Week in Review: 8-11 September 2020

BRIEF19

A daily review of covid-19 research and policy.

POLICY BRIEFING

Supply scarcity drags mask manufacturing.

Last month the Food and Drug Administration created a list of current medical supply shortages, and there is no indication that the situation has improved since then. The list of supplies in need augments the FDA's list of medications currently in shortage, which it has maintained for years.

In a series of new interviews published in the Associated Press with hospital administrators, supply manufacturers and administration officials, there appears to be a discrepancy between the official stance and the reality on the ground. Administrators state that it is still difficult to purchase the necessary supplies, requiring continued reuse of certain materials by providers.

The limiting factor appears to be melt-blown material, used in the production of many surgical and N95 masks. While the Defense Production Act has helped some companies scale local production of the material, much of it is still exported without restriction and many companies rely on global supply chains that cannot keep up with demand.

The current thinking focuses on encouraging domestic production of both raw materials and finished products. However, hesitation from the manufacturing sector has slowed ramp-ups in production. Federal officials have not committed to buying supplies beyond 2021, leaving many companies concerned that the millions of dollars invested in new machinery, supplies and employees will need to be written off as a loss.

Such fears are not unprecedented, as many experienced exactly this scenario during and after the H1N1 pandemic. In that instance, demand for relevant products also spiked at first. Increases in supply followed but the demand for these items quickly plummeted following resolution of the emergency. Without any assurances or monetary support, it is difficult for these businesses to justify the risks that the upfront costs will not be recuperated. *11 September 2020.* *—Joshua Lesko, MD*

Draft published of proposed vaccine distribution plan.

The National Academies of Sciences, Engineering, and Medicine has just closed discussion on a draft plan for the equitable distribution of any future coronavirus vaccine. The committee that oversaw the production was assembled in July via a joint request from the National Institutes of Health (NIH) and United States Centers for Disease Control and Prevention (CDC) using lessons learned from the H1N1, Ebola, and covid-19 epidemics to create a framework for future decision-making. The four primary factors considered were risk of acquiring infection, risk of severe morbidity and mortality, risk of negative societal impact, and risk of transmitting the disease to others.

Using these principles, and during the initial period of vaccine production, when demand is certain to outpace supply, a four phase approach is recommended.

- Phase 1a: high-risk workers in healthcare facilities; first responders.
- Phase 1b: people of all ages with high-risk medical comorbidities; seniors living in congregate or overcrowded situations.
- Phase 2: critical risk (essential) workers; teachers and school staff; people of all ages with moderate-risk medical comorbidities; people in homeless shelters, group homes, or those with disabilities in recovery; incarcerated individuals and staff working in jails and prisons.
- Phase 3: young adults; children; essential workers not covered by Phase 1 or 2.
- Phase 4: anyone not previously covered.

A final draft is expected this fall with updated phase guidance, information about vaccine distribution, supply and demand, vaccine hesitancy education (i.e. addressing those among the public who are unsure about whether they wish to be vaccinated), risk communication, and global considerations. *The National Academies of Science, Engineering, and Medicine. 8 September 2020.*

—Joshua Lesko, MD

AstraZeneca halts vaccine trial due to a possible serious side effect in one patient.

Currently, there are nine vaccines undergoing large "phase III trials" for SARS-CoV-2. One of them has been temporarily halted after a woman in the United Kingdom who was enrolled in the trial, being run by the pharmaceutical company AstraZeneca, developed a rare but serious neurologic condition known as transverse myelitis. It is unclear whether the vaccine itself was responsible.

Transverse myelitis is an inflammation-based neurological problem that affects one level of the spinal cord. Its features are similar to a compression of the spinal cord at the location of the inflammation. In some cases, transverse myelitis is caused by viruses, though other neurologic conditions such as multiple sclerosis are common causes. Vaccines have been rarely reported as a cause—though it is not unheard of in the medical literature. Symptoms can be mild (pain and tingling) or quite serious (incontinence, weakness of the arms and legs, and even paraplegia). This can often occur quickly, in hours to days. Treatments include steroids like dexamethasone, which has also been shown to be effective in severe cases of covid-19. Some patients recover fully, while others have devastating and long-lasting neurologic symptoms.

AstraZeneca now has to determine whether this was a one-off event, unfortunate and unrelated, or not. It was already determined that the patient in question received the vaccine itself, and not a placebo. What happens next will depend on whether any similar events are discovered among test subjects who have received the vaccine, and how many patients have received the vaccine overall in the trial.

The numbers matter. For example, if this one event occurred among the first 100 patients in this clinical trial, this could be a very bad indicator; in that case, more events like this might soon appear, which would lead to a termination on the trial altogether. But if the event occurred once in every 100,000 patients, and the vaccine were to be found to be 99% effective in protecting against SARS-CoV-2, the risks and benefits would have to be weighed. Of course, the possibility remains that this event was entirely unrelated to the candidate vaccine.

Meanwhile, the other eight vaccines being tested in phase III trials may turn out to have fewer, the same, or more side effects than the AstraZeneca vaccine, which is based on a technology that has never before been widely used. And some of those other candidate vaccines may be more effective than others. This is why gathering the most amount of phase III data—and not rushing a vaccine via an emergency use authorization based on incomplete data—is not only good science, but a matter of public safety. *STAT News. 10 September 2020.*

—Jeremy Samuel Faust, MD MS

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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.