk calculus, with an understanding and communication to stakeholders that the intent of this wasn't to become mainstay by any means. These [N95] respirators are designed, and have been studied as single-use devices, and eventually we have to get back there."

The FDA has the power to revoke the emergency use authorizations (EUAs) granted for stop-gap measures enacted during the pandemic but wanted to give the healthcare system some time to make the changes.

"This is not a flip of the switch," she says. "It is not like one day you are decontaminating, and the next you are giving out new ones for every single interaction. This has to be done thoughtfully, systematically, in a phased manner. That is why we

communicated in a letter format to put healthcare organizations essentially on notice: The revoking of these EUAs is forthcoming."

The FDA letter said the action was based on the increased domestic supply of new respirators approved by the Centers for Disease Control and Prevention's (CDC) NIOSH.

In the letter, the FDA recommends that healthcare personnel and facilities do the following:

• Limit decontamination of disposable respirators. Decontaminated respirators and respirators that have undergone bioburden reduction should be used only when there are insufficient supplies of new face-fitting respirators (FFRs) or if you are unable to obtain any new respirators.

• Transition away from a crisis capacity strategy for respirators, such as decontamination of N95 and other FFRs.

• Increase inventory of available NIOSH-approved respirators, including N95s and other FFRs, elastomeric respirators, including new elastomeric respirators without an exhalation valve that can be used in the operating room, and powered air-purifying respirators (PAPRs). Even if you are unable to obtain the respirator model that you would prefer, the FDA recommends that you obtain and use a new respirator before decontaminating or bioburden reducing a preferred disposable respirator.[2]

Changing Recommendations

To be clear, the longstanding recommendation by the CDC is to don a single-use N95 respirator to care for a patient with a novel respiratory virus like COVID-19. This CDC recommendation was downgraded to a less protective, basic surgical mask rather quickly, as it became apparent in the early days of the pandemic last year that there were insufficient stocks of N95s on a broad scale. Some hospitals began reusing N95s for a limited number of days by having staff wear a single-use surgical mask over the respirator. Under these systems, the masks were discarded between patients.

The FDA gave emergency approval to N95 respirator reprocessing using such bioburden reduction approaches as vaporized hydrogen peroxide, ethylene oxide, ultraviolet germicidal irradiation, and moist heat treatments. There was some controversy to these approaches, and some studies showed respirators should be reprocessed only a limited number of times or lose protective integrity.[3]

There also were questions about whether reuse compromised the need for a tight fit with N95s and whether the chemicals used in reprocessing could cause any long-term health effects.

"That guidance was based on over 10 years' worth of research that NIOSH had conducted on decontamination of filter facepiece respirators," says **Maryann D'Alessandro**, PhD, director of the NIOSH national personal protective technology laboratory.

This was done because NIOSH determined that in an influenza pandemic, N95 supplies could run short and decontamination could be a temporary solution, she explains.

"If you use this as a crisis capacity strategy, it should be based on a unit-by-unit situation and a manufacturer-by-manufacturer situation based the products' composition," D'Alessandro says. "For crisis capacity, we believe these types of techniques would be appropriate. But this is not something you would continue as conventional operations. They are meant to be single-use products."

Clarifying that there were no incidents nor occupational infections that led to the FDA letter, Schwartz says the EUAs were granted on a temporary basis based on lack of supplies.

"Because [this reprocessing] was very narrow, very specific to crisis capacity, we don't consider the exposures that have occurred to be the equivalent of chronic or long-term exposures," she says. "That is not to say that we have all the answers now in terms of real-world data. The benefit of having respiratory protection for healthcare workers as opposed to their exposure to COVID-19 [was the deciding factor]. Knowing that this is not a long-term solution, the FDA determination was that the benefit exceeds the risk."

Respirator Revisions

The CDC and NIOSH moved to be in sync with the transition on April 9, 2021, the same date as the FDA letter.

"NIOSH is part of CDC, so our recommendations are the same," D'Alessandro says. "We clarified that N95s should be discarded immediately after being removed — that is a contingency strategy."

In updating the respirator recommendations, the CDC stated, "Once PPE supplies and availability return to normal, healthcare facilities should promptly resume conventional practices. The supply and availability of NIOSH-approved respirators have increased significantly over the last several months."[4]

For conventional capacity strategies, which are essentially pre-

pandemic practices, the CDC added a recommendation that respirators used by a symptomatic healthcare worker for source control can be reused under certain conditions.

"Extended use of N95 respirators can be considered for source control while healthcare personnel are in the healthcare facility, to cover one's mouth and nose to prevent spread of respiratory secretions when they are talking, sneezing, or coughing," the CDC stated. "When used for this purpose, N95s may be used until they become soiled, damaged, or hard to breathe through. They should be immediately discarded after removal. Extended use of N95 respirators as PPE is a contingency capacity strategy."

For these contingency capacity strategies during expected shortages, the CDC recommends that N95 respirators be prioritized for those wearing them as PPE while caring for patients. Respirators should not be used by healthcare workers only as source control during the contingency stage.

For crisis capacity strategies during known shortages, the CDC revisions include the following:

- removed the strategy of using non-NIOSH-approved respirators developed by manufacturers who are not NIOSH-approval holders;
- highlighted that the number of reuses should be limited to no more than five uses (five donnings) per device by the same healthcare worker to ensure an adequate respirator performance;
- removed decontamination of respirators as a strategy with limited re-use;
- emphasized that facemasks for caring for a patient with suspected or confirmed SARS-CoV-2 infection should only be used for certain scenarios as a last resort if respirators are severely limited. ■

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U.S. COVID-19 Deaths Higher than Reported

Closer to 1 million than the 574,043 reported from March 1, 2020, to May 3, 2021

For some time, it has been known that the official numbers of COVID-19 cases and deaths are an undercount, in part caused by the lack of an active national surveillance.

For example, it was reported recently that there still are refrigerator trucks full of about 750 COVID-19 dead in New York City.[1] Maybe these have been counted, but there are many more who have not been.

Robert Redfield, immediate past director of the Centers for Disease Control and Prevention (CDC), estimated at one point that there probably were eight times as many cases as were actually reported nationally. He did not comment on the morality data. Although the number of deaths has remained something of a mystery, there was general consensus that the number was more than was being reported. Now we know. With many COVID-19 deaths unreported in the United States, researchers estimate that the actual death toll of the pandemic is closer to 1 million than the 574,043 reported from March 1, 2020, to May 3, 2021.[2]

Looking at excess mortality data, researchers at the University of Washington Medical School's Institute for Health Metrics and Evaluation (IHME) calculated that 905,289 COVID-19 deaths occurred in the United States during that time period. That is 58% higher than the official numbers. Moreover, they estimate that COVID-19 has caused 6.9 million deaths globally, more than double the official count. "Understanding the true number of COVID-19 deaths not only helps us appreciate the magnitude of this global crisis, but also provides valuable information to policymakers developing response and recovery

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plans," **Chris Murray**, MD, DPhil, IHME's director, said in a statement.

IHME estimated the total COVID-19 deaths by calculating anticipated deaths from all causes in pre-pandemic data. They compared that to all-cause deaths in the pandemic and determined excess mortality. That figure then was analyzed to remove deaths indirectly attributable to the pandemic — for example, people who had a heart attack because they could not or would not see their cardiologist during the pandemic. Another factor to sort out is deaths averted by the pandemic, such as fewer traffic accidents and other incidents related to the decline in mobility.

"The resulting adjusted estimates include only deaths directly due to the SARS-CoV-2 virus," the researchers concluded. ■

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CME/CE QUESTIONS

1. **Sarah Smathers, MPH, CIC, FAPIC, cited which of the following infection preventionist (IP)-to-bed ratios as the most recent published in a study?**

   a. One IP per 50 beds
   b. One IP per 250 beds
   c. One IP per 69 beds
   d. One IP per 137 beds

2. **The Centers for Disease Control and Prevention recommended that fully vaccinated healthcare workers can dine and socialize together in break rooms and conduct in-person meetings without wearing masks or social distancing. If an unvaccinated person is in the room:**

   a. that person wears a mask and the vaccinated persons do not.
   b. the unvaccinated person does not have to wear a mask but must be socially distant.
   c. all persons can be unmasked, since the workers are vaccinated.
   d. all persons must be masked and the unvaccinated worker must be socially distant.

3. **Ann Marie Pettis, RN, BSN, CIC, says the percentage of breakthrough infections in vaccinated healthcare workers she is seeing locally is:**

   a. 5%.
   b. 1%.
   c. 7%.
   d. 3%.

4. **The Occupational Health and Safety Administration stated that $100 million in additional funding granted under the American Rescue Plan of 2021 will be used in part to:**

   a. buy personal protective equipment for workers.
   b. develop an efficient collections system to collect fines.
   c. do a special emphasis program targeting ambulatory care.
   d. hire more than 160 new critical personnel.