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Game Changer: COVID-19 Delta Variant Breaks Through in Provincetown

*Vaccinated have similar viral load as unvaxxed,
suggesting transmission*

By Gary Evans, Medical Writer

The Provincetown, MA, COVID-19 outbreak in July made headlines because hundreds of fully vaccinated people had breakthrough infections. It has been cited by anti-vaxxers as proof the vaccines do not work, potentially undermining immunization uptake at a critical point in the pandemic. In any case, the vaccines held; four immunized people were hospitalized but none died.

The critical question is whether the Provincetown outbreak is more of an outlier, or is it a harbinger of the kind of outbreaks and vaccine breakthroughs we may see more often with the highly transmissible Delta variant?

“During July 2021, 469 cases of COVID-19 associated with multiple summer events and large public gatherings in [Provincetown] were

identified,” the Centers for Disease Control and Prevention (CDC) reported.¹ “Approximately three-quarters (346; 74%) of cases occurred in fully vaccinated persons.”

The CDC added the caveat that data “from this report are insufficient to draw conclusions about the effectiveness of COVID-19 vaccines against SARS-CoV-2, including the Delta variant, during this outbreak.”

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

“[On] rare occasions, some vaccinated people infected with the Delta variant after vaccination may

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be contagious and spread the virus to others," CDC Director **Rochelle Walensky, MD, MPH**, said at a press conference before the report was released. "This new science is worrisome and, unfortunately, warrants us to update our recommendations. Vaccinated individuals continue to represent a very small amount of transmission occurring around the country."

This science was not fully elucidated in the report, but it does mention that "cycle threshold values" of viral loads were similar among specimens from patients who were fully vaccinated and from those who were not vaccinated.

"High viral loads suggest an increased risk of transmission and raise concern that, unlike with other variants, vaccinated people infected with Delta can transmit the virus," Walensky said in a statement when the report was released. "This finding is concerning and was a pivotal discovery leading to the CDC's updated mask recommendation [on July 27, 2021]."

The Right Decision?

Although Delta had emerged in India in October 2020 and was being reported in other parts of the world, the CDC made the decision to lift mask requirements for vaccinated people on May 13, 2021, a time when cases were dropping and the pandemic had lulled in the United States. The potential for the Delta variant to spread to the United States, become the predominant strain, and undermine vaccine efficacy was not anticipated by the nation's leading public health agency.

"This [recommendation to mask again] doesn't undo that serious error that the CDC made earlier," said **Larry Gostin, JD**, a professor at

Georgetown University Law Center in Washington, DC. "I understand why the CDC did that. It was not an unreasonable scientific decision, but it was a really poorly thought-out public health decision because it was entirely foreseeable at the time that both the vaccinated and unvaccinated would unmask. And that's what happened — on day one."

Of course, CDC scientists also were shocked to find Delta could mount sufficient viral loads in the vaccinated to actually transmit the virus. A study published recently in preprint found that Delta replicates to viral loads a thousand times higher than the original SARS-CoV-2 strain.² That could in part explain its shorter incubation period, high transmissibility, and ability to cause breakthrough infections in the vaccinated.

Another study in Singapore documented breakthrough infections, but encouragingly found less serious infections and saw viral titers drop more quickly in vaccinated people.

"Of 218 individuals with B.1.617.2 [Delta] infection, 84 had received a mRNA (messenger ribonucleic acid) vaccine, of which 71 were fully vaccinated, 130 were unvaccinated, and four received a non-mRNA [vaccine]," the authors reported.³ "Despite significantly older age in the vaccine breakthrough group, the odds of severe COVID-19 requiring oxygen supplementation was significantly lower following vaccination. PCR (polymerase chain reaction) cycle threshold (Ct) values were similar between both vaccinated and unvaccinated groups at diagnosis, but viral loads decreased faster in vaccinated individuals."

According to a Yale Medicine report, Delta spreads 50% faster than the first Alpha variant, which itself was about 50% more transmissible

than the original SARS-COV-2 strain.⁴ The question of enhanced virulence still is somewhat unresolved, but a CDC internal meeting slide set says Delta is “likely more severe.”⁵

The CDC cites three studies in the meeting materials that report indicators of increased virulence, with one from Canada finding higher odds of hospitalization, intensive care unit (ICU) admission, and death.⁶ Another study from Singapore cites higher odds of oxygen requirements, ICU admission, pneumonia, and death.⁷ Finally, a study from Scotland reports higher odds of hospitalization with the Delta variant.⁸

In the meeting slides, the CDC emphasizes that “vaccines prevent > 90% of severe disease [caused by Delta] but may be less effective in preventing infection or transmission. Therefore, more breakthrough and more community spread [may occur] despite vaccination.”

Breakthroughs always were expected at some level with coronavirus and, in general, the higher the vaccination rate of a given population, the greater proportion of infections will represent breakthroughs.

For example, Singapore has vaccinated about 75% of its population. In a recent report of about 1,000 recent infections, 44% were fully vaccinated. None of them became seriously ill.⁹

Independence and Illness

None of the aforementioned factors about Delta were widely known or suspected — certainly not among the general public — when a large gathering of gay men went to Provincetown recently for the annual of Fourth of July week celebration.

“Most cases occurred in males (85%); median age was 40 years,” the CDC reported. “Persons with COVID-19 reported attending densely packed indoor and outdoor events at venues that included bars, restaurants, guest houses, and rental homes. [D]emographics of cases likely reflect those of attendees at the public gatherings, as events were marketed to adult male participants. Further study is underway to identify other population characteristics among cases, such as ... underlying health conditions, including immunocompromising conditions.”

That raises the issue of human immunodeficiency virus (HIV) infection, which possibly could undermine vaccine efficacy.

“There is that issue, and there are all kinds of subsidiary issues, like people with undiagnosed HIV infections — are they the same [as those diagnosed]?” says **William Schaffner**, MD, an epidemiologist at Vanderbilt University in Nashville, TN. “Are they more or less likely to be vaccinated? When were they vaccinated? There are a lot of potential confounding variables here that are not acknowledged in this [CDC] report.”

It should be noted that most men attending events in Provincetown were fully vaccinated and, again, had been given the green light by the CDC in May 2021 that they could remove masks if immunized. A fully vaccinated man who attended the Provincetown festivities and came down with COVID-19 upon return to his hometown described the experience in a published account. Upon testing positive for SARS-CoV-2, he went into quarantine and kept hearing from gay friends — about two dozen — who also were in Provincetown and now were sick despite being vaccinated.

“This was to be our government-approved ‘hot vax summer,’ when masks came off and inhibitions could finally breathe again,” he wrote. “... For months, the CDC had advised us that breakthrough cases among the vaccinated were rare events.”¹⁰

Although there have been no reports of the pandemic respiratory virus being transmitted sexually in the traditional understanding of that term, the spatial closeness of intimate encounters at the gathering could have led to some transmission of the Delta variant, Schaffner says. It could be that maskless encounters in public and private over several days made the highly transmissible variant a kind of opportunistic infection among this population.

Cases Surge Nationally

The general thinking is that breakthrough infections and transmission by vaccinated people still are relatively rare. However, the Provincetown outbreak raises the question of whether they may become more common with the Delta variant now the dominant strain in the United States.

“Those [breakthrough] numbers seem inflated because it’s a relatively isolated [outbreak], if you will,” says **Ann Marie Pettis**, president of the Association for Professionals in Infection Control and Epidemiology (APIC) “We need a lot more data before we can really decide, can you spread the virus if you are vaccinated, as readily as you might believe, if you just looked at this one report? The jury’s out in my mind.”

Meanwhile the Delta surge is driving cases nationally, with those hospitalized still primarily the unvaccinated. “In late June, our seven-day moving average of reported

cases was around 12,000,” the CDC reported.¹¹ “On July 27, the seven-day moving average of cases reached over 60,000.”

Shockingly, the latter case rate looks more like the toll of infections seen before the COVID-19 vaccines were widely available, the CDC noted.

“We’re seeing a lot younger people becoming infected, as well as hospitalized,” says Pettis, director of infection prevention for the University of Rochester (NY). “I know IPs (infection preventionists) like myself all over the country are really struggling with this right now — some areas worse than others. In my own area, just this last week, we more than doubled our number of cases. In our hospital, we went to zero cases to 15 in the matter of a day or two.”

On the other hand, the silver-lining effect of Delta is that it may finally push some of the hesitant population to be vaccinated. “All of this attention that has been devoted to Delta, including having to change the CDC guidelines, I think may have conspired in a positive way to drive up vaccine acceptance,” Schaffner says. “We are still nowhere near where we want to go, but in my own state — which has been very vaccine-reluctant — I’ve seen an increase in vaccinations.”

The CDC’s renewed emphasis on masking has brought that issue back, not only for people in public but now recommended by the agency for all school children this fall, he adds. “There has been a fair amount of chatter among the ID (infectious disease) docs in my community, and so far I haven’t found anyone who is against wearing masks in school,” he says. “We all think that it ought to be a standard practice across the country.”

Mandates Inevitable

There still is the question if vaccinated people will start donning masks again, although the Delta variant certainly appears to warrant the measure.

“This time around, people are not quite as willing to pick up their cross and carry it, if you will,” Pettis says. “We are seeing more skepticism and reluctance in some people, but that is why it is important to keep sharing the data and the messaging.”

Unfortunately, the CDC complicated its new message by recommending a return to indoor masking for fully vaccinated people in areas with “substantial or high transmission” of COVID-19, Gostin says.¹² The CDC referred to a map of U.S. counties for determining whether any given local area has high or substantial transmission.¹³ Overall, about 89% of U.S. counties were designated as high or substantial transmission as of August 8, 2021.

“The current guidance, while better, is still confusing to the public,” Gostin says. “It differentiates in a different way — between communities with higher case rates and lower case rates. Well, no ordinary person is going to know whether they are in a high or low area. The data are changing every day. Guidance to the public has to be consistent and simple — a simple message like ‘mask up if you are indoors irrespective of vaccination.’ That should have [remained] the guidance all along. It’s very hard to turn the spigot on and off. When people throw away their masks, it is going to be hard to get them to put them back on.”

The lack of a national identification system to verify vaccination status remains a problem, and Gostin thinks the Biden

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

The Department of Health & Human Services vaccine cards “are being procured, forged, and stolen,” he says. “It is not a credential within a system in any sense of the word. It should be reliable and confidential. A lot of countries have done this — Israel, France. I think they are resisting it [in the United States] because anything with any whiff of mandatory vaccination is ultimately going to fail. There is no scientific or public health reason for it — it is purely political.”

Yet, with the Delta variant proving to be a game-changer, vaccination mandates of various kinds are looking inevitable.

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

The nation is at a tipping point on mandates, as more companies and universities require them, he adds.

“Hospitals and health systems should have had mandates months ago, and any one of them that doesn’t have a mandate now is acting recklessly,” Gostin says. ■

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Bacteriophages: Strange Viruses that Eat Bacteria for Breakfast

‘Nobody could believe that a guy could come back from near-death’

For an American couple, it began with a 2015 dream trip to the Valley of the Kings in Egypt. It turned into the curse of the pharaohs. The husband developed a pan-resistant Gram-negative infection that turned septic, and at one point his wife asked him if he wanted to keep fighting for life hooked up to machines.

“I knew he was already on a ventilator and on three pressors —

that this was the trifecta of organ system failure,” says **Steffanie Strathdee**, PhD, at that time an epidemiologist at the University of California San Diego (UCSD). “I decided to have a conversation with [my husband] Tom, and I asked him if he wanted to live.

“Even though he was in a coma and I wasn’t sure if he could hear me, I asked him to squeeze my hand if he wanted to live and then I would leave

no stone unturned. And he squeezed my hand.”

Strathdee, for reasons that will become clear, now is co-director of the Center for Innovative Phage Applications and Therapeutics (IPATH) at UCSD.

She told her story recently at the 2021 virtual meeting of the Association for Professionals in Infection Control and Epidemiology (APIC), beginning when her husband

became violently ill during the Egypt vacation.

“I just assumed that he had food poisoning, but it was more serious than that,” she said. “He was rushed to the closest clinic — there was no hospital in Luxor, where we were based.”

The clinic staff diagnosed him with pancreatitis, saying they thought he might have a gallstone blocking his bile duct, and stabilized him enough to be medevacked to Germany.

“He was too weak to be sent home to the U.S. right away,” Strathdee said.

The German clinicians did a computerized axial tomography scan and found a “giant abscess the size of a small football in his abdomen,” she said. “They removed a gallstone. The abscess in his abdomen was full of this putrid, stinking fluid and that meant that it had been there for quite some time.”

The infecting organism was cultured, and Strathdee awaited word on what they were dealing with.

Bad News

“The doctor came back — and he was in full PPE (personal protective equipment) this time — and he said, ‘Look, I’m sorry to tell you this bad news, but this is the worst bacteria on the planet,’ she said. “This is *Acinetobacter baumannii*.”

Initially, it was partially sensitive to a few antibiotics, but as treatment continued, it became pan-resistant, what the Centers for Disease Control and Prevention calls “carbapenem-resistant *Acinetobacter*,” which it gave its highest threat level of “urgent” in 2019.¹

“Well, that’s when I started to get a bit worried,” she said. “I realized that my husband was now a poster

child for this post-antibiotic era that we’re entering, where by the year 2050, one person every three seconds, or 10 million a year, are going to be dying from superbugs.”

The physicians in Germany stabilized her husband as best they could and he was medevacked back to the United States and hospitalized at UCSD.

“So now my colleagues were caring for him, but Tom was hospitalized for months,” she said.

One day, an internal drain slipped and contamination spread within the patient. “He went into septic shock because it had dumped all that infected fluid into his abdomen, into his bloodstream,” she said. “Sepsis is a horrible thing to witness. Well, from that moment on, he was fully colonized with *Acinetobacter baumannii* and this organism had acquired even more resistance, so it was now pan-resistant. So the doctors said look, there’s nothing that we can do.”

This is the point the handheld exchange between wife and husband occurred, with Tom squeezing Stephanie’s hand to express the will to keep fighting.

The Search Begins

“I went home and I did what anybody would do, I hit the internet and I used PubMed, our National Library of Medicine’s wonderful search engine, and put in the key words ‘multidrug resistance, *Acinetobacter baumannii*,” she told APIC attendees. “Up popped this paper about something called phage therapy. I vaguely remembered what this was from my classes in microbiology back in the 1980s.”

Phages have been going in and out of style since they were discovered a

century ago. After it was discovered that these viruses could kill bacteria, a French-Canadian microbiologist, Félix d’Hérelle, dubbed them bacteriophage for something that, translated from the Greek, “devours” bacteria. Bacteriophages had something of a treatment heyday in the 1930s, but fell out of favor with the discovery of penicillin and the dawn of the antibiotic age in the 1940s. However, bacteriophages seem poised for a renaissance as bacteria evolve resistance to antibiotics and more infections threaten to become untreatable.

Under electron microscopy, bacteriophages can be seen to have a “head” containing nucleic acid, a stem body, and spidery legs or fibers. It’s not unlike an oil drilling rig in appearance and it is designed to penetrate and invade bacterium.

“The phage attaches to the bacterium through a receptor, and it drills into it and its genetic material, usually DNA, takes over the bacterial cell wall and turns it into a phage manufacturing plant,” Strathdee said. “Now if this is the lytic cycle of the phage, the phage makes progeny called virions, and when given the kill signal, they burst out and then they go on to attack new bacteria. They only attack the bacteria that they’re a match to. If there are no matches, the reticuloendothelial system, usually the liver and the spleen, filter out these phages and there are no side effects.”

The next step in her quest was to find bacteriophages that matched *A. baumannii*, sending out an urgent request that was answered by phage researchers at Texas A&M University, the U.S. Navy, and others. Four matches initially were found.

“Nobody really knows at this point how many phages you really need to have a cure, but you definitely want to have different phages that

will attack different receptors, and we didn't have the time to sequence the phages to know if we did," she said. "But the more phages, the better, was what we thought."

However, it was found that the level of the level of endotoxins in some of the phages may be high enough to trigger septic shock.

"Luckily, San Diego State researchers who had been studying phage had the perfect setup with an octanal extraction and they were able to reduce the endotoxin level to what we thought was probably safe," she says.

Miracle or Virus?

After titrating the doses to about a billion phages per dose, the first phage doses were injected into the catheter in the patient's abdomen. They waited a few days and injected phage doses in his peripherally inserted central catheter line.

"And three days later, even though he had been in multisystem organ failure and in a deep coma, he lifted his head off the pillow and opened his eyes and kissed his daughter's hand," she said. "Well, everybody in the ICU (intensive care unit) freaked out. Nobody could believe that a guy could come back from near-death like this. And, in fact, the head of the ICU said she'd never seen somebody so close to death that has made a near full recovery."

As a result of the case, the ensuing publicity, and the attendant funding, UCSD founded IPATH in 2018.

"We've gone on to treat over a dozen phage therapy patients at UCSD, and we've consulted on numerous other cases internationally," she says. "Our goal is really to disseminate our knowledge, to be able to treat other patients. We've

CDC: Resistance Emerging to Last-Line Carbapenem Drugs

Screen patients who received care overseas

Carbapenems are a last-line antibiotic, one of the final weapons in the formulary against multidrug-resistant bacteria. But the ever-evolving bugs are starting to solve this drug class and have found an ingenious way to do it — genetic transfer of resistant properties to another Gram-negative bacterium.

Transferred on a plasmid, genetic material enables the recipient bacterium to produce carbapenemases, enzymes that inactivate beta-lactam antibiotics, including carbapenems. The Centers for Disease Control and Prevention (CDC) established its Antibiotic Resistance Laboratory Network (AR Lab Network) in 2016 to support nationwide lab capacity to detect these emerging antibiotic-resistant organisms rapidly.

"Through the AR Lab Network, public health laboratories test carbapenem-resistant Enterobacterales, carbapenem-resistant *Pseudomonas aeruginosa* (pCRPA), and carbapenem-resistant *Acinetobacter baumannii* isolates for carbapenemases," the CDC reports.¹ "During October 2012-April 2019, CDC documented 151 isolates harboring multiple carbapenemase genes from 100 patients in the United States."

The threat of the genetic transfer from these carbapenem-resistant organisms (CRO) to susceptible bacteria has a multiplier effect that increases the risk to patients well beyond this 100, who were a median 63 years of age.

"Among 93 incident cases with available data, 62 (66.7%) occurred in patients who had traveled internationally in the 12 months before their incident culture," the CDC found. "Among patients with a history of international travel, most (89.5%) had received inpatient healthcare while abroad."

When the CDC lab began to do its own testing in 2017, a pattern of increasing microbial threats began to emerge.

"Among 89 (84.8%) incident cases reported since AR Lab Network testing began in 2017, a total of 15 were reported in 2017, 51 in 2018, and 23 in the first four months of 2019," the CDC reported. "Multi-CRO in healthcare facilities are an emerging concern in the U.S.," the authors concluded. "Although hospitalization outside the U.S. was the most common risk factor, we found a substantial proportion of cases that were probably acquired in healthcare facilities in the U.S."

The CDC recommendations included screening patients who were hospitalized outside the U.S. recently and investigating possible transmission when a multi-CRO is identified. ■

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published a number of case reports and are moving toward clinical trials now.”

Those trials may be instrumental in getting the Food and Drug Administration to license phage therapy beyond compassionate use. The potential for enlisting viral phages against resistant bacteria is promising, particularly as it may be used in support of antibiotic stewardship programs.

“Can you imagine having an ever-expanding phage library that maps onto a superbug library?” she says. “You’ll be able to go back to that library and match a new phage to the bacterial mutants that arise. We should be treating phage like a living antibiotic and moving it through all of those translational studies that we need to be able to take it to Phase III trial.” To that end, the National Institutes of Health is

planning a \$12 million bacteriophage therapy trial using a network of research institutions. ■

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IP Cuts SSIs by 55%, Saves a Net \$805,000

‘More than anything, we achieved better outcomes for our patients’

A hospital saved a tidy sum and left 10 patients much happier — those who did not have surgical site infections (SSIs), as predicted by the SSI rate prior to an intervention that revamped the patient preparation protocol.

“Considering that the average cost to treat one SSI is \$90,000, the reduction of 10 SSIs in the post-implementation period represents potential savings of \$900,000 in SSI treatment costs,” said **Patti Steger**, CLS, MT(ASCP), CIC, infection prevention manager at Hoag Orthopedic Institute in Orange, CA. “More than anything, we achieved better outcomes for our patients, and that is ultimately what we are here for.”

Recently, Steger detailed her program success at the 2021 virtual conference of the Association for Professionals in Infection Control and Epidemiology (APIC).

“The pre-operative prep went from two to five days, and the scope was expanded to include nasal decolonization,” she said. “By giving patient kits with SSI prevention education, we believe we achieved

high rates of patient compliance. We did not have any increase of pre-operative skin issues reported, and we did see a decrease in the incidence of complex SSIs.”

SSIs are costly and may require surgery and prolonged antibiotic treatment.

“At our facility, these treatment costs can range between \$30,000 and \$175,000,” Steger said. “The readmission also results in prolonged lengths of stay, and the SSI increases the patients’ morbidity and mortality risk. The more intangible impacts on the patient’s life include longer recovery time, increased pain, prolonged antibiotic exposure, and delayed return to work, which may have substantial social and financial impacts on the patient and their family.”

To address an increased incidence of SSIs, a multidisciplinary workgroup was formed that included infection prevention, surgeons, anesthesiologists, hospitalists, pre-operative leaders and nurses, and staff and patient educators.

“Patient factors, such as nasal and body colonization, were identified as

possible contributors to the increase in our SSIs, and due to the prevalence of SSIs caused by skin organisms, the decision was made to revamp the presurgical patient preparation process,” she said.

For example, patients complained about a chlorhexidine gluconate (CHG) skin preparation product that caused stickiness on application.

“Not only was this a patient dissatisfier, but during the pre-operative skin check, we discovered that the patient would have skin tears in their skin folds, presumably from the tackiness of this product prior to drying,” she said. “Lastly, nasal decolonization was only addressed on the day of surgery. Patients reported that the product had an unpleasant odor and feel. The nurses reported that they would have to stop patients who would instinctively try to blow their nose because of the feeling of nasal congestion.”

The New Protocol

In 2019, a new presurgical universal decolonization protocol was implemented that included bathing

with a chlorhexidine gluconate (CHG) foam product once a day and twice-a-day application of an alcohol-based nasal antiseptic product. A “universal decolonization kit” was created that included the CHG foam product, alcohol-based nasal swabs, a shower mitt, a timer, and instructions on how to use each product. These kits were distributed to the surgeons’ offices to be given to patients during their preoperative appointment. The patient then receives a preadmission phone call a week before surgery to confirm they have received the kit and then given verbal instructions on its use. Prior to implementation, all staff were educated on the new universal decolonization protocol and a frequently asked questions document was posted to address issues as they came up, she explained.

“Preoperative nurses continue to use the 2% CHG wipes on the surgical site as before; however, we have changed the nasal decolonization product to the alcohol-based agent,” Steger said. “After surgery, the alcohol-based agent is also used twice a day until the patient is discharged. The patient is advised [to] continue to use any remaining product at their surgeon’s discretion until consumed.”

On the day of surgery, the preoperative nurse confirms that the patient has completed the universal decolonization protocol. This is documented in the medical chart.

“Once the new universal decolonization protocol process was stable, an audit of a random sample of patient charts was conducted,” she said. “This showed that our patient-reported compliance with our protocol was greater than 93%. In informal interviews, our patients reported that the CHG foam product was easy to apply with the provided shower mitt, and they did not report any issues with stickiness after application. The nasal product was also reported to be simple to use.”

An 18-month pre- and post-analysis was completed, showing that during the pre-implementation period, from March 2018 to August 2019, there were about 6,800 procedures and 22 complex SSIs. This resulted in a standardized infection ratio (SIR) of 1.2 and a rate of SSI per 100 procedures of 0.3.

Post-implementation period results, including about 6,300 procedures from September 2019 to February 2021, were impressive. SSIs dropped 55% to 12, and the SIR was

halved to 0.6. The rate of SSIs per 100 procedures also fell to 0.1.

“Prior to the change, the total cost for presurgical patient preparation was approximately \$22 per patient,” Steger said. “This translates to just under \$150,000 for the 18-month pre-implementation period. Post-implementation, the cost per patient was approximately \$38.50 and the total for the 18-month post-implementation period was almost \$245,000.”

The new protocol raised costs \$95,000 but prevented 10 surgical infections for a net gain of about \$805,000.

“We learned several lessons during this process,” she concluded. “It’s critical to have all members of the healthcare team represented so you can gather all their viewpoints and achieve a comprehensive examination of the entire process. We also considered what our patients’ feedback was to staff and physicians. Finally, it was important to involve our clinical informaticist to make the necessary changes in the electronic health record order sets and documentation so that it would match our new process.” ■

Reducing Immediate-Use Steam Sterilization

‘We understood that this was not an acceptable rate’

Once called “flash sterilization,” a term that took on a negative connotation, the practice of quickly sterilizing a surgical instrument and returning it to the sterile field now is called immediate-use steam sterilization (IUSS). Regardless of the name, it generally has been discouraged if used as a substitute for lack of sufficient supplies or to save time for a non-emergency reason.

“IUSS should be limited to situations where the need is urgent for an instrument or we have an emergency situation,” said **Zachary Juno**, MBA, MHA, director of Operations and Perioperative Services, Emory University Hospital Midtown, in Atlanta.

Juno collaborated with **Jill Holdsworth**, MS, CIC, FAPIC, NREMT, CRCST, manager of

infection prevention at the hospital, to prevent surgical site infections (SSIs) by reducing IUSS of surgical instruments. They gave a joint presentation on the project recently at the 2021 virtual conference of the Association for Professionals in Infection Control and Epidemiology (APIC).

There was no defined national benchmark for an appropriate level of

IUSS, so Juno and Holdsworth set a target of no more than 2%.

“Our facility noticed that we needed a call to action around the time of January in 2018, when we had an IUSS rate of over 25% and 200 IUSS cycles per month,” Holdsworth said. “We understood that this was not an acceptable rate, and [we had] way too many IUSS cycles per month that were not for an urgent need. We had the goal of 2%, and we knew that we had a lot of work to do.”

A multidisciplinary approach team was formed that ensured all stakeholders were at the table, understood the problem, and had input in the process.

“The facility decided to use March 1, 2019, as a hard stop where IUSS would no longer be acceptable without the permission from OR (operating room) and sterile processing leadership,” Juno said. “Before this date, extensive education had to be performed for the OR

team members, surgeons, and sterile processing department (SPD).”

The IUSS process was designated as an SPD tech responsibility to ensure proper training and competency, he said. Workflow challenges were identified as the main barrier in reprocessing, causing delays and the need to perform IUSS for instruments not processed in a timely manner. Changes implemented to improve the process were extensive, including installing a fourth washer, creating a pass-through window to eliminate traffic from contamination to clean, and adding a second ultrasonic machine.

“We replaced three older sterilizers with new versions, added a second low-temperature sterilizer, and purchased new instruments to create additional sets,” he said. “Data collection changed from manual to electronic in June of 2019.”

Surveillance of 10 surgical procedures showed a drop in SSI rates, Holdsworth said.

“Our overall IUSS rates were observed to go down pretty dramatically in the beginning, starting with that March 1 hard go-live date in 2019,” she said. “Ever since that go-live date, we have consistently kept our IUSS rates below 2%. Not only that, we have consistently, for the last year and a half, been below 1% and with many months of zero IUSS.”

When they occur, IUSS events are discussed to see if the problem is inventory, overscheduling, not enough instruments, or other issues, she adds.

“[We want to] involve the surgeons more. How we can make sure that they know when their instruments are going through an IUSS cycle?” she said. “We also review these in response to SSI investigations and include those as part of our review process. We want to make sure that we’re very transparent with this data.” ■

Reinfection: COVID-19 Vaccine Twice as Effective as Antibodies

Data indicate vaccines offer better protection than natural immunity alone

CCOVID-19 vaccination is more than twice as protective as circulating antibodies in people who had a prior infection with SARS-CoV-2, the Centers for Disease Control and Prevention (CDC) reports.

“A study of COVID-19 infections in Kentucky among people who were previously infected with SAR-CoV-2 shows that unvaccinated individuals are more than twice as likely to be reinfected with COVID-19 than those who were fully vaccinated after initially contracting the virus,” the

CDC states.¹ “These data further indicate that COVID-19 vaccines offer better protection than natural immunity alone and that vaccines, even after prior infection, help prevent reinfections.”

This has been something of an ongoing issue, with some who acquired COVID-19 citing natural immunity and no need for vaccination.

This is a doubly dangerous view that comes amid the national struggle to get the unvaccinated to roll up their sleeves. Other emerging

incentives are that COVID-19 is being seen in younger patients, and almost all hospitalizations and deaths are in the unvaccinated.

“The study of hundreds of Kentucky residents with previous infections through June 2021 found that those who were unvaccinated had 2.34 times the odds of reinfection compared with those who were fully vaccinated,” the CDC reported. ■

REFERENCE

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C. auris Can Be Stopped, but Not Easily

Infection preventionist stops transmission from index case

A superbug that can become pan-resistant to fungal drugs, *Candida auris* first was reported in the United States in 2013 and continues to spread and cause hospital outbreaks.

First discovered in 2009 in Japan, the fungus continues to spread globally. This is an unusual bug in the world of fungi, in part because *C. auris* spreads more like bacteria. It can transmit to patients on the hands of healthcare workers, contaminate and persist in the environment, and colonize people, who then serve as a reservoirs. *C. auris* can cause high mortality rates, particularly if it is a highly drug-resistant strain or becomes an invasive infection.

“It is a skin commensal rather than gut flora,” said **Elizabeth Jefferson**, BS, PhD, CIC, infection preventionist and clinical epidemiologist at Scripps Memorial Hospital in La Jolla, CA. “Patients can remain colonized indefinitely, environmental surfaces can stay contaminated for months. It’s more difficult to identify in conventional labs, leading to misdiagnosis.”

From 912 isolates from around the world, about 65% were resistant to fluconazole, about 20% to amphotericin B, and 5% to echinocandins, she said. “[J]ust looking at the U.S. isolates, 33% are multidrug-resistant, and several have pan-resistance,” Jefferson said.

Not surprisingly, “a single confirmed case of *C. auris* from any body site is a cause for investigation

and notification to public health authorities,” she told attendees at the 2021 virtual conference of the Association for Professionals in Infection Control and Epidemiology.

In 2020, there were 714 case of *C. auris* in the United States, 112 of which were in California. One of those was the first *C. auris* case in San Diego, Jefferson said.

“The patient arrived with healthcare history from abroad, so the case was imported, but still needed to be contained, because if unchecked, *C. auris* can spread like wildfire through a facility,” she said.

The male patient had a motorcycle accident in South Africa, experiencing injuries to the femur, tibia, and fibula. He was hospitalized in South Africa in two separate facilities before being transferred to San Diego 13 days after the accident and overseas treatment. The patient met criteria for carbapenemase-producing organism (CPO) screening because he had healthcare abroad, Jefferson explained.

“In this case, the patient was placed in preemptive contact precautions in a private room where gown and gloves were required and shared equipment was cleaned and disinfected,” she said. “The disinfectant was EPA (Environmental Protection Agency)-approved for killing *C. diff*.”

The preemptive precautions were wise; CPO screening was positive for OXA-48 carbapenemases. That triggered a test for *C. auris*, which

has been detected in association with CPOs. *C. auris* was confirmed positive by a public health lab, then identified by the hospital microbiology lab.

“The *C. auris* case took place right at the beginning of the COVID-19 pandemic, so there were potential challenges,” Jefferson said. “The patient had a long length of stay — 45 days — so more time for transmission to occur. The patient had multiple trips to the OR (operating room), so more opportunities for contamination.”

Impressively, no transmission to other patients occurred despite a patient stay of about six weeks. Patients in adjacent rooms were tested for colonization, and the patient soon was moved to a remote corner room, she noted.

Infection control measures included “meticulous hand hygiene,” with alcohol-based rubs preferred over soap and water. “We used contact precautions requiring gown and gloves,” Jefferson said. “You need to use an EPA-approved disinfectant with label claims for killing *C. auris* or *C. diff* spores, and you have to adhere to the contact time.”

The patient room’s high-touch surfaces were cleaned and disinfected twice a day.

“The patient’s [six] surgeries were scheduled at the end of the day,” Jefferson said. “The OR was terminally cleaned and disinfected using both a chlorine-based disinfectant as well as UV (ultraviolet)



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disinfection. All rooms that the patient vacated were cleaned and disinfected twice. Processes were observed and audited.”

Another critical infection prevention measure was making sure the patient's shared equipment was cleaned and disinfected. “This included the patient's physical therapy equipment, the portable X-ray equipment, and so on,” she said. “As always, it is important to know who cleans what.”

Fortunately, the infecting strain of *C. auris* was not particularly resistant to fungal drugs, but still required extensive treatment. “So, although *C. auris* is commonly multidrug-resistant, levels of resistance can vary,” she said.

The patient was treated with micafungin, amphotericin B, and posaconazole. “On day 20, there was no fungus growth and on day 45, the patient was discharged home,” Jefferson said.

The patient was tested for *C. auris* colonization several months later and was found negative. His electronic medical record was flagged, indicating contact precautions for future admissions. No other cases of *C. auris* have been detected in the hospital a year following the case.

“This is a success story,” she said. “Surveillance and aggressive infection control measures are needed to prevent the transmission and spread of *C. auris*.” ■

CME/CE QUESTIONS

1. What other microorganisms do phages attack?

- a. Viruses
- b. Fungi
- c. Bacteria
- d. Algae

2. According to Patti Steger, CLS, MT(ASCP), CIC, changes to presurgical patient preparation reduced surgical site infections by:

- a. 19%
- b. 25%
- c. 38%
- d. 55%

3. In a project to reduce immediate-use steam sterilization, what was identified as the main barrier to appropriate reprocessing?

- a. Broken sterilizers
- b. Overbooking surgeries

- c. Workflow challenges
- d. Surgeons' resistance to change

4. A COVID-19 study by the Centers for Disease Control and Prevention showed that previously infected, unvaccinated people were more likely to experience which of the following compared to those who were fully vaccinated after initially contracting the virus?

- a. Onset of long COVID
- b. Strong antibody protection
- c. Reinfection with COVID-19
- d. Rapid diminishment of antibodies