BRIEF19

A daily review of covid-19 research and policy.

POLICY BRIEFING

United Kingdome approves Pfizer/BioNTech covid-19 vaccine.

On Wednesday, the United Kingdom became the <u>first</u> Western nation to approve a vaccine against the SARS-CoV-2 virus responsible for covid-19. Russia and China have previously approved vaccines engineered within their own countries, though robust and transparent efficacy data on these products has not been widely available.

The Pfizer/BioNTech product approved in the UK is expected to be available for use as early as next week and will be delivered in a two-injection regimen, spaced three weeks apart. The first persons to receive vaccines will be those who live or work in nursing care facilities followed by healthcare and social services workers and individuals over 80 years old. In total, nine groups have been prioritized to receive the vaccine by the UK's joint committee on vaccination and immunization. Health Secretary Matt Hancock noted that the country expected to receive 800,000 doses in the immediate future and had been able to secure a total of 40 million doses, enough to vaccinate 20 million people. Several other regulatory bodies, including those in the United States, Canada and the European Union, are currently reviewing the vaccine and its current competitors, Moderna and AstraZeneca/Oxford University.

The announcement of vaccine approval in the UK <u>raised eyebrows</u> in the Trump administration as to why the United States' Food and Drug Administration (FDA) has said they will not be able to approve a vaccine for at least another week. FDA commissioner Stephen Hahn said that his teams have been working "around the clock" to speed a vaccine to the American people as soon as possible, but also noted that they must "make sure that any vaccine meets [the FDA's] high standard of safety and efficacy."

Significant concerns have been raised throughout vaccine development that the speed of the process, and resulting product safety questions, will keep Americans from volunteering to receive the injections. Dr. Anthony Fauci recently said that the speed of the process did not reflect any corner cutting.

On Tuesday, the United States' Advisory Committee on Immunization Practices met and recommended that the first group to receive any available vaccinations in this country should be healthcare workers and those who live in nursing homes. These groups accounts for roughly 24 million out of 330 million people living in the United States. Forty million doses of vaccine are expected to be available by the end of this calendar year. Some experts believe that over 200 million doses will be available to Americans by this coming summer. 3 December 2020.

—Jordan M. Warchol, MD MPH

With compliance in mind, CDC shortens quarantine.

Due to a recent uptick in reported covid-19 cases following the Thanksgiving holiday, the Centers for Disease Control and Prevention (CDC) <u>updated</u> its quarantine recommendations this week. While still endorsing symptom monitoring for two weeks after a possible exposure, the agency has created two new options for a more abbreviated quarantine period. Those without symptoms may return to normal activities after ten days without a negative screening test, or after seven with negative testing. Despite these updates, the CDC stresses that it still believes that the fourteen day period is ideal, and <u>continues</u> to promote masking and social distancing.

This policy may also be problematic because some patients spread disease longer than 10 days after initial exposure, regardless of symptoms. Nevertheless, the reduced restrictions may help unburden the healthcare system and critical industries struggling to maintain adequate staffing and may encourage better compliance. *The CDC*. <u>4 December 2020</u>. —*Joshua Lesko*, *MD*

States to determine vaccine prioritization, not a federal plan.

The United States, and the world, appears to be on the brink of a safe and effective vaccine for the coronavirus. So far, at least three different candidates appear to <u>boast</u> an efficacy of 90 percent or greater (with the caveat being that the Oxford/AstraZeneca vaccine was only found to be that effective in a subset of test subjects who received an unexpectedly low concentration of vaccine at their first injections, owing to miscalculations that affected production).

One of the three manufacturers, Pfizer, has already <u>partnered</u> with United Airlines to establish a distribution network. To prepare for what will surely be a limited initial supply, the National Academies of Sciences, Engineering, and Medicine (NASEM) has <u>released</u> its final recommendations for a four-phased approach to mass inoculation. It is with this backdrop that Alex Azar, Secretary for the Department of Health and Human Services (HHS), <u>announced</u> that governors will have the final say as to how any approved vaccine will be prioritized within their individual states.

While there is general consensus that frontline healthcare workers and the elderly are at the highest risk for developing severe or critical covid-19 illness (and should be among the very first to receive the vaccine), the anticipated forty million doses (the number of doses expected to be available via Pfizer's pending Emergency Use Authorization request and Moderna's anticipated application) are not enough to adequately cover even these two groups.

Meanwhile, the US Centers for Disease Control and Prevention (CDC) has convened its Advisory Committee on Immunization Practices (ACIP), but is awaiting formal Food and Drug Administration (FDA) Emergency Use Authorization (EUA) approval of candidates before publishing its guidelines.

Complicating matters is the administration's Operation Warp Speed, which has announced plans to begin shipping doses within twenty-four hours of EUA finalization and the decision to divide supplies to the states based on population, rather than the number of coronavirus infections. Together, this means that fifty different distribution plans will have to quickly be established—not to mention the supporting logistical infrastructure—in order to make this rollout successful. *Various*. 30 November 2020.

—Joshua Lesko, MD

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Brief19 is a daily executive summary of covid-19-related medical research, news, and public policy. It was founded and created by frontline emergency medicine physicians with expertise in medical research critique, health policy, and public policy.