ED CLIPS!

A Deeper Dive into the Science: COVID-19 Updates from Concerned Physicians, Elucidation of Pathology, and Initiation of Clinical Trials for Experimental Treatment

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Coronaviruses cause upper respiratory tract infections indistinguishable from the common cold throughout the world in all age groups, leading to work and school absence, physician visits, and inappropriate antibiotic use. However, the emergence of novel coronaviruses—such as COVID-19 (or SARS-CoV-2), MERS-CoV, and SARS-CoV—has led to more severe respiratory infections with a limited understanding of the pathology in infected patients. The COVID-19 pandemic has exceeded the threshold for containment and is posing a real, and rapidly growing, threat.

Is it time to panic? No. The information in this article is intended to help school administrators and educators understand the facts and the realistic implications related to the COVID-19 pandemic. The threat is real, and the leaders of this nation are coming to realize that we need to face this threat together with all our resources.

What will be the impact on our healthcare system?

On Wednesday, March 18, 2020, President Donald Trump announced the invocation of the Defense Production Act to mobilize the private production capacity of the United States to address the shortage of medical supplies needed to combat the coronavirus outbreak. The Defense Production Act was enacted in 1950, which enables the president to compel American businesses to produce materials for national defense, such as ventilators and medical supplies for healthcare workers. Senate Minority Leader Chuck Schumer stated Wednesday morning on the Senate floor, "It is used in times of war, but we must mobilize as if it were a time of war when it comes to hospital beds, supplies and equipment."

Physicians and other healthcare staff are on the front lines of this pandemic, and the healthcare system in the United States, as it currently stands, is not sufficiently equipped to handle the impending exponential growth of infectious cases over such a short timeframe. In other parts of the globe, such as Italy, healthcare systems have already buckled under this strain. The readiness and effectiveness of our healthcare system to respond to the sudden onslaught of severe respiratory illness is at stake.

Hospitals are creating contingency plans for when there is a shortage of appropriate medical supplies for protection and assessing staffing models to ensure there are enough physicians and healthcare staff to cover the anticipated surge volume. Because of this, major medical centers across the country are cancelling elective medical cases and procedures to increase the availability

of hospital beds for the patients who need them. Healthcare systems are evaluating whether there are enough intensive care unit beds, ventilators, other mechanical devices, and medications. Some hospitals already had to utilize the most extreme methods to oxygenate lungs of infected patients when the most aggressive ventilator settings fail, and in some cases even these measures have proved unsuccessful as the virus causes viral cardiomyopathy and lethal arrhythmias.

Who is at risk?

The short answer? Everyone. While as individuals, we are naturally concerned about the personal risk to ourselves and our loved ones, physicians are most concerned about the systemic risk. As school administrators and educators, you understand this level of concern and can empathize with those who provide care for the greater community. Our healthcare system, like all complex systems, functions because all the moving parts align and interact cohesively such that the system functions under normal loads, lower-than-normal loads, and slightly higher-than-normal loads. However, we can anticipate that this system may break down under the very high loads physicians and healthcare staff foresee with COVID-19.

Healthcare providers, by the dozens, have fallen ill with COVID-19, and even more have been quarantined after exposure to the virus. This development was expected, but nevertheless worrisome, as the healthcare system prepares for the anticipated surge of infections. Liam Yore, Board Member of the Washington State Chapter of the American College of Emergency Physicians, stated, “The risk to our healthcare workers is one of the greatest vulnerabilities of our healthcare system in an epidemic like this. Most ERs and healthcare systems are [already] running at capacity in normal times.”

However, gauging exactly how badly our healthcare providers have been hit has been a challenge because no nationwide data has been released by the Centers for Disease Control and Prevention, medical associations, or healthcare worker unions. In previous outbreaks of infectious disease, healthcare providers have experienced a disproportionate share of infections, leading them to worry about their protection against COVID-19. Not only do they experience increased risk of exposure due to the nature of their work, but also by shortages of personal protective equipment, such as N95 respirators and surgical masks.

Bonnie Castillo, Head of National Nurses United, the largest nurses’ union with 150,000 members, implicated that the shortage of protective equipment is the most critical issue for healthcare workers. “Nurses take risks every day because they are willing to do that; they are called to do that; and they want to do that,” she said. “When you are being sent out there with one of the most highly contagious viruses without your tools and your weapons and without a coordinated plan, it is frightening.”

Various protocols and recommendations have been developed by the Centers for Disease Control and Prevention to provide guidance to healthcare professionals to reduce their risk of infection from increased exposure to viral loads. Because of the extensive and close contact with vulnerable individuals in healthcare settings, healthcare facilities have taken a conservative approach to monitoring healthcare providers to quickly identify early symptoms and prevent transmission from potentially contagious healthcare providers to patients, other healthcare providers, and visitors.

While the pathology of the novel COVID-19 has not yet been fully elucidated, Michael Osterholm, Director of the Center for Infectious Disease Research and Policy at the University of Minnesota, stated, "We now know that asymptomatic transmission likely [plays] an important role in spreading this virus." Osterholm further emphasized that asymptomatic infection "surely can fuel a pandemic like this in a way that is going to make it very difficult to control." Other experts have also concluded that people who do not display serious symptoms do still play a substantial role in the spread of the new coronavirus. Dr. William Schaffner, Professor at Vanderbilt University School of Medicine and longtime advisor to the Centers for Disease Control and Prevention, said, "Asymptomatic and mildly symptomatic transmission are a major factor in transmission for COVID-19."

In efforts to dampen transmission of the virus, President Trump announced that his administration is working with "several groups" to evaluate the accuracy and precision of self-administered SARS-CoV-2 tests in order to expand access to testing for the fast-spreading COVID-19. These groups have been tasked in determining whether "self-swab" tests are as accurate as those being performed by healthcare providers. Trump added that he is urging speedy approval from the Food and Drug Administration—however, there are no "self-swab" tests available at this time.

Although currently there are no therapeutics approved by the Food and Drug Administration to treat persons infected with COVID-19, the National Institutes of Health has begun clinical trials on the experimental drug Remdesivir. The safety and efficacy of Remdesivir is being evaluated at the University of Nebraska Medical Center, with studies being performed in hospitalized adults who have been diagnosed with COVID-19. This is the first clinical trial in the United States to evaluate an experimental treatment for COVID-19. Remdesivir has shown promise in animal models for treating Middle East Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS), which are caused by other coronaviruses. However, Dr. Anthony S. Fauci, Director of the National Institute of Allergy and Infectious Diseases and member of the U.S. Coronavirus Task Force, cautioned, "We urgently need a safe and effective treatment for COVID-19. Although Remdesivir has been administered to some patients with COVID-19, we do not have solid data to indicate it can improve clinical outcomes."

When will a vaccine be available?

On Monday, March 2, 2020, President Donald Trump held a meeting in the White House with members of the U.S. Coronavirus Task Force and pharmaceutical company leaders to discuss his Administration's response to COVID-19. When Trump pressed the executives to deliver a vaccine within a few months, Dr. Anthony Fauci, spoke up, "A vaccine that you make and start testing in a year is not a vaccine that is deployable." Fauci added that the earliest a vaccine would be deployable is "in a year to a year-and-a-half, no matter how fast you go." At the Monday meeting, Trump said, "I like the sound of a couple months better, if I must be honest." John Shiver, the global head of vaccine research and development at the multinational pharmaceutical company Sanofi, which is developing a COVID-19 vaccine, participated in the Monday meeting with Trump. Shiver said, "There was some confusion there," and clarified to officials that testing in a human clinical trial is not the same as delivering a product. Shiver added that a timeline is difficult to predict, "knowing that a vaccine has to be both safe and efficacious because it is given to healthy

people." The development, licensure, and manufacturing a COVID-19 vaccine on a global scale within twelve months would be a revolutionary, if not unprecedented, accomplishment. No vaccine has ever been developed that quickly.

Currently, clinical trials with the National Institutes of Health are under way to evaluate an investigational vaccine for protection against COVID-19. Over the course of 6 weeks, the study will examine various doses of the experimental vaccine for its safety and ability to induce an immunological response in 45 healthy adult participants ages 18 to 55 years. The first participant received the vaccine on March 16, 2020. Currently, there are no approved vaccines to prevent SARS-CoV-2 infection, which causes COVID-19. Dr. Fauci stated, "Finding a safe and effective vaccine to prevent infection with SARS-CoV-2 is an urgent public health priority. This Phase 1 study, launched in record speed, is an important first step toward achieving that goal." These studies are crucial to the national and global response to the threat of this emergent coronavirus.

Since the containment of COVID-19 is no longer possible, mitigating the spread of the viral infection is currently our best plan of action to decrease the rate at which people will be admitted to the hospital. The Trump Administration has stated that we need to "flatten the curve." In other words, we must slow the rate of infection so that the number of people who require hospital services remains within the range that our healthcare system is capable of supplying and prevent the healthcare system from collapsing. Mitigation measures include several forms of social isolation, such as school closures, business closures, and cancellation of various events.

About the Author:

Shelly Leung is the Director of Economic Development at Powell Youngblood & Taylor, LLP and oversees the daily operations of our transactions related to the Texas Economic Development Act (Texas Tax Code § 313). Shelly joined the Firm in 2016 as a Paralegal after having relocated from her home state of Michigan. She earned both her Bachelor of Science and Master of Science degrees from the University of Michigan, Ann Arbor. During her tenure as a doctoral candidate, Shelly studied the mechanisms of action for nanoemulsion-based vaccines. After deciding to switch professions, Shelly delved into the legal world and gained much of her invaluable experience working in Immigration law and Intellectual Property law. But, after working as an after-school youth care provider and as a pre-school teaching assistant, as well as volunteering at Side-By-Side Kids and coaching for Science Olympiad, Shelly decided to continue her legal career in the education sector. Since joining the Firm, Shelly has earned her Paralegal certification from Huston-Tillotson University. Shelly is also an active member of the State Bar of Texas Paralegal Division, a voting member of the Capital Area Paralegals Association, and a Notary Public.

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