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EpiNotes

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Historical Perspective: Guillain-Barre Syndrome and 1976 Swine Flu Vaccine

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In early 1976, a young, previously healthy Army recruit in Fort Dix died abruptly of influenza pneumonia, caused by a novel H1N1 strain, thought to be closely related to the 1918 influenza strain responsible for a devastating pandemic. An intensive epidemiological and serological investigation into this influenza A variant, later known as the “swine flu,” ensued.

The Advisory Committee on Immunization Practices (ACIP) reviewed the results, concluded that there was evidence for person-to-person respiratory spread and pandemic potential with persons aged <50 years having no prior exposure and therefore no antibodies to this strain. A vaccine targeting other influenza strains had been created for the general public for 1975-1976, but it did not include H1N1. The rush was on to add H1N1 coverage and vaccinate “every man, woman, and child” in the US. President Gerald Ford was publicly vaccinated to encourage vaccine confidence.

A small number of Guillain-Barre Syndrome (GBS) cases occurred that were temporally related to vaccine administration. Later analyses with other viral strains demonstrated that the risk of GBS from influenza disease is far greater than the risk with vaccine, but in 1976, the public outcry and fear of GBS impeded vaccine efforts. Nevertheless, by December 1976, more than 40 million Americans had received the swine flu vaccine. No swine flu pandemic emerged: but was it because of early intervention with a protective vaccine, or was it that the H1N1 strain was not as transmissible as public health leaders had feared? Was acceptance of the chance of GBS with vaccination appropriate, or an unnecessary risk?

Dr. David Sencer, CDC director 1966-1977, wrote in retrospect that "when lives are at stake, it is better to err on the side of overreaction than underreaction."

At the time of this writing, about 100 cases of GBS have occurred among 12.8 million people who have received the Janssen (Johnson & Johnson) COVID vaccine. The FDA has added a warning of the risk of GBS to the consent form for Janssen vaccine without any quantitative information, stating simply that "the chance of having this [GBS} occur is very low."

The unprecedented avalanche of information (and misinformation) presented to the general public from multiple media sources creates new challenges in risk communication.

Some argue that the general public is not equipped to understand quantitatively rare risks, but to offer no relative perspective (e.g., 100/12.5 million) seems problematic.

Can the general public understand risk and give informed consent? Yes, GBS has been associated with Janssen COVID vaccine. It is also associated with Shringrix vaccine, food poisoning, and other viral infections at a background rate of about 10/million.

Certainly, a paternalistic, non-transparent public health approach (e.g., just don't mention rare events) is counter to the ethical principle of informed consent. The challenge is translation of risk-benefit ratio into language the public can understand.

We need better visualization tools to help people grasp this concept

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Myocarditis and the smallpox vaccine

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A small number of cases of mild myocarditis have been associated with COVID-19 mRNA vaccines (Pfizer and Moderna). More than 95% of cases investigated have been mild and have resolved.

But a lingering question remains: Could even these mild cases have long-term effects? Let's look at what we know about other vaccine-associated myocarditis cases.

Myocarditis (inflammation of the heart muscle) has been associated with other immunizations e.g., with DTaP (diphtheria, tetanus, acellular pertussis) and influenza vaccines. But the strongest association has been with the smallpox vaccine. Between 2002 and 2018, more than 2 million US armed service members were vaccinated against smallpox, as preparedness against possible bioterrorism using this pathogen. The incidence of confirmed myocarditis secondary to smallpox vaccination is estimated to be 16.1 per 100,000 service members, similar to the rate for SARS-CoV-2 mRNA vaccines.

Smallpox vaccine-induced myocarditis requires supportive care (i.e., anti-inflammatory medication, heart failure or anti-arrhythmic medication, if indicated). Permanent debility and death are rarely reported. The vast majority of cases of smallpox vaccine-associated myocarditis cases were self-limited, resolved completely, and did not lead to long-term cardiac dysfunction. There is no evidence at this time that myocarditis associated with SARS-CoV-2 vaccination will follow a different course.

We need to acknowledge the rare, potentially serious side effects such as myocarditis associated with SARS-CoV-2 vaccine (and other vaccines as well) but weigh these against the risks of COVID disease.

Imagine a stadium that seats 80,000 people (Clemson's, for example). All 80,000 are boys aged 12-17 years, all vaccinated. There will be on average 5-6 cases of myocarditis, zero deaths. Now imagine another stadium of 80,000 boys aged 12-17 years, all unvaccinated. There will be, on average, over the next 3 months, 456 cases of COVID infection, of whom 18 are hospitalized, 5 admitted to the ICU, and 0.2 deaths. A low number of deaths, to be sure, but not zero.

Vaccination is the way out of this COVID-19 pandemic. We must continue to find vivid visual ways to explain and put risk in perspective.

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Legionellosis in the Time of COVID-19

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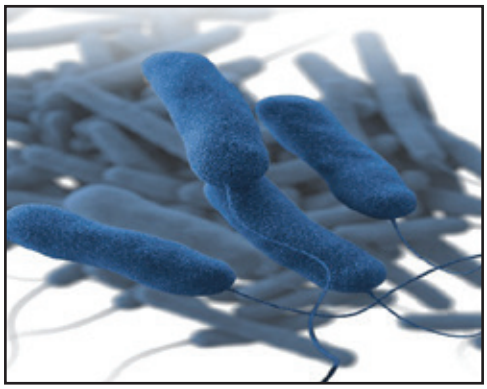
The bacteria species *Legionella* has caused pneumonia in humans for decades, despite only being identified in 1976. A large outbreak at an American Legion conference in Philadelphia earned the disease its name, Legionnaires' disease, and remained an epidemiological puzzle for several months.

Today, however, Legionnaires' disease is much better understood and as the COVID-19 pandemic continues, preventing exposure to *Legionella* and identifying co-infections of COVID-19 is critical.



Legionella bacteria are naturally found in freshwater environments. More cases of Legionnaires' disease typically occur in summer and early fall, related to warmer temperatures favorable for *Legionella* growth. Transmission to people can occur when the bacteria grow in building water systems and people inhale aerosolized water droplets that contain *Legionella*. Hot tubs, decorative water fountains, cooling towers and other human-made water structures can be potential sources of *Legionella* if not maintained appropriately. This disease is not known to spread person to person.

In the last 20 years, the incidence of Legionnaire's disease has increased in South Carolina and across the United States. In 2001, there were 15 cases statewide, just 0.4 cases per 100,000 persons. In 2019 there were 88 cases representing 1.7 cases per 100,000 persons.

The exact cause of this increase is unclear, but it may be due to increased awareness and testing, increased susceptibility of the population, increased *Legionella* in the environment, or a combination of these factors.

Legionnaires' disease does not always show up as a large outbreak from a common water source. In fact, outbreaks represent a minority of the reported cases. Environmental surveillance for *Legionella* can be challenging due to the sporadic nature of the bacteria. It may be present as a contaminant in a cooling tower one week and gone the next.

Additionally, negative environmental testing does not mean the bacteria was not there or will not come back later. Therefore, working to prevent *Legionella* growth in building water systems through routine system maintenance checks in accordance with national standards is essential in minimizing the risk for *Legionella* exposure. Healthcare facilities should also develop and maintain water management plans to address any possible cause of hospital-acquired legionellosis.

The Centers for Disease Control and Prevention (CDC) offers a variety of resources regarding water management programs and maintenance of building waters systems in multiple settings including healthcare facilities and hotels (cdc.gov/legionella/wmp/index.html).

Pre-pandemic, *Legionella* pneumophila was estimated to cause around 3% of community acquired pneumonias (CAP). It is common enough that the recommended antibiotics for CAP include coverage for *Legionella*. However, the diagnostic calculations all change when a novel respiratory viral pandemic sweeps the world.

With the current infection rates of COVID-19, most pneumonias are presumably caused by the novel coronavirus SARS-CoV-2, especially when tests are positive for COVID-19. However, a co-infection might be missed, and treatment delayed if additional diagnostic testing is not performed. Some laboratories have the ability to do combined viral tests for influenza, RSV, and COVID-19, and testing for atypical bacteria can easily be done through urinary antigen testing. Performing routine testing is important for distinguishing between clinically similar pathogens and ensuring patients are cared for properly.

Legionnaires' disease can be lethal if not recognized and treated, especially in older adults and immunocompromised people who are considered at higher risk of developing illness if exposed to *Legionella*. The preferred diagnostic tests for Legionnaires' disease are culture of lower respiratory secretions on selective media and the urinary antigen test. Serological assays can be nonspecific and are not recommended in most situations. Obtaining respiratory sputum samples for special *Legionella* cultures is helpful to identify and track outbreaks.

Identifying cases of Legionnaires' disease is also important for epidemiological investigations. All cases of legionellosis are reportable to DHEC, and investigations into their possible exposure are conducted by DHEC staff. Information is collected regarding potential sources of exposure in the 10-14 days prior to illness onset, including exposure to hot tubs and potential travel-related exposures.

Timely identification and reporting of cases help to establish a baseline case rate, which can be used to help identify increases in cases and potential outbreaks.

Recognizing, treating, and preventing legionellosis during a pandemic is not an easy task. Implementing systems and routines to keep water safe is paramount to prevention. Prompt screening and recognition of legionellosis infection in people with pneumonia through testing can improve patient outcomes and aid in surveillance, especially during the pandemic.

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Soltani S, Faramarzi S, Zandi M, et al. Bacterial coinfection among coronavirus disease 2019 patient groups: an updated systematic review and meta-analysis. New Microbes New Infect. 2021;43:100910. doi:10.1016/j.nmni.2021.100910

Additional Resources

CDC Water Management Plan Toolkit
cdc.gov/legionella/wmp/toolkit/index

CDC Legionella Diagnostic Testing
cdc.gov/legionella/clinicians/diagnostic-testing

Revisions - 2021 School and Childcare Exclusion List

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The 2021 School and Childcare Exclusion List became effective June 2021 for the 2021-2022 school year. South Carolina Regulation 61-20 requires that DHEC publish an *Official School and Childcare Exclusion List of Contagious or Communicable Diseases* applicable to students and staff to include specific conditions for the duration of school or childcare exclusion, as well as criteria for return.

Revisions were made in August 2021 to the *Exclusion Criteria for Contacts (Exposures) - COVID-19* section. This document may be updated as new information on this novel virus and evolving situation becomes available.

Refer to the current 2021 School and Childcare Exclusion List, which can be found on the DHEC website.

Please contact the DHEC Division of Acute Disease Epidemiology (803-898-0861) with any questions about the School and Childcare Exclusion List.

2021 LoRC Update: Reporting of SARS-CoV-2 Sequencing Results

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COVID-19 is an urgently reportable condition in South Carolina, meaning cases, deaths and multisystem inflammatory syndrome in children (MIS-C), should be reported to DHEC within 24 hours. Additionally, unlike most other reportable conditions, all COVID-19 test results (positive, negative, indeterminate, and whole genome sequencing [WGS] results) must be reported to DHEC by all entities performing testing. WGS allows the identification and characterization of the variants of SARS-CoV-2 that are circulating.

Since March 2021, the Centers for Medicare and Medicaid Services (CMS) has allowed facilities that perform SARS-CoV-2 genetic sequencing on identified specimens to report patient-specific results to public health authorities (state, local, tribal, or territorial public health departments) regardless of the CLIA certification status of the laboratory. Any sequencing data can be reported to public health.

Therefore, pursuant to SC laws and regulations (see S.C. Code Ann. § 44-29-15(A)), DHEC requires this reporting. Per the South Carolina List of Reportable Conditions, all laboratories, whether located in or outside of South Carolina, that test specimens from patients living in South Carolina are required to report to DHEC all test results related to the detection or characterization of SARS-CoV-2, including positives, negatives, and WGS to detect variants of SARS-CoV-2.

Any facility that has been performing WGS of COVID-19 specimens and have not provided results of South Carolina residents to DHEC should start doing so, including sending any WGS results not previously provided to DHEC. The reporting of the sequencing data should include:

- all the original patient demographic data
- the viral test report content
- the second test with viral genetic lineage identified

For questions related to the reporting of COVID-19 WGS results, please contact the DHEC SCION Helpdesk at SCIONHELP@dhec.sc.gov or call 800-917-2093. You may also review the DHEC Health Update sent on June 14, 2021, DHEC COVID-19 Compendium of Reporting and the CDC Guidance for Reporting SARS-CoV-2 Sequencing Results.

References:

DHEC – South Carolina List of Reportable Conditions
scdhec.gov/sites/default/files/Library/CR-009025.pdf

DHEC – COVID-19 Compendium of Reporting
scdhec.gov/sites/default/files/Library/CR-012859.pdf

CDC – Guidance for Reporting SARS-CoV-2 Sequencing Results
cdc.gov/coronavirus/2019-ncov/lab/resources/reporting-sequencing-guidance

CMS – Regulatory Position on Reporting Sequencing Results to Public Health Departments
cms.gov/files/document/clia-sars-cov-2-variant.pdf

Contaminated Ultrasound Gel Recall

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On August 4, 2021, Eco-Med Pharmaceutical issued a voluntary recall of ultrasound gels from specific lots after being associated with a multi-state outbreak.

As of July 2021, cases of *Burkholderia cepacia* complex were identified in five states, with many cases being linked through whole-genome sequencing. Many of these cases resulted in bloodstream infections and were linked to ultrasound-guided procedures. Later, the U.S. Food and Drug Administration (FDA) extended Eco-Med Pharmaceutical's voluntary recall to include all ultrasound gels and lotions.

The FDA is asking in a letter all healthcare providers and healthcare facilities to immediately stop the use of and to quarantine all Eco-Med Pharmaceutical manufactured ultrasound gels and lotions due to the concern for contamination with Burkholderia cepacia complex bacteria. Ultrasound gels and lotions identified in the recall should be discarded or returned to Eco-Med Pharmaceutical per their instructions.

The Centers for Disease Control and Prevention (CDC) is working with local and state public health partners and the FDA on this investigation. Healthcare providers and facilities should follow the medical device manufacturer's instructions for use regarding device disinfection between patients.

Additionally, sterile ultrasound gel should be utilized during ultrasound-guided procedures, especially those that may involve vascular access or lead to another invasive procedure (i.e., amniocentesis). Cases with infections associated with potentially contaminated medical products or devices should be reported to the FDA's MedWatch Adverse Event Reporting Program.

Please contact the Healthcare Association Infections Section at hai_section@dhec.sc.gov with any questions.

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Multi-state Outbreak Investigations Impacting Healthcare Facilities

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DHEC's Healthcare Associated Infection (HAI) Section within the Division of Acute Disease Epidemiology (DADE) participates in the Centers for Disease Control and Prevention's (CDC) Healthcare Associated Infection/ Antimicrobial Resistance (HAI/AR) program. Through the HAI/AR program, the HAI Section contributes to many grant-funded projects and activities, preventing and mitigating HAIs and antimicrobial resistance within South Carolina's various healthcare settings.

One primary activity for the HAI Section is to collaborate and participate with the CDC and other partners, such as the U. S. Food and Drug Administration (FDA) to prevent the spread of infections in healthcare facilities, which may be associated with newly-identified multi-drug resistant organisms (MDROs) or through contaminated medical devices and products.

The collaboration can lead to early case identification through information sharing, implementation of effective mitigation measures, and the availability of consultation and laboratory resources from federal partners when warranted.

Currently, there are several multi-state investigations impacting healthcare facilities that the SC HAI Section is monitoring, in addition to the Eco-Med Pharmaceutical Ultrasound Gel and Lotion Recall mentioned in this Epi Notes issue. The CDC posts past and current Outbreak Investigations in Healthcare Settings along with relevant resources for state HAI/AR programs and healthcare providers (HCPs). We present here a summary of recent outbreak investigations.

Non-travel Associated *Burkholderia pseudomallei* Infections

Historically, *Burkholderia pseudomallei* infections (melioidosis) identified within the U.S. have been associated with travel to tropical and sub-tropical geographical locations where disease is endemic. Burholderia pseudomallei can affect both humans and animals and is a Tier 1 select agent. Non-travel associated cases of B. pseudomallei within the U.S. are rare. Infections may present as bloodstream infections, abscesses, wounds, and respiratory infections, including pneumonia. Symptoms can vary and be nondescript depending on the type of infection making diagnosis difficult, often leading to a delay in appropriate treatment. Additionally, melioidosis may be mistaken for another type of infection, such as Mycobacterium tuberculosis.

On July 1, 2021, DHEC relayed a CDC Health Advisory through the South Carolina Health Alert Network (HAN). The HAN recounted three reported non-travel associated melioidosis cases with one resulting in death and one each identified in Kansas, Texas and Minnesota by their respective public health departments. In addition to infection type and symptom variation, misidentification of the bacterium, B. pseudomallei can further delay appropriate treatment and possibly negatively impact the patient's outcome. Misidentification of the pathogen may occur with the use of automated laboratory identification algorithms. The HAN provides additional background information along with recommendations for prompt identification and treatment.

Candida auris (C. auris)

Candida auris is a fungus known for outbreaks in healthcare settings and often resistant to all three classes of antifungal medication.

C. auris can cause serious illness, including invasive infections and death. Mortality rates of *C. auris* infected patients ranges from 30-60%. Risk factors for *C. auris* infection include a prolonged hospitalization or stay in a healthcare facility, particularly a long-term care facility, presence of an invasive medical device (i.e., central venous catheter), recent antimicrobial use, recent surgery, diabetes, and an overnight stay within the past year in a non-U.S. healthcare facility located in a country with documented *C. auris* transmission.

C. auris may be misidentified with standard laboratory methods, which can lead to inappropriate management and further transmission. In the past few months, public health departments have reported an increase in *C. auris* cases. Healthcare providers (HCPs) should consider *C. auris* if a patient is not responding to treatment. Additionally, a facility may suspect *C. auris* if it has an increase in unspecified Candida species infections. A facility should ensure they are utilizing a disinfectant from the Environmental Protection Agency's List P once a case is identified in a patient or resident. See the Centers for Disease Control and Prevention's Candida auris webpage for additional information and resources.

Carbapenem-resistant Pseudomonas aeruginosa (CRPA) Associated with Medical Tourism

Medical tourism refers to international travel for the purpose of having elective and non-urgent, invasive procedures. Many travelers participating in medical tourism are seeking economical medical care for complex procedures that may not be covered by insurance such as cosmetic or gastric-bypass surgery.

Between August 1, 2018 and January 31, 2019, multiple states reported surgical site and other infections associated with medical tourism procedures with most being linked to one hospital in Tijuana, Mexico; most infections were with a highly resistant strain of Pseudomonas aeruginosa.

Through collaboration with the CDC, Mexican public health officials initiated an investigation to identify a common source and other at-risk patients who were notified of the potential risks. The outbreak was determined to have resulted from poor infection prevention and control practices and lack of adherence to proper disinfection and sterilization practices and standards. Many patients received letters from their respective state health departments with advice to follow-up with their primary care physician to discuss post-exposure management. The outbreak was declared over on April 30, 2019.

In February 2021, the CDC provided an update on the Pseudomonas aeruginosa Outbreak Associated with Medical Tourism. Eight cases were reported from various states with the earliest case occurring in July 2020. Six of the eight cases reported having a procedure or receiving medical treatment while at different hospitals in Tijuana, Mexico. The *P. aeruginosa* associated with these medical tourism-associated infections is highly resistant to the carbapenem antimicrobials, expressing an enzyme, referred to as a carbapenemase, specifically Verona-integrated metallo-β-lactamase (VIM). Carbapenemase-producing organisms (CPO), such as VIM carbapenem-resistant *P. aeruginosa* (CRPA VIM) are considered a public health threat requiring public health action to contain the threat.

Public health jurisdictions and the CDC are asking that healthcare providers (HCPs) report suspect VIM-CRPA cases who had an invasive procedure outside the U.S. within the last year. Additionally, HCPs should consider screening hospitalized patients for CPOs if the patient reports hospitalization outside the U.S. within the past year.

Please contact the Healthcare Association Infections Section at hai_section@dhec.sc.gov with any questions.

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West Nile Virus Updates

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According to the Centers for Disease Control and Prevention (CDC), West Nile virus (WNV) is the No. 1 cause of mosquito-borne illness in the United States. This virus is endemic in South Carolina, and cases are urgently reportable to the South Carolina Department of Health and Environmental Control (DHEC).

WNV is transmitted to humans and animals through the bite of an infected mosquito, and WNV activity typically increases during warm weather months when mosquito activity is also increased. In South Carolina, this is usually March through September.

As of October 21, 2021, thirteen human cases of WNV have been reported across the state, and all have been identified since August 6. While all regions have reported WNV-positive mosquito samples, the Upstate region has the highest number with 34 positive samples. Additionally, four WNV-positive horses have been reported in the Lowcountry region, and one WNV-positive horse has been reported in the Midlands region.

Most people infected with WNV do not develop symptoms. For those who do develop symptoms, the clinical presentation can range from a febrile illness (non-neuroinvasive) to a more serious illness affecting the central nervous system (neuroinvasive). In addition to fever, non-neuroinvasive WNV cases can have symptoms such as headache, stiff neck, arthralgia, myalgia, rash, and gastrointestinal symptoms. Encephalitis, meningitis, or acute flaccid paralysis can develop in neuroinvasive WNV cases. Less than 1% of infected individuals are estimated to develop neuroinvasive disease; however, the overall case-fatality ratio for individuals with neuroinvasive disease is approximately 10%. Most patients with the non-neuroinvasive disease typically recover completely.

WNV disease should be considered in any person with a febrile or acute neurologic illness who has had recent exposure to mosquitoes or recently received a blood transfusion or organ transplantation, especially during summer months in areas where WNV activity has been reported. Laboratory diagnosis of WNV in people is typically accomplished by testing serum or cerebrospinal fluid for WNV-specific IgM antibodies, which are usually first detectable three to eight days after illness onset. Therefore, patients who test negative for WNV, but had serum collected within eight days of illness onset may need to be retested on a later specimen. Positive WNV results should be reported to DHEC, and the sample should be sent to the DHEC Public Health Laboratory for further testing at CDC, including testing by plaque-reduction neutralization testing (PRNT). Because WNV IgM antibodies can cross-react with other flaviviruses, PRNT can help distinguish WNV from other flaviviruses.

The recent cases of WNV detected in people, animals and mosquitoes highlight the importance of preventing mosquito bites. Some effective ways to do this include:

- Eliminating all sources of standing water, including flowerpots, buckets, pool covers, birdbaths, old car tires, rain gutters, and pet bowls.
- Using repellents to keep mosquitoes from biting. Apply insect repellent containing DEET, picaridin, oil of lemon eucalyptus, IR3535, or 2-undecanone according to label instructions.
- Wearing light-colored clothing to cover skin reduces the risk of bites, especially during the hours of dusk, dawn, and twilight.
- Ensuring doors and windows have tight-fitting screens to keep mosquitoes out of homes and buildings.

For more information about West Nile virus and mosquito control in South Carolina, please visit scdhec.gov/mosquitoes.

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