HOSPITAL EMPLOYEE HEALTH

THE PRACTICAL GUIDE TO KEEPING HEALTHCARE WORKERS HEALTHY

NOVEMBER 2020 Vol. 39, No. 11; p. 121-132

INSIDE

Relias Media

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CDC: Healthcare Workers First in Line for COVID-19 Vaccine

But will they take it? Mistrust weighs heavy on vaccine process

By Gary Evans, Medical Writer

Healthcare workers have been designated as the highest priority group to receive the first safe and effective COVID-19 vaccine cleared for use in the United States, according to recent discussions and materials reviewed in a non-voting meeting of top immunization advisors to the Centers for Disease Control and Prevention (CDC).

Facing a dearth of data that awaits clarification in a host of clinical trials, the CDC's Advisory Committee on Immunization Practices (ACIP) used an ethical framework to make what one member described as a series of Solomonic decisions at its Sept. 22 meeting.

"When and if a safe and effective COVID-19 vaccine is approved by the Food and Drug Administration [FDA], healthcare workers would be tier one recipients," ACIP recommended. "This group includes some 20 million people who work in hospitals, long-term care facilities, assisted living facilities, skilled nursing facilities, outpatient settings, home healthcare, pharmacies, EMS, public health and other groups." *(More information is available at this link: https://bit.ly/2GgmY4U.)*

> "WHEN AND IF A SAFE AND EFFECTIVE COVID-19 VACCINE IS APPROVED BY THE FOOD AND DRUG ADMINISTRATION, HEALTHCARE WORKERS WOULD BE TIER ONE RECIPIENTS."

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HOSPITAL EMPLOYEE HEALTH

***Hospital Employee Health*®, ISSN 0744-6470, is published monthly by Relias LLC, 1010 Sync St., Ste. 100, Morrisville, NC 27560-5468. Periodicals postage paid at Morrisville, NC, and additional mailing offices. POSTMASTER: Send address changes to *Hospital Employee Health*, Relias LLC, 1010 Sync St., Ste. 100, Morrisville, NC 27560-5468.**

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After healthcare workers, the subsequent 1B priority groups for COVID-19 vaccination were open to further refinement, but the order described at the meeting placed non-healthcare essential service workers next, followed by people with high-risk medical conditions, and those older than age 65 years.

Some ethical models for pandemic vaccine uptake have stratified frontline medical workers, but ACIP argued for a broader immunization strategy throughout healthcare. The ACIP healthcare category includes those not directly involved in patient care but potentially exposed to infectious agents while working in a healthcare setting.

"The epidemiology of COVID-19 disease among healthcare personnel demonstrates that cases at risk of disease extend beyond frontline [workers]," said **Sara Oliver**, MD, MPH, an epidemiologist with the CDC National Center for Immunization and Respiratory Diseases (NCIRD).

Healthcare workers drew 1A status, akin to the military service draft, but the tone of discussions clearly suggested broad reticence to making a such a newly developed vaccine compulsory. Indeed, there was an undercurrent of skepticism about whether healthcare workers would be immunized voluntarily unless safety and efficacy truly can be assured.

In comments before the meeting, ACIP liaison member **William Schaffner**, MD, professor of preventive medicine at Vanderbilt University, told *Hospital Employee Health* there is distrust of the vaccine process even in healthcare.

"There is a lot of skepticism in the medical community, and I don't just mean doctors — I mean nurses and other staff — about the process whereby vaccines will be evaluated both for effectiveness and safety," says Schaffner, an ACIP liaison member for the National Foundation for Infectious Diseases.

The politicization of the pandemic response threatens to undermine the response even if a safe and effective vaccine is developed.

"I've had exchanges with people through email and phone. Virtually everyone around the country is saying, 'We are seeing medical colleagues express both annoyance and real skepticism about the vaccine evaluation process,'" Schaffner notes. "Even among healthcare workers, we are going to have to do an awful lot of education and provide data and reassurance in order for them to take the vaccine."

One critical issue will be whether the FDA submits the data for evaluation to its highly regarded Vaccines and Related Biological Products Advisory Committee, he says.

"If that committee speaks to the American public and says, 'We have reviewed this and think it is appropriate to go forward for emergency use authorization,' I think practicing doctors, nurses, and others will take much comfort and reassurance in that," Schaffner says.

Right now, there is little short of open suspicion, including a question during the meeting about whether the eventual ACIP vote and recommendations would have to be signed off by the Department of Health and Human Services (HHS). "Let us get back and confirm that for you," said ACIP Executive Secretary **Amanda Cohn**, MD, of the CDC NCIRD. "Typically, the CDC director makes the final decision and informs the HHS director."

There was some discussion of voting on the matter at a previous

meeting, but ACIP Chair **José Romero**, MD, FAAP, secretary of the Arkansas Department of Health, said the committee would await weigh-in from the FDA before formally voting.

"Once the data are available from Phase III clinical trials, the ACIP Vaccine COVID-19 Work Group will conduct an independent review of safety and efficacy data and present policy options to the full committee," Romero said. "If and when the FDA authorizes or approves a vaccine, then ACIP will have an emergency meeting and vote on vaccine recommendations and populations for use."

Ethical Principles

An ACIP work group reviewed ethical principles by several medical groups on allocating a potential vaccine, concluding all ranked vaccine administration to healthcare workers as critical to the pandemic response. The ethical standards ACIP consulted include the World Health Organization's Strategic Advisory Group of Experts (SAGE), the Johns Hopkins Bloomberg School of Public Health, and the National Academies of Sciences, Engineering, and Medicine (NAM).

"These are the right principles. They take the best components of the SAGE, Hopkins, and NAM models," said ACIP member **Peter Szilagyi**, MD, MPH, a pediatrics and research professor at the University of California, Los Angeles. "I think one of the challenges we are all facing — and this feels very much like a Solomon's choice — we have to remember that over [time] the vaccine supply will go up. What we are really talking about is making the decisions for shorter time periods. One of the challenges we feel is that there is a wide diversity of risk in all of these groups. Even in the healthcare group, essential workers, and those with chronic conditions, there is a wide diversity of risk."

Given the unknowns, the emphasis on safety and trust must be underscored throughout the process, said ACIP member **Grace Lee**, MD, MPH, professor of pediatrics at Stanford University.

"I agree that it is challenging to communicate around vaccines and vaccine confidence without actually having the clinical trial data in hand," she said. "But I still think that perhaps what we can do is continue to emphasize the process for decision-making and how much emphasis we are all placing on transparency."

With transparency placed as the key structural underlying principle, ACIP's ethical reasons for selecting healthcare workers as priority-one recipients of a COVID-19 vaccine included such factors as maximizing immunization benefits essential to the pandemic response, and equity — because healthcare includes high representation of minorities and low-income workers.

"In terms of feasibility, large health systems have occupational health departments to facilitate vaccine clinics," said **Kathleen Dooling**, MD, MPH, a member of the ACIP work group and a medical officer in the CDC's division of viral diseases.

Healthcare facilities also may use freezers if needed for cold storage of vaccines. Another plus is that influenza vaccine acceptance is fairly high among healthcare workers.

"However, it will be more challenging to reach rural healthcare facilities, long-term care, small, independent clinics, and home healthcare workers," Dooling noted. Medical workers also have high scientific literacy, a factor ACIP weighed in favor of beginning with healthcare overall.

While healthcare workers may be more open to vaccine receipt than members of the public, particularly vulnerable minority populations, the theme of distrust in the process and the ultimate vaccine that emerges was a common thread through ACIP discussions. Romero warned vaccine hesitancy and distrust will be an ongoing issue.

"I can only speak from my experience within the advisory groups from our department of health for underrepresented minorities," he said. "There is an extreme disconfidence in this vaccine. I have been trying to reach out to the Latino population primarily by having specific, targeted talks with the leaders of that group. I think we need to begin these now if there is to be any sense of confidence in the vaccine among the minority populations."

Social Vulnerability and COVID-19

The challenge was underscored by a presentation showing how maps of COVID-19 cases and hospitalizations virtually mirrored maps of ethnic minority and poverty indicators. **Megan Wallace**, DrPH, MPH, described the Social Vulnerability Index, which was developed by CDC to identify communities that need support before, during, and after public health emergencies. The index measures social determinants of health using census data and ranks each county and census tract on 15 social vulnerability factors. Counties with the highest social vulnerability are at greater risk of COVID-19 outbreaks compared to counties with the lowest social vulnerability. Racial and ethnic minority groups represent

40% of the total U.S. population, but nearly 60% of COVID-19 cases, Wallace explained.

"We need to be very proactive in our educational pieces to reach out to racial and ethnic minorities, essential workers, and people with low economic means," said **Sandra Fryhofer**, MD, an ACIP liaison member representing the American Medical Association.

The problem is that medical researchers, even some ostensibly representing the government, have given minority populations multiple historical reasons not to trust them. To cite one of the most infamous, the Tuskegee syphilis experiment studied the progression of the disease in elderly Black men from 1942 to 1972. Astonishingly, their syphilis was allowed to progress, and the experiment continued for decades after the availability of penicillin for effective treatment in the 1940s.[1] The education campaign on this vaccine effort faces a steep uphill struggle, in part because of the mixed messaging and waffling that have characterized the federal response to the pandemic.

In addition, the nation's antivaccine movement has endangered routine immunization rates, as evidenced by measles outbreaks after the measles, mumps, and rubella vaccine was falsely linked to autism. Given this backdrop, one ACIP member said the federal government's name for its vaccine development push is unfortunate.

"The title 'Operation Warp Speed' scares a lot of people," said **Lynn Bahta**, RN, MPH, CPH, an immunization consultant in the Minnesota Department of Health. "It would be helpful if our national leaders at the FDA and CDC could talk about what that means in plain language. [That] might help people with some of the anxiety that we have been hearing about vaccinations for COVID-19."

While commending a practical CDC "playbook" for eventual administration of a vaccine by state and local health officials, ACIP member **Paul Hunter**, MD, of the City of Milwaukee Health Department, questioned the lack of security planning.

"The one thing I didn't see is security at the sites," he said. "I'm a bit worried at the threats of violence that have been perpetrated against visible leaders of public health. These have led in part to the resignation of commissioners of health, like my commissioner of health in Milwaukee — that is part of the reason she resigned."

CDC officials at the meeting clarified they have worked with the administration in running some tabletop security exercises and will be adding more details in future iterations of the immunization planning playbook.

Ethical Framework for Prioritizing Healthcare Workers to Receive Vaccine

Centers for Disease Control and Prevention advisors cited ethical reasons for selecting healthcare workers (HCWs) as first to receive a COVID-19 vaccine, including these:

Maximize benefits

- HCWs are essential for response.
- Vaccine may help decrease transmission to patients, co-workers, and community.
- It may decrease COVID-19 morbidity and mortality in some HCWs, as approximately 40% have high-risk conditions or are older than age 65 years.
- HCWs may hold positions where absenteeism may compromise/stop care.

Equity

- There is overrepresentation of some racial or ethnic minority groups and lower-income earners in the healthcare field.
- Seroprevalence of SARS-CoV-2 is higher among Hispanic and non-Hispanic Black HCWs.
- Long-term care facility staff largely comprise female and non-Hispanic Black persons, and are disproportionately lower-wage workers.

Justice

- HCWs recommended for early vaccination have an equal opportunity to access vaccine.
- Definition of HCW includes "paid and unpaid persons serving in healthcare settings."

Fairness

- The vaccine can help reduce disparities in health outcomes.
- HCWs are at increased risk of COVID-19 exposure. ■

Even a relatively routine public health measure for a new vaccine — the planned heightened surveillance for adverse effects and text message monitoring of immunized healthcare workers' symptoms — took an ominous tone.

"With all the discussions going on around the country and some people expressing concerns [about] the process of assessing the safety and effectiveness of these vaccines, requiring continued monitoring for safety after the vaccine is rolled out may be a cause of concern to some," said ACIP member **Robert Atmar**, MD, of the Baylor College of Medicine in Houston. "We want the public to be reassured that any vaccine that is rolled out has gone through the appropriate review process, and this additional safety collection is what we do with all vaccine products. Again, it is voluntary for the initial recipients of the vaccine."

Tom Shimabukuro, MD, MPH, MBA, of the CDC's COVID-19 Vaccine Safety Team, said text message monitoring of healthcare workers will not be mandatory, and they can opt out after initial contact. The vaccine safety assessment for essential workers (V-SAFE) is a smartphone-based survey program for early vaccine recipients, he explained.

"It is reassuring to me that many healthcare workers, including myself, are already participating in daily symptom monitoring within our own healthcare systems," Szilagyi said. "I think people are getting used to this very quick daily monitoring."

The existing Vaccine Adverse Event Reporting System (VAERS) also will include a COVID-19 vaccine component. That includes a requirement that COVID-19 vaccine-related deaths be reported in one day, serious incidents in three days, and non-serious reports within five days.

The FDA has said it would accept a vaccine with 50% efficacy as long as there was high confidence that it would be no lower than 30% effective.[2]

> "WE NEED TO BE VERY PROACTIVE IN OUR EDUCATIONAL PIECES TO REACH OUT TO RACIAL AND ETHNIC MINORITIES, ESSENTIAL WORKERS, AND PEOPLE WITH LOW ECONOMIC MEANS."

"I never heard the FDA say that before — and the FDA is not exactly the most trusted agency anymore. None of them are," says **Richard Wenzel**, MD, MSc, emeritus chairman and professor of internal medicine at Virginia Commonwealth University. "If it is only 50%, I think there will be some reluctance."

Wenzel is not a member of the ACIP committee, but the veteran epidemiologist is closely following the vaccine process.

"I think one of the questions people will have is if the [first one] is sort of 50% to 60% efficacy, do they wait for data to come in on vaccine number two, which might have 70% or higher efficacy?" he asks. "Another question healthcare workers will ask is how safe is it? If it is sort of borderline effective and people say, 'I felt like I had the worst flu for two or three days,' that will obviously influence the level of acceptance."

That said, Wenzel is confident a SARS-CoV-2 vaccine will be developed, in part due to lingering signs of immunity in people infected with the original SARS in 2003. Infectious antibodies faded within a few months, but "there is T cell recognition 17 years after SARS in some patients," he says.

There is precedent for a disastrous rollout of a pandemic vaccine. In 1976, the H1N1 "swine flu" vaccine was linked to paralysis and fatalities in the infamous "pseudo-pandemic." One adverse effect was an increase in Guillain-Barré paralytic syndrome (GBS), a rare autoimmune disease in which the body turns on its own nerve cells. In 1976 — responding to a feared H1N1 pandemic that never materialized — public health officials immunized more than 40 million people with a newly developed vaccine. Several hundred cases of GBS included a reported 25 deaths, prompting the enduring observation that the vaccine killed more people than the disease did. The adverse reactions were not fully recognized until a large rollout of the vaccine program, which was then halted.[3] ■

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CDC: COVID-19 Infections in Healthcare Personnel Increase Tenfold

Almost half of occupational cases have underlying conditions

In what is likely a substantial undercount, the Centers for Disease Control and Prevention (CDC) reports that between Feb. 12 and July 16, there were 100,570 COVID-19 cases in healthcare workers and 641 deaths reported in the United States.[1]

"Healthcare personnel (HCP) status remains missing for most cases reported to CDC," the agency noted. "HCP might be prioritized for testing, but the actual number of cases in this population is most certainly underreported and underdetected, especially in asymptomatic persons."

Minority Workers Affected

General trends in COVID-19 in HCP mortality include the deaths occurred in those who were older, male, Asian, Black, and with an underlying medical condition, the CDC reported. The agency cobbled together data from various reporting systems and methods, and some data reflect only the subset provided by forms and limited public health jurisdictions.

"Compared with nonfatal COVID-19 HCP cases, a higher percentage of fatal cases occurred in males (38% vs. 22%), persons aged ≥ 65 years (44% vs. 4%), non-Hispanic Asians (20% vs. 9%), non-Hispanic Blacks (32% vs. 25%), and persons with any of the 10 underlying medical conditions specified on the case report form (92% vs. 41%)," the CDC reported.

The CDC previously reported COVID-19 in healthcare workers using national case surveillance data in April 2020.[2] "Since then, the number of reported HCP with COVID-19 has increased tenfold," the CDC noted.[1]

The CDC did not clarify in the report whether such a dramatic increase also was seen for the number of HCP deaths. But a look back at the first CDC surveillance report reveals 27 deaths occurred among 9,282 cases in healthcare workers, meaning by the same crude extrapolation the latest death count would be greater than a tenfold increase. There also is the larger issue of underreporting, as the CDC estimates actual cases in the pandemic for all groups could be 10 times higher than totals. *(For more information, see Have 1 Million Healthcare Workers Been Infected in Pandemic? in the August issue of* Hospital Employee Health*, at: https://bit.ly/3mYCMtU.)*

Longstanding Inequities Contribute

This updated report used national data reported from February 12 to July 16, 2020. Among 69,678 HCP cases with data on race and ethnicity, 47% were in non-Hispanic whites, 26% were in Blacks, 12% were in Hispanics or Latinos, and 9% were in Asians.

"Longstanding inequities in social determinants of health can result in some groups being at increased risk for illness and death from COVID-19, and these factors must also be recognized and addressed when protecting essential workers in the workplace, at home, and in the community," the CDC emphasized. "Ensuring adequate allocation of PPE [personal protective equipment] to all HCP in the workplace is one important approach to mitigating systemic inequalities in COVID-19 risk. As the COVID-19 pandemic continues in the United States, HCP are faced with increasing fatigue, demands, and stressors. HCP who are at higher risk for severe illness and death from COVID-19 should maintain ongoing communication with their personal healthcare providers and occupational health services to manage their risks at work and in the community."

Of those with known hospitalization or intensive care unit (ICU) admission status, 8% were hospitalized and 5% were treated in an ICU. Forty-four percent had at least one of 10 underlying medical conditions specified on the case report form.

"The most common were cardiovascular disease (18%), chronic lung disease (16%), and diabetes mellitus (13%)," the CDC stated. "The vast majority (92%) of fatal HCP cases were among HCP with an underlying medical condition. More than one half had cardiovascular disease (61%) or diabetes mellitus (52%) — conditions known to increase the risk for severe COVID-19 — [and] 32% were reported to have both conditions."

In the update, most HCP with COVID-19 were reported to work in nursing and residential care facilities.

"Large COVID-19 outbreaks in long-term care facilities suggest that transmission occurs among residents and staff members," the CDC reported. "During the COVID-19 pandemic, multiple challenges in long-term care settings have been identified, including inadequate staffing and PPE, and insufficient training in infection prevention and control."

Nurses and healthcare support workers have frequent, close contact with patients that put them at risk, but cases also are occurring in nonmedical staff, administrative, and environmental services.

"Risk to HCP can occur through pathways other than direct patient care, such as exposure to co-workers, household members, or persons in the community," the CDC concluded. "HCP who acquire SARS-CoV-2 can similarly introduce the virus to patients, co-workers, or persons outside the workplace. Thus, practices such as universal use of face masks at work, wearing masks in the community, observing social distancing, and practicing good hand hygiene remain critical strategies to protect HCP and the populations they serve. Screening HCP for illness before workplace entry and providing nonpunitive sick leave options remain critical practices." ■

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COVID-19 Precautions Reduce Flu Cases

Masking and other measures prevent seasonal flu

There are encouraging signs that masking and other measures taken to prevent COVID-19 are diminishing seasonal influenza globally. Flu virus circulation declined when COVID-19 measures were taken in the Northern Hemisphere, with the same epidemiology observed as the flu season began later below the equator, the Centers for Disease Control and Prevention (CDC) reported.[1]

"Following widespread adoption of community mitigation measures to reduce transmission of SARS-CoV-2, the percentage of U.S. respiratory specimens submitted for influenza testing that tested positive decreased from > 20% to 2.3% and has remained at historically low interseasonal levels (0.2% vs. 1-2%)," the CDC noted. "Data from Southern Hemisphere countries also indicate little influenza activity."

Although there are caveats and cautions, the CDC is leaning into the findings, and even suggested they may carry implications for future flu seasons.

"Although causality cannot be inferred from these ecological comparisons, the consistent trends over time and place are compelling and biologically plausible," the CDC said. "Like SARS-CoV-2, influenza viruses are spread primarily by droplet transmission; the lower transmissibility of seasonal influenza virus (R0 = 1.28) compared with that of SARS-CoV-2 (R0 = 2-3.5) likely contributed to a more substantial interruption in influenza transmission."

The formula for continuing this trend as the 2020-21 flu season begins in the United States is high immunization levels for influenza and the measures that have become standard for COVID-19: masking, social distancing, and hand hygiene.

"I have had some communications with colleagues in Australia and they did indeed have a very mild influenza season," says **William Schaffner**, MD, professor of preventive medicine at Vanderbilt University. "They attribute it to two things. The first is that they used influenza vaccine more than they ever have before — they really promoted influenza immunization. The other is, of course, the COVID precautions. They were far from perfect, but they have the sense that the country was reasonably compliant — more so than we are here in the United States."

There may be the rub, as mask use became politicized and undermined early in the pandemic in the United States. "There are lots of people who have COVID fatigue and wish to go back to the old normal. There is a thrust of that certainly in our part of the country," Schaffner says. "When you get out of the cities and go into the country, there is not only an aversion to wearing masks, but real hostility. These COVID-19 interventions have been so politicized

that is has been a huge impediment to solid, sensible public health."

Questionable compliance makes the flu vaccine more important. It appears there is a good match between the shot and circulating virus, says Schaffner, who leads the annual seasonal flu press conference at the National Foundation for Infectious Diseases. "One message strongly reinforced every year is that flu is infamously unpredictable."

"Any one year it could be mild, moderate, or severe," adds **Richard Wenzel**, MD, MSc, emeritus chairman and professor of internal medicine at Virginia Commonwealth University. "In the last decade — where they have counted deaths the same way — it was as low as 12,000 to a high of about 86,000 deaths."

Based on the forecast that the circulating flu will leave a smaller footprint, COVID-19 precautions could halve the aforementioned 12,000 deaths of a mild season, he says.

"I think it will cut down flu as much as 50% or more if we continue to use the masks. Hopefully, we will," Wenzel says. "Even when the flu vaccine begins to roll out, people should continue to wear masks because we won't have any kind of herd immunity [for COVID-19] until the end of spring next year."

The findings raise the question of whether masking will be encouraged in post-pandemic flu seasons. "There is evidence to support the use of face masks by infected persons to reduce transmission of viral respiratory illnesses to others and growing evidence to support their use (in the healthcare setting, in households, and in the community) to protect the healthy wearer from acquiring infection," the CDC noted. "Data from the current pandemic might help answer critical questions about the effect of community mitigation measures on transmission of influenza or other respiratory diseases."

A tool to make that critical distinction is a new Food and Drug Administration-approved multiplex diagnostic assay for detection of both SARS-CoV-2 and influenza virus that could improve future surveillance efforts.[2]

"Assessing acceptability of effective measures would be critical, because acceptability is likely to be inversely correlated with the stringency of the measure," the CDC cautioned. ■

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FDA: Barrier Enclosures for Aerosol-Generating Procedures May Increase Risk to HCPs

Agency revokes EUA for those without negative pressure design

Citing increased risk to healthcare workers and patients, the Food and Drug Administration (FDA) has revoked emergency use authorization (EUA) for barrier enclosure devices that cover a COVID-19 patient's head and upper body during aerosol-generating procedures such as tracheal intubation.

The FDA describes these so-called "passive protective barriers" as "a transparent device designed to cover a patient's head and upper body that incorporates one or more ports through which the HCP's hands are passed to perform medical procedures, and that does not include fans, air filters, or other features and is not intended to generate negative pressure."[1]

Healthcare personnel (HCP) "should not use passive protective barrier enclosures without negative pressure, as they may not be effective in decreasing HCP exposure to airborne particles, and in some circumstances, may instead increase HCP exposure to airborne particles," the FDA wrote in a letter to industry and healthcare. "Their use also may contribute to complications such as increased intubation times, lower first-pass intubation success rates, increased patient hypoxia time, and damage or tearing to PPE [personal protective equipment] from the enclosures. These complications may be due in part to the barrier enclosure design characteristics and restricted mobility of the HCP's arms in a restricted space to maneuver the accessories needed to establish a definitive airway."

On May 1, the FDA issued an EUA for passive protective barrier enclosures to reduce the risk of transmitting COVID-19 from patients to HCPs.

"However, the FDA now is aware of preliminary evidence[2,3] in simulated intubation procedure models of potential adverse events that could occur or complications with protective barrier enclosures without negative pressure recently reported in the literature," the FDA stated.[1,2] "Although the FDA has not received any medical device adverse event reports related to the use of passive protective barrier enclosures during the COVID-19 pandemic, the FDA believes HCPs should be aware of potential risks or complications associated with their use so they can take appropriate precautions. Based on this information, the FDA is also revoking the current umbrella EUA for passive protective barrier enclosures issued in May."

Other FDA recommendations in the letter include:

- Use negative pressure devices while using protective barrier enclosures. FDA-authorized negative pressure barrier enclosures can be found on FDA's EUA website. According to the FDA, a detailed review of data showing decreased HCP exposure to airborne particles, usability, and other safety and performance measures of negative pressure devices indicate the benefits of the devices outweigh the risks.
- Protective barrier enclosures — with or without negative pressure — are not a replacement for PPE.
- Any protective barrier enclosure should be removed if it is an impediment to performing a medical procedure on the patient. ■

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CDC Backtracks on Testing Controversy

After widespread criticism from the medical community, the Centers for Disease Control and Prevention (CDC) dropped a controversial recommendation that de-emphasized the importance of testing asymptomatic contacts of COVID-19 cases.[1]

The CDC also recently issued guidance warning about airborne spread of the virus indoors, then quickly withdrew it as a "draft," drawing more concerns about mixed messaging and politicization of the agency.[2]

"As a career public health guy, my perspective from the very beginning is that the CDC has an untarnished brand," says **Will Humble**, MPH, executive director for the Arizona Public Health Association. "They were the most trusted brand within the federal government. We knew we could trust the CDC for evidence-based recommendations and analysis. That has changed over the last six months. I think even public health people think the reputation of the agency is tarnished."

In a clarification issued Sept. 18, the CDC stated that "due to the significance of asymptomatic and pre-symptomatic transmission, this guidance further reinforces the need to test asymptomatic persons, including close contacts of a person with documented SARS-CoV-2 infection."

The previous version that caused the uproar — particularly since the CDC had emphasized the importance of contact tracing because 40% of cases are asymptomatic — included this guidance on Aug. 24: "If you are in a high COVID-19 transmission area and have attended a public or private gathering of more than 10 people (without widespread mask-wearing or physical distancing): You do not necessarily need a test unless you are a vulnerable individual or your healthcare provider or state or local public health officials recommend you take one."

The revised version drops the "not necessarily" qualifier, now reading, "If you are in a high SARS-CoV-2 transmission zone and attended a public or private gathering of more than 10 people (without universal mask wearing and/or physical distancing):

- Your healthcare provider or

public health official may advise a SARS-CoV-2 test.

• If you are tested, you should self-isolate at home until your test results are known, and then adhere to your healthcare provider's advice. A negative test does not mean you will remain negative at any time point after that test.

• Even if you have a negative test, you should wear a mask, physically distance, avoid crowds and indoor crowded places, wash your hands frequently, and monitor yourself for symptoms.

• Take special precautions in the home to protect any person(s) with increased risk of severe illness according to CDC."[1,3] ■

REFERENCES

1. Centers for Disease Control and Prevention. Overview of testing for SARS-CoV-2 (COVID-19). Updated Sept. 18, 2020. https://bit.ly/2Gf5fdZ
2. Gumbrecht J, Christensen J, Cohen E, et al. CDC abruptly removes guidance about airborne coronavirus transmission, says update 'was posted in error.' CNN. Sept. 22, 2020. https://cnn.it/36lXg9Q
3. Centers for Disease Control and Prevention. Caring for someone sick at home: Advice for caregivers in non-healthcare settings. Updated May 8, 2020. https://bit.ly/3cCnq9H

CMS Identifies Telemedicine Quality Tracking Measures

The Centers for Medicare & Medicaid Services (CMS) is providing more detailed guidance for how healthcare providers should report electronic clinical quality measures for telehealth encounters. A total of 39 electronic clinical quality measures (eCQMs) were recently published for the 2021 performance period.[1]

Any eligible professionals or eligible clinicians participating in CMS quality reporting programs for the 2020 performance period can use these updated telehealth-eligible CQMs for the Merit-based Incentive Payment System and Advanced Alternative Payment Models, Comprehensive Primary Care Plus, Primary Care First, and the Medicaid Promoting Interoperability Program for Eligible Professionals, according to CMS.

CMS notes "there may be instances where the quality action cannot be completed during the telehealth encounter by eligible professionals and eligible clinicians. Specifically, telehealth-eligible CPT and HCPCS codes may be included in value sets where the required quality action in the numerator cannot be completed via telehealth." It is the eligible professionals' and eligible clinicians' responsibility to make sure they can meet all other aspects of the quality action "within the measure specification, including other quality actions that cannot be completed by telehealth," CMS says.

CMS has identified 50 telehealth-eligible CQMs and 42 telehealth-eligible eCQMs for clinicians for 2020 performance period reporting, says **Lauren Patrick**, president of Healthmonix, a healthcare analytics company based in Malvern, PA. These are measures that represent quality actions that can be performed remote to the patient, Patrick explains.

Some examples of these measures include Advance Care Plan, Pneumococcal Vaccination Status for Older Adults, Documentation of Current Medications in the Medical Record, Screening for Depression and Follow-Up Plan, and Controlling High Blood Pressure.

These are quality measures that existed prior to the COVID-19 pandemic and were developed to include telehealth visits in their patient population. Because of the shift to telehealth in 2020, there has been a renewed interest in understanding which measures can and should be tracked for these visits.

"Healthcare providers and organizations have exponentially increased the use of telehealth in their practices during the public health emergency brought on by COVID-19. Since they are required by the QPP [quality payment program] to report quality measures, [providers] need to understand which measures are relevant to these telehealth visits," Patrick says. "Many of the quality measures require the inclusion of telehealth visits in their reporting. Providers need to understand this, and work to ensure that these quality actions are met in the telehealth visits."

If the quality measures are not met during telehealth visits, they will negatively affect the providers' quality score in the QPP and other quality and value-based programs, Patrick cautions.

Telehealth visits cannot be excluded in the quality measure reporting. They will be scored as "quality not met" when they are not handled during these visits. Telehealth visits need to conform

to standard clinical workflows and patterns of care. This new modality of patient care needs to incorporate all aspects of the established in-patient visits that can support the quality measures.

It is important to ensure quality measure actions are included in the workflows for telehealth visits, just as they are included for in-person visits, Patrick says.

"The ultimate purpose of any medical care is to maintain or improve health and well-being. Thus, how clinical applications of telemedicine affect the quality of care and its outcomes is a central evaluative question, as it is for any health service," she says. "CMS should continue to evaluate and evolve quality measures to reflect and reinforce new technology that can assist in patient care. Note that if we find that quality is trending downward when viewing telehealth visits, this could be used as an argument to reduce telehealth visits."

As a point of reference, Patrick notes that when studying quality data in years past and comparing the performance against in-person visits, one could see a significant decrease in the performance of those measures. "It can be difficult to ensure that these quality measures are met as providers transition to telehealth workflows and/or the patients are remote," she says. "Ensuring that the quality actions and documentation of such are included in the workflows for telehealth visits provides a path to better performance." ■

REFERENCE

1. Centers for Medicare & Medicaid Services. Telehealth guidance for electronic clinical quality measures (eCQMs) for eligible professional/ eligible clinician 2020 quality reporting. https://bit.ly/2BGIP3w

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CE QUESTIONS

1. **In creating an ethical framework of administration of the COVID-19 vaccine, a CDC advisory committee said the key underlying principle must be:**

   a. transparency.
   b. justice.
   c. maximizing benefits.
   d. equity.

2. **According to Megan Wallace, DrPH, MPH, racial and ethnic minority groups represent 40% of the total U.S. population, but nearly what percentage of COVID-19 cases?**

   a. 50%
   b. 60%
   c. 70%
   d. 80%

3. **The majority of fatal COVID-19 cases occurred in healthcare workers with underlying medical conditions. The CDC reported 32% of the fatal cases had:**

   a. cardiovascular disease.
   b. diabetes mellitus.
   c. chronic lung disease.
   d. both cardiovascular disease and diabetes mellitus.

4. **Based on a coronavirus-related inspection, the Occupational Safety and Health Administration cited a facility for a serious violation of failure to provide what type of personal protective equipment to healthcare workers caring for residents exhibiting symptoms of COVID-19?**

   a. Gloves
   b. Masks
   c. Respirators
   d. Goggles

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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.

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Statement of Ownership, Management, and Circulation
UNITED STATES POSTAL SERVICE® **(All Periodicals Publications Except Requester Publications)**

1. Publication Title	2. Publication Number	3. Filing Date
Hospital Employee Health	0 7 4 4 - 6 4 7 0	10/1/2020
4. Issue Frequency	**5. Number of Issues Published Annually**	**6. Annual Subscription Price**
Monthly	12	$299

7. Complete Mailing Address of Known Office of Publication *(Not printer) (Street, city, county, state, and ZIP+4®)* — Contact Person: Sabrina Johnson
1010 Sync St., Ste.100, Morrisville, NC 27560-5468. — (919) 459-9495

8. Complete Mailing Address of Headquarters or General Business Office of Publisher *(Not printer)*
1010 Sync St., Ste.100, Morrisville, NC 27560-5468.

9. Full Names and Complete Mailing Addresses of Publisher, Editor, and Managing Editor *(Do not leave blank)*
Publisher *(Name and complete mailing address)*
Relias LLC, 1010 Sync St., Ste.100, Morrisville, NC 27560-5468.

Editor *(Name and complete mailing address)*
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13. Publication Title	14. Issue Date for Circulation Data Below
	September 2020

15. Extent and Nature of Circulation			Average No. Copies Each Issue During Preceding 12 Months	No. Copies of Single Issue Published Nearest to Filing Date
a. Total Number of Copies *(Net press run)*			190	168
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DocuSigned by: Philipp Russli 40074DA3CF8246E... Chief Financial Officer	24-Sep-2020

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