

Dr. Delgado COVID-19 Update 07-24-20

TREATMENT UPDATE

The National Institutes of Health is preparing to launch a “flurry” of large clinical trials to test new approaches to potentially treating Covid-19.

Among the trials: studies of antiviral monoclonal antibodies to treat Covid-19 in both hospitalized patients and patients who can be treated at home; studies of drugs to stymie the overreaction of the immune system that the agency has picked from dozens of approved treatments; and studies of blood thinners in very sick Covid-19 patients to prevent problems caused by blood clots. Those treatment studies will be on top of the work that the NIH is also doing on vaccines.

Currently, only two drugs have been shown to be effective in patients with the disease. In clinical trials, Gilead’s Remdesivir reduced the time it took patients to recover and dexamethasone, a steroid, which prolonged survival in the sickest patients in a study conducted in the U.K.

The science around both treatments and vaccines is complicated and unpredictable, and requires doing lots of different things with the knowledge that some and possibly most will fail. But the only solution, presently, is to run many studies in parallel and see what emerges.

MORE TESTING

The NIH is also trying to fix another problem: the need for better, faster Covid-19 tests, through a \$1.5 billion effort called the Rapid Acceleration of Diagnostics or RADx initiative. Their goal is to expand testing capacity so that by December 2020 approximately 2% of the U.S. population (6 million

persons) can be tested per day and receive their results more expeditiously.

Current testing technology based on the polymerase chain reaction (PCR) doesn't seem to work very well in terms of handling demand when the demand begins to accelerate rapidly. RADx has settled on a "Shark Tank"-like format where small startups audition technologies to receive NIH support. Applications have come from 600 efforts, of which 27 have entered the initial stages of approval based on promise; one is getting ready to begin efforts aimed at manufacturing scale up and clinical validation.

Expanding the capacity, throughput, speed of returning results, analytic performance, and regional placement of diagnostic technologies are urgently needed and, if successful, will contribute importantly to the current national efforts to curb the Covid-19 pandemic.

VACCINE ALLOCATION

On Tuesday, the National Academy of Medicine, tasked by top U.S. health officials, named an expert panel to develop a framework to determine who should be vaccinated first, when available doses are expected to be scarce. But that panel is ostensibly encroaching on the role of the Advisory Committee on Immunization Practices, a panel that has made recommendations on vaccination policy to the Centers for Disease Control and Prevention for decades, including drawing up the vaccination priority list during the 2009 H1N1 flu pandemic.

There is also the matter of Operation Warp Speed, the government's vaccine fast-tracking program that has claimed authority over, among other things, distribution decisions when it comes to Covid-19 vaccines. Amid so many players, public health experts are expressing concern and confusion. Who will make the final determination and how that process will unfold

becomes more muddled on a daily basis. This will likely be contentious and proceed to political theater with so many disparate factions trying to secure their allocation.

Initial supply will likely be limited to frontline workers. Additionally, most vaccines will probably be given in two-dose regimens, meaning any figure of available doses would have to be divided in half to see how many people could be vaccinated.

There is no doubt that healthcare workers will be offered vaccines first. But after that, tough decisions will have to be made about the order in which other frontline workers — which? how many? — are offered priority access to vaccines and who will follow, in what order.

Older adults are most at risk of dying if they become infected. But essential workers in food production and distribution may be at higher risk of contracting the virus. Who should move to the front of the line? Should the vaccination program prioritize people of color, who have contracted and died from Covid-19 in disproportionate numbers?

Other questions asked of the National Academy panel include what criteria should be used to set priorities for equitable allocation of vaccines — for example, how to weigh individual risk, due to age, underlying health conditions, or occupation, versus group risks posed by being in prison, being homeless or being a resident of a long-term care facility. The panel is also being asked to provide input on how to communicate vaccine priority decisions to the wider public, and how to address vaccine hesitancy, especially in high-risk populations.

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