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Mandates Work: Hospitals Hit 91% Flu Vaccination Rate

Far too many unvaccinated healthcare workers in long-term care

By Gary Evans, Senior Staff Writer

Healthcare worker influenza immunization rates continue to climb as the 2016-2017 flu season sets in, providing a critical measure of safety to vulnerable patient populations. Mandatory vaccination policies are driving a trend that saw 91% of hospital workers immunized during the last flu season — a far cry from the lagging levels of the voluntary flu shot era.

However, vaccination rates for healthcare workers in long-term care settings falls well below hospitals, with 31% skipping the seasonal shots despite caring for frail and elderly people at risk of serious flu infections, the CDC reports.¹

This year's public health message for universal flu vaccination of everyone age six months and older must overcome the typical questions about flu

shot safety and side effects, the vaccine match with circulating strains, and the loss of the live attenuated influenza vaccine (LAIV) nasal spray mist this season for lack of efficacy. (*See related story in this issue for more information.*)

All of the above were discussed at a recent press conference on seasonal flu immunization at the National Foundation for Infectious Diseases (NFID) in Washington, DC, where public health of-

ficials and clinicians on the panel repeatedly returned to the prime directive of universal flu vaccination unless medically contraindicated.

Given the negative view of vaccines in general among some people and the occasional mismatch between the vaccine and the circulating flu strains, immunization advocates were understandably reluctant to get mired in discussions

31% OF LTC WORKERS SKIP FLU SHOTS DESPITE CARING FOR FRAIL AND ELDERLY PEOPLE AT RISK

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about vaccine efficacy or the lack thereof. Still, last year's overall flu vaccine efficacy was only 41% against the predominate H1N1 influenza A strain and 55% against circulating B strains.² Historically, the seasonal vaccine efficacy is an estimated 59%.³

"Flu is unpredictable," **Tom Frieden**, MD, director of the CDC, noted at the NFID meeting. "We know there'll be a season, but when it is and which vaccines — which flu strain predominates — only time will tell. The safest thing you can do is to get vaccinated. And this vaccine does match the flu strains we've seen so far, but it's still too early to predict what the rest of the season will hold."

Perhaps a more real-world measure of flu vaccine efficacy is reduced hospitalizations. The CDC estimates that some 200,000 people are hospitalized with flu infection annually in the U.S., and the number seems to be increasing as the population ages.⁴

"A 5% increase in the flu immunization rate nationally would prevent nearly 10,000 hospitalizations and about 800,000 illnesses," Frieden said.

Healthcare Vaccination Rates Rise

In contrast to the past struggles to get healthcare workers immunized, the field was framed as a success story at the press conference, where results were shared from a recently published CDC survey¹ that found overall immunization rates of 79% in healthcare personnel during the 2015-16 influenza season. By comparison, the estimated overall flu coverage among healthcare workers in the 2014-15 season was 77%.

In the 2015-2016 season, hospital workers led the way with an aforementioned 91% immunization rate,

while those in ambulatory care had an 80% rate and those in long-term care settings were only at a 69% vaccination level. Coverage was highest among physicians (96%) and lowest among assistants and aides (64%).

"For [hospitals], more than nine out of 10 got vaccinated." Frieden said. "That's a steady increase. I can remember just a few years ago when that was down around 60%. Now, 96% of doctors got vaccinated. And why do you think that is? Because we know that it works, that it protects ourselves, our families, our patients."

As infection preventionists are well aware, there is another contributing factor: mandates for flu shots as a condition of employment. The CDC reported that during the 2015-16 influenza season, vaccination coverage was 96.5% among healthcare personnel working in settings where vaccination was required. However, overall only 38% of healthcare workers surveyed were required to be vaccinated against influenza. Hospital mandates were in place for 61% of respondents. By occupation, 51% of physicians and 50% of nurses reported that they were immunized under a mandate. However, only 22.5% of assistants and aides reported influenza vaccination requirements.

To estimate influenza vaccination coverage for the 2015-16 influenza season, the CDC conducted an internet panel survey of 2,258 healthcare workers from March 28 to April 14, 2016.

Typically, mandated flu shot policies have a declination clause for those citing a medical or religious reason not to be vaccinated. Healthcare settings vary on how they handle these requests for exemption, with some allowing those not vaccinated to continue working if they wear a surgical mask during patient care activities. This is

based on the concern that healthcare workers with early-stage, asymptomatic flu infection may transmit the virus to vulnerable patients.

Another approach, taken at the University of North Carolina (UNC) Medical Center in Chapel Hill, is that any employee with fever — whether immunized for flu or not — cannot report to work.

“Our upper respiratory policy is that any employee with a fever can’t come to work; they have to be out of work for 24 hours minimum and it could be several days,” says **David Williams**, RN, of UNC occupational health. “They have to be fever-free for 24 hours to come back to work.”

In addition, if healthcare workers have upper respiratory type symptoms of runny nose or cough, they have to wear a mask to go into patient care areas, he tells *Hospital Infection Control & Prevention*.

“If they have symptoms that cannot be contained by a mask, they have to stay out of work,” he adds. “That is our general policy that applies to those with and without flu vaccination.”

The CDC survey found that, in the absence of mandated policies, flu immunization rates were highest (83%) for those workers in settings where vaccination was encouraged and available at the worksite at no cost for at least one day. There are various educational approaches to improve vaccination rates, many which include busting the common myths that the vaccine is unsafe or actually causes flu. More on that shortly, but first consider the approach used by **Terri Rebmann**, PhD, RN, CIC, FAPIC, professor of environmental and occupational health at Saint Louis (MO) University.

At a recent talk in Nashville at the annual APIC conference, Rebmann cited her own severe flu infection as a cautionary tale, saying she tells healthcare workers to compare the

Flu Facts: A Snapshot for the 2016-17 Season

As gleaned from the CDC and flu immunization advocates speaking at a recent press conference at the National Foundation for Infectious Diseases in Washington, DC, here are some take-home points for the 2016-2017 season.

- The three-component vaccines contain the following strains: A/California/7/2009 (H1N1)-pdm09-like virus, A/Hong Kong/4801/2014 (H3N2)-like virus, B/Brisbane/60/2008-like virus (B/Victoria lineage).
- Four component vaccines will include the three strains above, plus B/Phuket/3073/2013-like virus (B/Yamagata lineage).
- There will be between 157-168 million vaccine doses available, with 93 million doses currently on the market.
- The hospitalization rate for flu infection is highest in people over 65 and second-highest in those age 50 to 64.
- Though some progress is being made, some 30 million children recommended for flu vaccination do not get immunized. Not only are they at risk of flu complications, but children can spread the flu to their elderly relatives and contacts.
- Pregnant women should receive the flu vaccine unless medically contraindicated. In the 2009 influenza pandemic, pregnant women were six times more likely to die than non-pregnant women if they acquired flu. Pregnant women vaccinated against the flu may also instill some protection to their newborns, which are not recommended to be vaccinated until age six months.
- The recommendations for people with egg allergies have been updated. People who have experienced only hives after exposure to eggs can get any licensed flu vaccine that is otherwise appropriate for their age and health. People with egg allergies that have more severe reactions may be able to receive the vaccine under medical supervision. However, those with a previous severe allergic reaction to flu vaccine should not be immunized, the CDC advises. (*For more on this, visit: <http://bit.ly/2dRqW06>.)* ■

possible mild side effects of the vaccine with a full-blown flu infection.

“I actually had the flu and I was like, ‘oh my gosh I think I might be dying,’” Rebmann said. “I had it for 10 days. I got it the year the vaccine coverage was really poor because the strains didn’t match. It was awful, so I’ve become much more passionate when I talk about the side effects of the vaccine versus the actual symptoms of the flu.”

Whereas some people can feel like they almost have a mild viral illness for a brief time after the flu shot, flu

symptoms can be “extreme” in terms of high fever, sore throat, and severe body and head aches, she said.

Frieden told a similar story at the NFID press conference, saying a CDC staff member had a severe flu infection last year.

“A young, healthy woman thought she was going to die,” he said. “She was desperately ill, really scared, sicker than she’d been in her life. That was flu. Flu each year sends hundreds of thousands of people to the hospital. In a bad year, it kills up to 49,000 Americans, including

the elderly, people with underlying conditions, and infants. Each year, we see 100 or more infants or children who die from flu. And when we've analyzed those infants, we've seen that about 90% didn't get vaccinated."

Failure to Communicate

Such anecdotes certainly add a human context and sense of urgency to vaccination, but some healthcare facilities still do not educate workers about flu or encourage them to be immunized. The CDC survey found that only 45% of healthcare workers were vaccinated at sites where flu shots were not required, encouraged, or offered on site. This type of environment was reported by 21% working in ambulatory care and 28% of healthcare workers in long-term care.

As noted, immunization rates for healthcare workers in long-term care were at a meager 69% last flu season, but on the plus side, that represents a 5% improvement over the prior year. Though they work with vulnerable elderly residents, long-term care workers have historically been less likely to be vaccinated for flu as their counterparts in hospitals and other settings. Moreover, studies have linked low immunization rates in long-term care workers with increased mortality in residents.⁵⁻⁷ Fortunately, the needle is moving in the right direction, as flu vaccination of long-term care workers has improved by 17% since the 2011-2012 season, the CDC reported.

The problem in long-term care settings is compounded by the limited protective value of flu vaccine in elderly residents who may have a poor immune response, even after immunization. In addition, a study⁸ published last year found that long-term care workers had lingering concerns about the safety

of the vaccine, including the old myth that it could cause the flu.

Risk to Elderly

"All the injectable vaccines ... are killed vaccines purified so that you cannot get flu," says **Wilbur Chen**, MD, of the University of Maryland School of Medicine's Center for Vaccine Development. "It is possible for you to get an adverse reaction, but it is really just mild injection site reactions and maybe some pain, swelling, and some muscle tenderness that really is very mild and lasts for a couple of days. But that's really the extent of it, so it's an extremely safe vaccine."

The elderly experience "immune senescence," a decline in the body's ability to respond and fight off infection, he noted at the NFID press conference. Similarly, they may not have a great post-vaccination bounce in immunity for flu, but the vaccine could lessen the severity of infections and prevent death.

"As far as efficacy, it's the best we have," Chen said. "A vaccine that is at least partially protective is better than no vaccination at all."

There is a new option for those over 65 this flu season, a vaccine containing an adjuvant designed to boost the immune response, he says. The CDC and FDA approved the adjuvant vaccine based on safety and efficacy results in other countries. There is also a high dose vaccine, which contains four times the antigen level in the regular flu shot, available for those age 65 and over. The CDC does not recommend one over the other.

"We know that, at least in small clinical studies, that [the adjuvant] vaccine does seem to be very efficacious," Chen said. "We're very excited in the flu world that we have additional vaccines: the high-dose vaccine and

the adjuvant vaccine for the elderly."

The cutting-edge vaccines won't do much good if the elderly decline to be immunized. Historically, about a third of those 65 and over ignore a standing recommendation to be vaccinated for seasonal flu that has been in place for decades. Thus, many are at high risk of flu infections due to poor vaccination rates and the aforementioned immune competence issues.

"The impact of flu every year hits the elderly the hardest," Chen said. "Seventy percent to 90% of influenza deaths every year occur in those 65 years and older. For hospitalizations, 50% to 70% due to flu occur in [this] population."

Thus, it's worth reiterating that it is critical to improve flu immunization rates in healthcare workers in long-term care settings, as the residents may be vulnerable even if vaccinated. Immune compromised patients in hospitals and other settings are in a similar plight, potentially highly vulnerable to a flu infection in a worker providing their care. ■

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Dropping Live Nasal Flu Vaccine Leaves Some Disappointed

Unclear why efficacy plummeted

Some pediatricians and their patients were taken aback by the decision to drop the live attenuated influenza vaccine (LAIV) nasal spray as a recommended flu vaccine for the 2016-2017 season in the U.S.

Citing declining efficacy that essentially bottomed out last flu season, the CDC did not recommend LAIV this year, though it will still be available in Canada.

“I was really disappointed in their recommendation,” says **Scott Field**, MD, a pediatrician and flu researcher at the University of Alabama School of Medicine in Tuscaloosa. “In our experience, we had the lightest flu season I’ve ever seen this past year. So I couldn’t say whether any of the vaccines did not work well. I was very surprised that they came out saying don’t use the flu mist [vaccine].”

Field has had success with the LAIV vaccine in the past, and fears some of his patients may be less willing to be immunized now that the needleless spray option is gone. The change could translate to vaccination avoidance in needle-sensitive children who were immunized with the nasal spray.

“I’m really concerned about that,” he says. “We had a child who got the shot because he had asthma. His siblings got the [LAIV]. He was the only one in the family who got the flu. We finally got around to doing

the [LAIV] on him, and ever since we did that he has not had flu. So the mom’s real upset this year that we are not going to have the mist.”

In making the decision, the CDC and its Advisory Committee on Immunization Practices (ACIP) conceded that in previous years LAIV was as effective or more effective than the seasonal flu shots. However, for reasons that are not completely clear, the LAIV showed lower effectiveness from 2013 through 2016. In addition, for the 2015-2016 season, LAIV effectiveness among children 2 years through 17 years was only an estimated 3% — meaning that no protective benefit could be measured, according to the CDC.

Of course, effectiveness of any flu vaccine may vary from year to year due to the vagaries of antigenic “drift” and the more dramatic “shift” of circulating influenza virus. Still, as recently as the 2014-2015 season, the CDC recommended the nasal spray vaccine over the flu shot for young children. During the 2015-2016 season, no preference was cited for either the LAIV or regular flu shots.

Canada Disagrees

LAIV contains live, weakened influenza viruses, which in theory

should prompt a stronger immune response than the standard inactivated virus in flu shots.

“We don’t know why, but the vaccine efficacy data for the last couple of years suggest that it was not protective, and therefore we’re not recommending it,” CDC Director **Tom Frieden**, MD, noted at a recent flu vaccine press conference at the National Foundation for Infectious Diseases in Washington, DC. “It’s a really important vaccine. We know there are lots of kids who would much rather have the nasal spray than a shot. It’s a surprising finding, and we really do hope that we can get an effective intranasal vaccine or nasal spray back on the market and recommended as soon as possible.”

LAIV was initially licensed in 2003 as a trivalent flu vaccine and was expected to be taken this season in the U.S. by about 20 million people — primarily about one-third of vaccinated children.

Asked about the decision by Canadian health officials to continue to recommend LAIV this season, Frieden said, “Each country has to make its own recommendation. In the U. S. we have a very open, transparent process through ACIP, [which] looked at data from the U.S. and elsewhere of vaccine efficacy, and we found that there was no convincing evidence of efficacy. In contrast, the

flu shots did have evidence of efficacy. So we feel that our responsibility in public health is to provide full information and to make recommenda-

tions based on information that's openly and objectively derived."

As it became apparent that LAIV would not be recom-

mended, the CDC reached out to other manufacturers, who increased their production and distribution, Frieden says. ■

Recent Studies Complicate Flu Shot Message

Some may not need shot due to 'innate resistance'

Children are at risk of flu complications and can spread the virus to vulnerable populations like the elderly, so they are an important target for annual vaccination. However, a recent study¹ found some parents do not seek vaccination for their children based on the perception that it is not needed or their kids don't get the flu.

That is a troubling sign, given that children can be hospitalized and even die after acquiring influenza. And it is not particularly surprising that some parents may say their kids skip the seasonal flu vaccine because they never get the flu. Flu vaccine and immunizations in general are subject to a host of myths and false assumptions. However, the problem with this one — particularly in terms of the overall goal of universal vaccination — is that at some level it might be true.

Evidence of "genetically determined innate resistance" to rotavirus has been found, suggesting a gene variation in some people is more protective than the rotavirus vaccine.

"[In previous rotavirus research], the gene variations were more protective than the vaccines themselves," says study author **Scott Field**, MD, a pediatrician and flu researcher at the University of Alabama School of Medicine in Tuscaloosa. "This isn't immunity like we think of from getting a vaccine or having an infection. This is an inability, a resistance in the body to uptake of virus. They do not have the [cellular] receptors

that are needed to get infected by the virus. The people who didn't have [the genetic variation] were more susceptible to rotavirus and are needed to get the vaccine."

Field raises a fascinating point in the paper, asking, "could some parents be right in saying that their child's risk of getting influenza without the vaccination is low?

... Natural or innate influenza resistance has biologic plausibility and could explain this study's finding of previous influenza as a potentially important modifier of vaccine efficacy and disease risk."

A Key Marker

In looking at flu specifically, the researcher found that one genetic variation more often found in African-Americans lowers expression of a protein that is a key marker in people hospitalized with flu infection.

"[The protein] is rare in Sub-Saharan African populations, which may relate to the lower vaccination rates among black patients because of their perceived and possibly true lower risks," the author reports. "This could partially explain the discrepancy in the literature and in this study between influenza vaccination rates in blacks versus whites."

While a compelling scientific point, getting into this level of minutia has the potential to confound the critical public health message to immunize everyone

six months and older with the flu vaccine, which is safe and generally effective year to year.

"At this point, I think it still needs to be recommended universally," Field says. "There may come a day you can do a gene test on everybody and say these people need [flu shots] as these people don't. I don't think we are at that point right now."

The study also found that having had influenza before may increase a child's risk significantly for being infected again in the absence of vaccination. This seems counterintuitive to some degree, as one might assume prior infection may provide some level of immunity and less severe future infection.

"The increased risk there would be that people who have had flu have the right kind of receptors to get flu," Field says. "There are [several] strains of flu — in fact, some people get more than one strain in the same season. They get an A strain early in the season and are infected with flu again the second time with B strains. So even though you get immunity from having the disease, that is only for that strain. You can still get flu from a different strain, and you would be more likely to get flu again later with a different strain than someone who can never get the flu."

The study used an attitudinal survey and medical records from 131 patients in a pediatric practice who were tested for influenza in the 2012-2013 season. Medical records plus questionnaires determined

vaccine, disease history, and attitudes toward flu vaccine. Influenza-negative and positive cases were closely matched to control groups. The study shed light on the infrequency with which many families experience influenza firsthand. Most positive patients had no history of infection, but those that had been infected had significantly more risk of acquiring flu again, Field notes.

“These are not all absolutes — they are probably all relative things,” he says. “Some may be at low risk, but they are not at no risk.”

Perfect Storm

In another flu vaccine study² that has raised some questions and concerns, Canadian researchers report that under certain conditions, a history of immunization increases the likelihood of flu infection. The study is a potentially important, but not necessarily welcome, finding as the never-ending struggle to immunize the population against

seasonal influenza continues.

The lead author could not be reached for comment as this issue went to press, but the paper describes a “perfect storm” of factors behind the finding that people who were immunized every year since 2012–2013 were at a 54% higher risk of contracting influenza A(H3N2) infection than those consistently unvaccinated. The effect was preceded by antigenically drifted virus and successive seasons of identical, but mismatched, vaccine.

A vaccine expert was asked about the findings at a recent press conference on influenza at the National Foundation for Infectious Diseases in Washington, DC.

“Our Canadian colleagues who have published that [found] with repeated seasonal vaccination, it looked like there was a statistically significant decrease in the vaccine efficacy compared to those who are not vaccinated every season,” said **Wilbur Chen**, MD, of the University of Maryland School of Medi-

cine’s Center for Vaccine Development. “This has not been replicated, as I understand, by the CDC in the U.S. So this is an observation that has been seen. We don’t know what to think about it. It is statistically significant, but I don’t think that it detracts away from our message that everyone should get vaccinated. I think it’s a very interesting scientific question and people are exploring it. I’m not sure if there’s a biological mechanism that we’ve been able to [detect] that solidly explains this phenomenon. And again, it hasn’t been replicated at this point.” ■

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Injection Safety Lapses All Too Common in Ambulatory Care

Surveyor reports frequent breaches with needles, vials

Injection safety issues related to the improper use of needles, syringes, and vials continue to put patients at risk of bloodborne and bacterial infections in ambulatory care clinics and outpatient surgery centers.

Though numerous outbreaks have occurred over the years, accreditation surveyors are still finding basic lapses that put patients at risk of infections that may go undetected unless they occur in a cluster.

“The earlier that a potential outbreak is identified and investi-

gated, the better,” says **Joseph Perz**, DrPH, MA, an epidemiologist who has investigated numerous injection safety outbreaks at the CDC. “The flip side of that is that unless you have a large outbreak with a large number of cases, sometimes it’s hard to use the statistical methods and analytics that empower us to get to a definitive root cause.”

Perz spoke at a recent CDC webinar that featured an inspector’s eye view of ambulatory settings as described by **Pamela Dem-**

ski Hart, BS, MT, ASCP, CHSP, founder of Healthcare Accreditation Resources in Plymouth, MA.

“Primarily, I work with ambulatory surgery centers, which include anything from pain management, endoscopy centers, oral surgery centers, cosmetic, and internal medicine,” Hart says. “This is actually my view of what I witness when I’m on site.”

Hart walked through a sobering set of slides and photos of clear violations of injection safety in

various settings, beginning with an ambulatory surgery center that had pre-drawn syringes and multi-dose vials in the same area where they are about to be administered.

“I’m careful about having a discussion in front of other people, patients, et cetera,” she says. “So when the opportunity arises, I explain that this is a direct violation of CMS requirements, CDC recommendations, and also the most current APIC paper that came out January 2016, [which] specifically stated that multi-dose medication vials used for more than one patient must be stored [and] labeled appropriately. They should not enter the immediate patient care area.”

In several outbreaks investigated by the CDC, reuse and improper reentry into vials was shown to contaminate the medication, setting up a scenario of cross-transmission of hepatitis C and other pathogens if small amounts of blood are aspirated into the vial.

“We try to discuss this in detail,” Hart says. “Again, it’s a case-by-case basis. It depends on the individual. Sometimes they say, ‘yes, absolutely, thanks for telling us.’ They’re positive. But I have heard probably too frequently that a partition will be put up or they will use a different room when the surveyors or an accrediting body comes to inspect.”

Citing other examples of what

she commonly sees, Hart showed a photo of a controlled substance narcotics in the same area as other medication vials. Another example was a single-dose vial used on multiple patients at a pain clinic. The vial label read, “Discard unused portion. One procedure only.”

“It is a myth that 50ml vials are intended for more than one patient,” she says. “The fact is that the label clearly states otherwise. And when I had this discussion at the pain management center, they were unaware.”

Red Flags

Hart sometimes sees pre-filled syringes of varying volumes, raising a red flag of possible reuse.

“[Here are some] IV bags — several of them had been pre-spiked,” she says about another site visit. “Some were stored in a closet on the floor. Some were hanging. They said they could be used weeks later.”

Another common problem she finds is inconsistent labeling and use of medication beyond expiration dates.

“We had expired meds in this area, but the bottle on the right shows only one date,” Hart says, explaining a shelf of medications. “When I asked what that meant, they did not know. I said, ‘Is that an expire date? Is that a

prep date?’ I’d like to use ‘beyond use date’ or a BUD because then I know it’s a no-brainer. If there’s a BUD and it says 5-1, that bottle should not be there on 5-2.”

Similarly, some medications contain no preservatives and should be disposed within a short time period after opening, but are sometimes found opened and undated in some facilities, she says. To address such issues, Hart helps facilities set up medication cart checklists and other ways of sorting and identifying medications and vials.

“The solution is multifaceted,” she says. “You need management commitment. All staff have to actually support that the criteria is implemented, but it comes from management. I find often that the people that are more the first-line preparers, workers, clinical staff — they understand this, but they don’t get the support to implement it. Everyone needs to be trained initially, annually, and as needed.”

A good approach is training staff about incidents that have been found in similar facilities, many of which have been investigated by the CDC.

“This isn’t meant to be punitive, but we need random and unannounced surveys,” she says. “Competency exams are a must for license renewal. We cannot turn our back on safety. We took a vow: First, do no harm.” ■

Did Prostate Cancer Treatment Lead to Fatal Zika Infection?

A closer look at the first U.S. Zika death

Most Zika infections are asymptomatic and non-consequential unless the infected person is pregnant or has had unprotected sex while the virus

was circulating in the blood or persisting in a human reservoir like semen. Thus, we have seen tragic birth defects, failed or terminated pregnancies, transmission to sexual

partners both male and female, and Zika infection following a needlestick.

But perhaps no case of Zika is as strange and alarming as that

of the first U.S. death due to the emerging virus in June of this year in Salt Lake City. While hospitalized, the 73-year-old patient apparently transmitted Zika to a visiting acquaintance — possibly through tears — before dying with an incredibly high level of circulating virus in the blood. The secondary case developed symptomatic Zika infection, but subsequently recovered.

It is concerning, but not completely unexpected, that a patient could transmit a virus that was circulating in high titers in his system, but the level of virus was off the charts. At 200 million particles per milliliter, the Zika viral load in the patient was 100,000 times higher than what had been reported in other Zika cases, researchers recently reported.¹

As a result, a previously healthy 38-year-old acquaintance of the index case — with no travel history or other Zika risk factors — acquired the virus after having wiped the index patient's watering eyes and helped a nurse reposition him in the bed.

"It is likely that Patient 2 acquired the infection from Patient 1, since Patient 2 had not traveled to an area in which Zika virus (ZIKV) is endemic in more than 9 months

and had not had sex with a partner who had traveled to such areas," investigators concluded. "Given the very high level of viremia in Patient 1, infectious levels of virus may have been present in sweat or tears, both of which Patient 2 contacted without gloves. Transmission of the infection through a mosquito bite appears to be unlikely, since *Aedes* species that are known to transmit ZIKV have not been detected in the Salt Lake City area. In addition, the second case occurred 7 to 10 days after contact with the index patient in the hospital, which implicates direct contact during hospitalization. ... No healthcare workers who had contact with Patient 1 reported having symptomatic illness."

No Smoking Gun

There are many unresolved aspects to the case, perhaps none greater than the central question of why the patient developed such a high titer of Zika virus. A variety of host and viral possibilities are being considered, but there is no smoking gun clearly suggesting a mutation that would enhance Zika virulence or an underlying illness that made the man highly susceptible to escalating infection.

One intriguing theory is that treatment for prostate cancer opened the door for Zika to aggressively multiply in the man's system. Before traveling to Mexico, where he reported being bitten by mosquitoes, the patient had completed radiation therapy for prostate cancer and was still on antiandrogen or "hormone" therapy when hospitalized.

"[R]adiation therapy and androgen blockade may have played a role in enhancing ZIKV virus pathogenicity," the investigators note. "In that regard, it is of interest that ZIKV persists in seminal fluid after clearance of viremia and may reach levels exceeding those in blood, suggesting that cells in the male reproductive system may provide a milieu particularly suitable for ZIKV persistence and replication. It is possible that radiation therapy may have enhanced ZIKV replication in irradiated tissues, and this may be a suitable area for further research." ■

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Lab Efficacy of Respirators over Masks Undermined by Real-World Use

Adjustment, removal for comfort negates protection

The notion that surgical masks provide the same protection from respiratory viruses in a hospital is commonly refuted by lab studies, which show the greater effectiveness of a well-fitted N95 in filtering out aerosols and particles that could go through a standard mask.

As part of its recent annual N95 Day respirator activities, the National Institute for Occupational Safety and Health (NIOSH) sought to bust several myths about respiratory protection, including the misconception that "respirators and surgical masks provide the same type

and level of protection for the user."¹

Indeed, NIOSH notes that, "Surgical masks are typically disposable, loose-fitting, and do not form a tight seal to the face. They are also not designed to capture a large percentage of small particles, which means that they cannot prevent the wearer from

breathing in airborne particles that may be transmitted by coughs, sneezes, or certain medical procedures (i.e. aerosol-generating procedures). Because of these factors, healthcare workers using surgical masks will not be protected against exposure to airborne transmissible diseases.”

However, actually determining the comparative efficacy of respirators and masks in clinical studies is much more difficult. In a recent meta-analysis, researchers in Canada could find no difference in protection between masks and respirators.² They reviewed three randomized clinical trials, one cohort study, and two case-control studies.

“No significant difference in risk of laboratory-confirmed respiratory infection was detected between healthcare workers using N95 respirators and those using surgical masks in the meta-analysis of the randomized trials,” the authors concluded. “It was not surprising to find that N95 respirators were generally more efficient filters with better face-seal characteristics than surgical masks when tested in the laboratory. However, transmission of acute respiratory infections is a complex process that may not be appropriately replicated by surrogate exposure studies.”

Fit-test Woes?

A contributing factor is likely that respirator use is compromised by a lack of adequate fit-testing, and workers may handle and readjust the equipment during use.

“N95 respirators are often considered uncomfortable for regular use, and improper wearing or adjustment of the respirator because of discomfort could lead to inadvertent face contamination, thus negating the potential protec-

tive benefit,” the researchers found.

Still, the authors concluded in the paper that “randomized controlled trials conducted in clinical settings represent the most valid information to evaluate the effectiveness of N95 respirators. They are more relevant to real clinical situations and report actual outcomes in healthcare workers, and therefore they are the best evidence on effectiveness to inform policy-making.”

HIC could not reach the lead author of the study as this issue went to press, but two NIOSH scientists commented jointly via email on the study: **Deborah Novak**, PhD, RN, and **Ronald Shaffer**, PhD, both of NIOSH’s National Personal Protective Technology Laboratory in Pittsburgh.

“We are aware of the meta-analysis published earlier this year,” Novak and Shaffer noted. “The article shares several similar themes as a paper³ with NIOSH co-authors that addresses this same topic. For example, both papers report that across many laboratory studies, N95 filtering facepiece respirators (FFRs) show less filter penetration, less face-seal leakage, and less total inward leakage than surgical masks and that randomized controlled trials (RCTs) are important.”

“However, the RCTs completed to date have yielded inconclusive results because of limitations in experimental design and implementation,” they added. “For example, study subjects failing to wear the assigned device during all times of potential exposure (i.e., poor compliance with the intervention) negate the superior fit and filtration properties of the FFR. Current studies such as ResPECT⁴ may be able to overcome some of these difficulties, but a complete face-fitting respirator vs. surgical mask clinical trial remains elusive.”

Indeed, in the recently published ResPECT study, the authors concluded, “While it may seem that N95 respirators should better protect healthcare personnel (HCPs) than medical masks against airborne infections in the workplace, this notion has not been validated by objective clinical evidence. Low tolerance to respirator wear among HCPs may prompt more frequent or longer periods of removal, compared to medical masks, to an extent that the benefits of higher levels of filtration and lower levels of leakage around the facial seal afforded by respirators are offset or subjugated.” ■

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CME/CE QUESTIONS

- 1. Tom Frieden, MD, estimated that a 5% percent increase in the flu immunization rate nationally would prevent nearly 10,000 hospitalizations.**
 - a. True
 - b. False
- 2. The CDC found that 83% of healthcare workers were immunized for flu in settings where the vaccine was:**
 - a. encouraged.
 - b. available at the worksite.
 - c. provided at no cost for at least one day.
 - d. all of the above.
- 3. According to Pamela Dembski Hart, BS, MT, ASCP, CHSP, it is a "myth" that which size medication vial is intended for more than one patient?**
 - a. 25 ml
 - b. 50 ml
 - c. 75 ml
 - d. None of the above
- 4. A visiting acquaintance of a patient dying of Zika virus that was in exceptionally high titers in the blood reported doing what patient care activity?**
 - a. Helping bathe the patient.
 - b. Putting lotion on mosquito bites.
 - c. Brushing the patient's teeth.
 - d. Wiping tears from the patient's eyes.

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Upon completion of this educational activity, participants should be able to:

1. Identify the clinical, legal, or educational issues encountered by infection preventionists and epidemiologists;
2. Describe the effect of infection control and prevention issues on nurses, hospitals, or the healthcare industry in general;
3. Cite solutions to the problems encountered by infection preventionists based on guidelines from the relevant regulatory authorities, and/or independent recommendations from clinicians at individual institutions.

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