The Focal Point: Advocacy & Legislative Update

June 9, 2020

COVID-19 Update

The global number of COVID-19 cases has reached 7 million with 407,009 deaths, according to the Johns Hopkins online dashboard. In the United States, there have been 1,961,187 confirmed cases of COVID-19 and 111,007 deaths.

Shutdown orders prevented about 60 million novel coronavirus infections in the United States and 285 million in China, according to a research study published in Nature that examined how stay-at-home orders and other restrictions limited the spread of the contagion.

As businesses across the country reopen and communities emerge from lockdowns, APIC has released a factsheet on how to stay safe from COVID-19, including basics to keep in mind while in public or at work.

At least 586 U.S. front-line healthcare workers have died of COVID-19, according to a new count published June 6 by *The Guardian* and *Kaiser Health News*. The number is part of the news sites' "Lost on the Frontline" project, which includes physicians, nurses and paramedics, as well as hospital janitors, administrators, nursing home workers and other healthcare support staff who were potentially exposed while caring for or supporting infected patients.

Study Suggests that COVID-19 Tests Miss a Significant Number of Cases

A team from Johns Hopkins Medicine has found that PCR-based tests for SARS-CoV-2 have a false negative rate of at least 20%, depending on the time of testing. Researchers analyzed seven studies that included data on 1,330 patient samples that used a RT-PCR based test and also reported the time since symptom onset or SARS-CoV-2 exposure. Their analysis found that the likelihood of a false negative result varied depending on the time since infection.

Over the 4 days of infection before the typical time of symptom onset (day 5), the probability of a false-negative result in an infected person decreases from 100% on day 1 to 67% on day 4. On the day of symptom onset, the median false-negative rate was 38%.

8 days following exposure, which is approximately 3 days following the onset of symptoms, is the optimal time for testing, although 20% of people will still have a false negative result. By 3 weeks postexposure, the chance of a false negative result reaches 66%.

If clinical suspicion is high, infection should not be ruled out on the basis of RT-PCR alone, and the clinical and epidemiologic situation should be carefully considered.

Physical Distancing, Masks Reduce Spread of COVID-19

A systematic review of 172 studies on coronavirus transmission found that physical distancing and use of face masks and eye protection are the best ways to reduce the risk of COVID-19. The findings, published in The Lancet, showed good hygiene and regular hand-washing are also critical in preventing SARS, MERS, and COVID-19.

The findings showed a reduction in risk of 82% with a physical distance of 1 m in both health-care and community settings (adjusted odds ratio [aOR] 0·18, 95% CI 0·09–0·38). Every additional 1 m of separation more than doubled the relative protection, with data available up to 3 m. This evidence supports community physical distancing guidelines.

Chu and colleagues reported that masks and respirators reduced the risk of infection by 85% (aOR 0·15, 95% CI 0·07–0·34), with greater effectiveness in healthcare settings (RR 0·30, 95% CI 0·22–0·41) than in the community (0·56, 0·40–0·79; p=0·049). They attribute this difference to the predominant use of N95 respirators in health-care settings which were 96% effective compared with other masks, which were 77% effective.

The other important finding for health workers was that eye protection resulted in a 78% reduction in infection (aOR 0·22, 95% CI 0·12–0·39). Infection via the ocular route might occur by aerosol transmission or self-inoculation.

No one intervention is completely protective and that combinations of physical distancing, face mask use, eye protection and hand hygiene are needed to mitigate the COVID-19 pandemic until we have an effective vaccine.

WHO Updates Guidance on Masks

The World Health Organization (WHO) updated its mask guidance, urging countries with widespread transmission to encourage mask use in situations where physical distancing is not possible.

The new guidance recommends that the general public wear cloth masks made from at least three layers of fabric on public transport, in shops, or in other confined or crowded environments. It also says people over 60 or with preexisting conditions should wear medical masks in areas where there's community transmission of the coronavirus and physical distancing is impossible, and that all workers in clinical settings should wear medical masks, not only workers dealing with COVID-19 patients.

The WHO now recommends that cloth masks should be made of three layers – with cotton closest to the face, followed by a polypropylene layer and then a synthetic layer that is fluid-resistant.

CDC Updates COVID-19 Transmission Webpage to Clarify Information about Types of Spread

The CDC has once again edited their webpage on COVID-19 transmission to provide clarity on how coronavirus spreads.

The primary and most important mode of transmission for COVID-19 is through close contact from person-to-person. Based on data from lab studies on COVID-19 and what we know about similar respiratory diseases, it may be possible that a person can get COVID-19 by touching a surface or object that has the virus on it and then touching their own mouth, nose, or possibly their eyes, but this isn't thought to be the main way the virus spreads.

Evidence Suggests Community Spread of COVID-19 Was Earlier Than Thought

Four separate lines of evidence (syndromic surveillance, virus surveillance, phylogenetic analysis, and retrospectively identified cases) suggest that limited U.S. community transmission likely began in late January or early February 2020, after a single importation from China, followed by multiple importations from Europe. Until late February, COVID-19 incidence was too low to be detected by emergency department syndromic surveillance for COVID-19–like illness.

The first U.S. cases of nontravel–related COVID-19 were confirmed on February 26 and 28, 2020, suggesting that community transmission was occurring by late February.

FDA Explains Different Types of COVID-19 Tests

FDA issued a new video resource explaining the different categories of tests in the fight against COVID-19: diagnostic tests and antibody tests. Diagnostic tests, which include molecular and antigen tests can tell if the tested person currently is infected. Antibody or serology tests detect if the person's blood contains antibodies to coronavirus, which indicate the person has been previously infected with the virus. Antibody tests do not detect whether a person is currently infected and should not be used to diagnose a current COVID-19 infection.

HHS Announces New Laboratory Data Reporting Guidance for COVID-19 Testing

Following concerns about a lack of demographic data for COVID-19 testing, HHS announced it will require laboratories to report the age, race, ethnicity, gender, ZIP code and type of test performed when reporting testing data to state and local public health departments and the CDC as soon as possible, but no later than August 1, 2020.

The new reporting requirements will provide information needed to better monitor disease incidence and trends by initiating epidemiologic case investigations, assisting with contact tracing, assessing availability and use of testing resources, and anticipating potential supply chain issues. Admiral Brett Giroir, assistant secretary for health, said the additional information will help "ensure that there is equitable access, especially for underserved minorities."

FDA Warns About Transport Media Safety Risk

FDA issued a letter to clinical laboratory staff and health care providers about a safety risk with using transport media and SARS-CoV-2 testing platforms that are not compatible. There is a risk of exposure to harmful cyanide gas when certain transport media are used with an incompatible testing platform or laboratory process that uses bleach.

FDA Explains How Pandemic Will Affect Reviews and Meetings

The FDA issued a guidance document entitled "Effects of the COVID-19 Public Health Emergency on Formal Meetings and User Fee Applications" to provide answers to frequently asked questions concerning requests for formal meetings with industry, user fee applications goals and timelines, and prioritization of drug and biological application reviews during the public health emergency.

The agency said all meetings will be held through teleconference or videoconference during the public health emergency and all of its resources will be focused on submissions and applications related to COVID-19 and other life-threatening illnesses.

FDA notes that it will still aim to conduct initial investigational new drug application (IND) 30-day safety reviews and respond to "other important safety issues that may emerge during IND development." FDA also explains that it will communicate directly with sponsors or applicants if it anticipates missing a goal date.

FDA Guidance Revises IRB Review Procedure in Response to COVID-19

FDA issued a new guidance that establishes procedures for single institutional review board (IRB) member review of individual patient expanded access requests for investigational drugs and biologic products to treat COVID-19. This is in response to physician requests for a waiver from the requirement for full IRB review.

The guidance also addresses considerations when assessing benefits and risks for a particular patient being treated under expanded access. The guidance applies only to expanded access requests on behalf of individual patients.

FDA Provides Free Method to Obtain Informed Consent Electronically for COVID-19 Clinical Trials

FDA is making its previously developed FDA MyStudies app available to investigators as a free platform to obtain informed consent securely from patients for eligible clinical trials when face-to-face contact is not possible due to the COVID-19 pandemic.

The app – released as "COVID MyStudies" – allows investigators to electronically send informed consent documents to patients or legally authorized representatives. Once a patient or representative has signed the form, they will receive an electronic copy. The investigator can then access the signed consent in a secure manner and print it or transfer the file electronically.

The app is available in the Google Play and Apple App stores. Investigators interested in using the app should contact the CDER Real-World Evidence Program and reference their pre-IND or IND numbers if applicable.

WHO's Updated Event Guidelines

The World Health Organization has released an update of its recommended guidelines for holding mass gatherings amid COVID-19. The new document offers suggestions for risk assessment, planning, and other high-level considerations for holding an event in the current climate.

The document considers event plans from two frames—when to assess potentially holding an event and what to do to prevent the spread of disease at the event. WHO recommends reading the new document in tandem with its older publication, *Public Health for Mass Gatherings: Key Considerations*, an in-depth work with specific recommendations for holding different types of events.

Operation Warp Speed Names 5 COVID-19 Vaccine Candidates

The Trump administration has selected five coronavirus vaccine candidates as the most likely to produce a viable vaccine in a record-breaking timeframe.

The five vaccines include Moderna's mRNA1273, currently in phase 2 trials; AstraZeneca and Oxford University's AZD1222, now in clinical trials at multiple UK sites; a candidate from Johnson & Johnson; a Merck vaccine based on that company's successful Ebola vaccine; and Pfizer and BioNTech's BNT162.

The accelerated programs are funded through $10 billion from Congress and $3 billion directed for National Institutes of Health (NIH) research. The firms will receive additional government funding and clinical trial support as well as financial and logistical assistance for scaling up manufacturing.

FDA MSM Policy Precludes Potential Cornea Donations

An FDA policy that automatically disqualifies men who have had sex with men (MSM) in the preceding five years from donating corneas cost eye banks an estimated 1,600 donated corneas in 2018, according to an analysis presented at the virtual Association for Research in Vision and Ophthalmology meeting.

Puente and colleagues called all 57 eye banks in the United States and all eight eye banks in Canada. Each eye bank was asked if it kept records of potential donors disqualified specifically due to MSM status, and if so, how many were disqualified in 2018 due to MSM status. Of the 24 eye banks with records, a reported 360 potential donors were turned away due to MSM status, equaling 720 corneas. These eye banks were responsible for more than 46.2% of all corneas recovered in the U.S. and Canada in 2018, which yields an estimate of 1,600 corneas disqualified in 2018.

Current HIV tests administered to all potential donors are more accurate and have a shorter window than tests available when the FDA policy was made in 1994. Two mandatory HIV antibody tests for donors have 20- to 25-day window periods, but the mandatory HIV nucleic acid test has a window of 4 to 8 days.

Stay Up to Date with ISBT 128

Version 7.37.0 of the ISBT 128 Product Description Code Database is now available to licensed facilities. All database updates are listed in the version control sheet. Download the new database and version control sheet here. The Standard Terminology for Medical Products of Human Origin v7.37 document provides definitions to all ISBT 128 terminology. The document should be used in conjunction with the ISBT 128 Product Description Code Database.

The new codes can also be found using the online Product Lookup Program. The program can also be used to submit requests for new codes if the combinations of Class, Modifier, and Attributes being searched for do not already exist.

The new IG-028 Use of ISBT 128 by North American Tissue Banks v1.4.0 has been published on the ICCBBA website.

Trump Announces U.S. Withdrawal from the World Health Organization

President Donald Trump announced that the U.S. will terminate its relationship with the World Health Organization (WHO), which he publicly blames for not being tougher on China in the early days of the COVID-19 pandemic. It's not immediately clear whether the president can fully withdraw U.S. funding for the WHO without an act of Congress, which typically controls all federal government spending. The United States has provided roughly 15% of the WHO's total funding over its current two-year budget period

Experts say that the move will deeply hurt world-wide public health efforts to detect and respond to disease threats beyond the pandemic. The U.S. has relied on its partnership with the WHO and other countries to share crucial data and information, including on treatments and potential vaccine development for the coronavirus, as well as other public health threats including HIV and Ebola.

Meanwhile, WHO launched the COVID-19 Technology Access Pool, which aims to provide greater access to medications, vaccines and diagnostics being developed for COVID-19 through voluntary, non-exclusive licensing arrangements.

DRC Detects New Ebola Outbreak

Health officials in the Democratic Republic of the Congo (DRC) reported a new outbreak of Ebola virus disease (EVD) in Mbandaka in the western Equateur province. The Health Ministry reported eight cases have been detected, four of whom have died.

The latest person confirmed with Ebola attended the burial of one of the first cases, but was detected in the town of Bikoro, 150 kilometers away from Mbandaka.

Congo has yet to declare an official end to Ebola in Eastern DRC, where at least 2,243 people have died since an epidemic began there in August 2018. The last known patient there was released in mid-May, but the country now must go about another month without any new cases before a declaration can be made.

FDA Warns North Coast Biologics for Marketing COVID-19 Vaccine

The FDA and Federal Trade Commission (FTC) warned Seattle-based firm North Coast Biologics for marketing an unapproved vaccine for COVID-19. The warning letter cites statements made on the company's website, Facebook page and their president's Facebook and LinkedIn pages.

The warning letter comes nearly a month after Washington Attorney General Bob Ferguson sent a cease and desist letter to North Coast Biologics President Johnny Stine ordering him to "immediately stop making misrepresentations" about the vaccine.

FDA notes that on 28 April North Coast Biologics' Facebook page was updated to say its vaccine "is no longer available due to a 'cease and desist' letter from the AG" but says that other claims still online at the time necessitated the warning letter. Due to the serious public health concerns related to the marketing and sale of unapproved drugs for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19, it is essential that you do not resume selling your product for prevention of COVID-19.

FDA requested a reply to the warning letter within 48 hours describing the steps taken to address the violations cited in the letter. Failure to immediately correct the violations cited in this letter may result in legal action, including, without limitation, seizure, and injunction.

Altaire Pharmaceuticals Cited for Environmental and Data Integrity Issues

The FDA has warned a New York based pharmaceutical company for data falsification and failing to establish adequate monitoring in aseptic processing areas. The firm, Altaire Pharmaceuticals, manufactures sterile ophthalmic drug products, as well as over the counter ophthalmic and homoeopathic products.

In its warning letter dated 12 March 2020, the FDA detailed findings from a 2019 inspection, where inspectors found that the firm failed to open investigations when plates taken from ISO 5 areas had growth that exceeded action limits.

Although post-activity personnel monitoring had lapsed for up to a year, technicians continued to record results of zero growth on report forms. Personnel monitoring samples are critical because they indicate whether or not personnel in the aseptic processing environment are adversely affecting quality.

Additionally, Altaire was cited for falsifying laboratory data used in making batch release decisions. Samples observed to be turbid were not tested for sterility, and the firm's commitment to have outside finished product sterility testing done for completed batches would not necessarily establish the sterility of all finished units, since distribution of contamination is usually non-uniform.

Gowning and gloving procedures were also observed to be inadequate during aseptic operations, where FDA inspectors also observed operators with exposed skin. Media fill batch records were also found inadequate. Finally, FDA noted that equipment on Altaire's filling line had aluminum foil and duct tape attached to its hopper.

The FDA asked the firm to provide a comprehensive response with the assistance of a qualified outside consultant to develop a current good manufacturing practice compliant data integrity program. The agency asked for a full investigation including retrospective analysis of data records and reporting, personnel interviews, as well as a risk assessment and management strategy.

FDA acknowledged that after the inspection Altaire ceased operations for some of its drug products and initiated a recall in June 2019.

President Signs PPP Loan Flexibility Legislation into Law

President Trump signed the Paycheck Protection Program Flexibility Act into law. The legislation passed the Senate earlier this week by unanimous consent and was passed by the House last week by a vote of 417 to 1 on May 28.

The bill extends the forgiveness period for Paycheck Protection Program (PPP) loans from eight to 24 weeks, reduces payroll spending requirements from 75% of loan funds to 60% of loan funds, and extends the June 30th deadline for rehiring workers to the end of this year. Businesses now have up to five years, instead of two years, to repay any money owed on a loan.

EBAA Statement on the Killing of George Floyd

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The Eye Bank Association of America (EBAA) shares the anguish and suffering of America's Black community and communities of color, not only for the death of George Floyd, but for the racism and discrimination within our society that precipitated his killing. These attitudes are contrary to the American ideal and the standards and culture of eye banking.

EBAA's Medical Standards stipulate that access to donor ocular tissue for transplantation and sight restoration shall be provided "without regard to a recipient's sex, age, religion, race, creed, color or national origin." But to fully embrace our mission to restore sight worldwide, we must move beyond not discriminating against others; we must reject and oppose those who do. Through our words and actions as a community that serves all people, we make it clear that there is no place for racism or injustice in our society.

"Injustice anywhere is a threat to justice everywhere."
Rev. Martin Luther King, Jr.

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