EYE BANK ASSOCIATION OF AMERICA

February 23, 2021

THE FOCAL POINT

ADVOCACY & LEGISLATIVE UPDATE

Organ Transplant Patient Dies After Receiving COVID-Infected Lungs

The first confirmed U.S. case of SARS-CoV-2 being transmitted through an organ transplant was described in the *American Journal of Transplantation*. The virus was transmitted when lungs from a woman from the Upper Midwest, who died after suffering a severe brain injury in a car accident, were transplanted into a woman with chronic obstructive lung disease at University Hospital in Ann Arbor. The donor had no clinical history or findings suggestive of infection with SARS-CoV-2 and tested negative by reverse transcriptase polymerase chain reaction (RT-PCR) on a nasopharyngeal (NP) swab obtained within 48 hours of procurement. Lower respiratory tract testing was not performed.

The recipient tested negative for COVID-19 several hours before the transplant procedure. Three days after the surgery, the patient developed fever, hypotension, and pulmonary infiltrates. Doctors decided to test samples collected from the patient's nose and throat as well as her lower respiratory system for COVID-19 after she developed septic shock and heart function problems. The NP swab specimen was non-reactive, but positive on bronchoalveolar lavage (BAL) fluid from her new lungs. She deteriorated rapidly, developing multisystem organ failure, and died 61 days after the transplant.

Suspicious about the origin of the infection, doctors returned to samples from the transplant donor. A sample of fluid washed from deep within the donor lungs was positive for the virus. Four days after the transplant, the thoracic surgeon who handled the donor lungs and performed the surgery tested positive, too. Genetic analysis revealed that the transplant recipient and the surgeon had been infected by the donor. No other organs were procured from this donor.

The incident appears to be isolated — the only confirmed case among nearly 40,000 transplants in 2020. Researchers concluded that transplant centers and organ procurement organizations should perform SARS-CoV-2 testing of lower respiratory tract specimens from potential lung donors, and consider enhanced personal protective equipment for health care workers involved in lung procurement and transplantation.

While the Michigan case marks the first confirmed incident in the U.S. of transmission through a transplant, others have been suspected. A recent Centers for Disease Control and Prevention report reviewed eight possible cases of what's known as donor-derived infection

that occurred last spring, but concluded the most likely source of transmission of the COVID-19 virus in those cases was in a community or health care setting.

Eye Nodules Found In 7% Of Small COVID-19 Patient Cohort

Almost 7% of hospitalized COVID-19 patients in France had abnormal eye nodules, according to a *Radiology* article, leading the authors to recommend looking for posterior pole nodules in patients who have severe disease.

The French Society of Neuroradiology study ran from Mar 4 to May 1, 2020, and researchers looked at 129 patients across 16 hospitals who had severe COVID-19 and underwent a brain MRI. Nine showed abnormal nodules in the posterior pole of the eyeball, although two people also had them outside of the macular region as well. Bilateral nodules were found in 8 of 9 people. No patient had optic nerve, chiasm, or tract abnormalities.

These nodules were not visible in the 3 patients who underwent ophthalmological examination. This might be due to the difficulty of giving an exam to a patient with severe COVID-19 or because of the delay between MRI and the ophthalmological examination.

While the study did not test for causality or risk factors, the researchers noted that 8 of 9 patients with eye nodules spent time in the intensive care unit and had to be intubated, with 7 of them staying in the prone position, 1 needing extracorporeal membrane oxygenation, and 3 needing dialysis.

The authors suggest that physicians begin routinely performing ocular examinations such as via MRI, fundoscopy, or optical coherence tomography on severe COVID-19 patients to look for posterior pole nodules, as they could later develop into adverse outcomes.

COVID-19 Response Team Warns of Rise in Variants

At least 1,549 cases of coronavirus strains first spotted in the UK, South Africa and Brazil have been reported in the United States, according to data updated Thursday by the CDC. The vast majority of these cases are the more contagious variant which was originally detected in the UK. This B.1.17 variant has been found in 41 states and Washington, DC. More than a quarter are in Florida. Recent research in the U.K. suggests the variant is not only 30 to 70 percent more transmissible, but also results in more COVID-19 hospitalizations and deaths.

In addition, there are 21 total cases of the B.1.351 (South African) variant, in nine states and Washington, DC and five total cases of the P1 (Brazilian) variant have been discovered among four states. CDC says this does not represent the total number of such cases circulating in the US but rather just those that have been found by analyzing positive samples.

Both the Pfizer-BioNTech and Moderna COVID-19 vaccines appear to be highly effective against the more transmissible B.1.1.7 variant of the virus, according to newly published studies in the *New England Journal of Medicine*. The vaccines, however, showed a decreased ability to neutralize the B.1.351 strain, worrying some researchers and prompting Pfizer and BioNTech to announce they were taking necessary steps to develop a booster shot or updated vaccine.

US Reaches 500,000 Coronavirus Deaths

A year into the pandemic, the U.S. death toll from the coronavirus topped 500,000 — a grim milestone reflecting how COVID-19 has ravaged the U.S. far worse than any other country. About 19% of total global coronavirus deaths have occurred in the United States, an outsized figure given that the nation accounts for just 4% of the world's population. And the *New York Times* pointed out the death toll means 1 in 670 Americans have died from the virus.

COVID-19 deaths have also surpassed the number of Americans killed during the Civil War (498,332); World Wars I and II (116,516 and 405,399, respectively); and all American wars since 1945 *combined*, — Korea (54,246), Vietnam (90,220); and Desert Storm/Desert Shield (1,948) — Department of Veterans Affairs records show.

The grim milestone was marked by a candle-lighting ceremony and moment of silence at the White House on Monday. But there is reason to hope - - new virus cases are down sharply, hospital admission rates have fallen for 40 straight days, deaths are slowing and approximately 1.6 million vaccinations are administered to Americans daily.

First COVID Vaccine Dose Lowers Disease Risk 30% to 75%

A single dose of the Pfizer/BioNTech COVID vaccine was associated with a 30% to 75% COVID rate reduction in healthcare workers (HCWs) during the first month, with an even higher reduction in symptomatic infection, according to a retrospective cohort study of 9,109 Israeli healthcare workers published in *The Lancet*.

Overall, there were 170 SARS-CoV-2 infections among HCWs in the period between Dec 19, 2020, and Jan 24, 2021, of which 99 (58%) HCWs reported symptoms and were designated as COVID-19 cases. Of the 170 HCWs who became infected, 89 (52%) were unvaccinated, 78 (46%) tested positive after the first dose, and three (2%) tested positive after the second dose. Among the 125 infections that could be traced, 87 (70%) were community acquired and there were no nosocomial clusters.

After adjusting for community spread, the infection rate reductions after the first dose were 30% (95% CI 2–50) and 75% (72–84) for days 1–14 and days 15–28 post vaccination, respectively.

Symptomatic infection rate reductions were even higher, with a 47% reduction observed during days 1 to 14 post vaccination and an 85% reduction seen in days 15 to 28 after the first dose (95% CI, 17 to 66 and 71 to 92, respectively).

US Seizes Millions of Counterfeit N95 Masks

The Department of Homeland Security has seized more than 11 million counterfeit N95 masks meant for front-line workers in recent weeks, including more than 1 million on Wednesday.

The fake masks closely resemble N95 masks produced by Minnesota-based company 3M, but there is no guarantee they provide the same protection as masks approved by the National Institute for Occupational Safety and Health (NIOSH).

Authentic N95 masks have an approval number, which is preceded by the letters TC, as well as a labeled model number and possibly a lot number. Valid masks also feature the NIOSH logo or the name of the agency in block letters and the brand name, registered trademark, or abbreviated name of the business holding approval for the mask. It will also have headbands, not ear loops, to secure the mask to the user's face.

A clear sign of a counterfeit mask is the presence of an FDA logo or mention of a Food and Drug Administration approval or registration; the FDA does not regulate face masks, only NIOSH does. And NIOSH does not approve face masks for children — so if there is any mention of child safety, that is another sign of a bogus mask.

Here's how to spot an authentic N95 and the 3M Notification and Guidance on Fraudulent Surgical Masks.

New Face Mask Standards Will Take the Guesswork Out of Choosing the Most Effective Mask

ASTM International -- an international standards organization -- published its guidance entitled "Standard Specification for Barrier Face Coverings." The new national mask standard outlines minimum fit, design, performance and testing requirements for face masks and would require user instructions, package labeling and a permanent tag on the product.

To meet ASTM standards, manufacturers are required to test their facial coverings in accredited labs to certify performance, register their products and use the outlined ASTM labeling system on their products. The standard has been created to evaluate only consumer masks. These new standards do not apply to medical masks and respirators used in healthcare settings.

ASTM tests for whether a mask can filter out particles measuring 0.3 microns. If a mask can handle these tiny particles, it can stop droplets most likely to carry viruses and bacteria.

The ASTM labeling requirements involve results of two testing criteria: breathability and filtration efficiency.

- **A level one mask** would require the product to filter 20% of particles -- something that would make the mask easy to breathe through, but that would provide minimal protection.
- **A level two mask** would require "high performance" filtration of at least 50% of particles but would provide less breathability.

How quickly consumers will see ASTM-labeled masks on store shelves may come down to whether OSHA will use the ASTM testing procedure to create a higher level of protection for workers in non-medical environments with less exposure that may not require an N95 mask.

Please click the links below to learn about the latest updates:

COVID-19 Science Update released: February 19, 2021 Edition 77

COVID Data Tracker Weekly Review

Interim Guidance on Testing Healthcare Personnel for SARS-CoV-2 -

Criteria for Return to Work for Healthcare Personnel with Confirmed or Suspected COVID-19 (Interim Guidance)

First Identified Cases of SARS-CoV-2 Variant B.1.1.7 in Minnesota — December 2020–January 2021

Detection of B.1.351 SARS-CoV-2 Variant Strain — Zambia, December 2020

SARS-CoV-2 Variants of Concern in the United States—Challenges and Opportunities

Reports of Anaphylaxis After Receipt of mRNA COVID-19 Vaccines in the US—December 14, 2020-January 18, 2021

Clusters of SARS-CoV-2 Infection Among Elementary School Educators and Students in One School District — Georgia, December 2020–January 2021

Identifying COVID-19 Risk Through Observational Studies to Inform Control Measures

Regulatory Updates

FDA Issues Policies to Guide Medical Product Developers Addressing Virus Variants

FDA issued guidances for vaccine, drug and diagnostic test developers to address the impact of COVID-19 variants on the efficacy and performance of their products. Several variants of the SARS-CoV-2 virus, including those first identified in the United Kingdom (B.1.1.7), South Africa (B.1.351) and Brazil (B.1.1.28), have raised international concern as they appear to be more transmissible and may diminish the efficacy of certain treatments or vaccines. FDA has also warned that some genetic variants of the virus may confound the results of molecular tests, potentially leading to false negatives.

FDA updated its October 2020 guidance, Emergency Use Authorization for Vaccines to Prevent COVID-19, to provide recommendations to vaccine developers, including those who have already received emergency use authorization (EUA) for their COVID-19 vaccines and are seeking to amend their EUA to address new variants.

The FDA issued a new guidance for test developers, Policy for Evaluating Impact of Viral Mutations on COVID-19 Tests. The guidance provides specific recommendations for evaluating the impact of viral mutations on molecular diagnostics, antigen tests and serology tests and explains that FDA is considering including a condition of authorization for test developers in EUAs that would require them to evaluate the impact of virus mutations on test performance.

To address the impact of emerging variants of SARS-CoV-2 on the development of monoclonal antibody products targeting the virus, the FDA has issued a new

guidance, Development of Monoclonal Antibody Products Targeting SARS-CoV-2, Including Addressing the Impact of Emerging Variants, During the COVID-19 Public Health Emergency.

FDA has also revised a second guidance covering drugs and biological products more broadly for COVID-19, COVID-19: Developing Drugs and Biological Products for Treatment or Prevention.

Pacific Stem Cells LCC Receives Untitled Letter

FDA issued an untitled letter to Pacific Stem Cells LLC, (Newport Beach, CA) for marketing unlicensed "stem cell therapy" products derived from umbilical cord and placental tissues to treat a wide variety of medical conditions including stroke, macular degeneration, Lyme disease, Parkinson's disease, heart disease, lupus, rheumatoid arthritis, and multiple sclerosis. Pacific Stem Cells appears to administer the products by various routes, including intraorally and intravenously.

FDA Approves First-in-World 3D Printed Bone Replacement

The FDA has issued a first-in-world approval for a customized 3D-printed bone replacement for humanitarian use. The Patient Specific Talus Spacer is designed to replace the talus bone, which sits at the top of the foot and forms part of the ankle joint, in patients with avascular necrosis (AVN) of the ankle. The implant provides a joint-sparing alternative to other surgical interventions commonly used in late-stage AVN that may disable motion of the ankle joint.

Russia Reports World's First Case of Human Infection with H5N8 Bird Flu

Russia has reported cases of the first known H5N8 avian flu infection in humans to the World Health Organization (WHO). Seven workers at a poultry plant in Russia's south had been infected with the H5N8 strain in an outbreak at the plant in December, with no onward transmission reported.