

BRIEF19

A daily review of covid-19 research and policy.

POLICY BRIEFING

Johnson & Johnson vaccine pause still in effect.

Earlier this week, the US Food and Drug Administration and the US Centers for Disease Control and Prevention announced a “pause” in the rollout of the Johnson & Johnson vaccine, after six women ages 20-50 in the United States developed a clotting disorder causing severe symptoms, and at least one death.

The Advisory Committee on Immunization Practices, an independent body of experts that advises the CDC, has since announced that the pause will remain in place. While the risk-benefit [analysis](#) for the Johnson & Johnson vaccine versus the risk of contracting a severe case of covid-19 seems to favor the vaccine in all adult age groups, the FDA and CDC wants to gather more information. The main reason is that there are still over 3 million people who received the vaccine who are still in the 14-day window which is thought to represent the highest risk period for the development of this rare complication. The FDA and CDC clearly want to know the rates of complications before proceeding.

More cases are likely to be reported during the pause. However, unless the numbers change by a very large amount, the risk-benefit calculation is unlikely to lean away from the Johnson & Johnson vaccine for almost any demographic, including women 20-50 in whom all of the clots have been found so far. For example, a doubling of clotting rates would not change the outcome of the risk-benefit calculation. However, if the pause allows areas that had previously expected Johnson & Johnson to scramble in order to arrange for Moderna and Pfizer/BioNtech instead (albeit, this is not so easily done, because of the extremely cold freezers that are needed and which are not-so-easily found), public health officials could try to triage the doses such that younger women are preferentially given the Moderna and Pfizer/BioNtech options, whenever possible.

However, the overall message remains the same: covid-19 is far more dangerous to all adult demographics than the rare clotting problem that appears to have emerged in 6 out of 1.4 million doses given to women ages 20-48. In fact, covid-19 itself raises the rates of blood clots, some mild, and some fatal. The rate of clots caused by covid-19 is debated, especially since we do not know how long the risk of that complication lasts. [16 April 2021](#).
—Jeremy Samuel Faust, MD MS

Medicare sequestration suspended through 2021.

President Biden signed a [law](#) on Wednesday which will suspend the 2 percent Medicare cut mandated by typical budgetary sequestration. Sequestration is the result of pay-as-you-go legislation which enforces across-the-board cuts to government spending if other savings cannot be obtained when passing new spending laws. Medicare payments to healthcare providers were exempted from this process at the beginning of the covid-19 crisis but expired two weeks ago, on April 1st. However, bipartisan agreement in the Senate late last month allowed for the continued suspension of the cuts until January 1, 2022.

Healthcare providers are expected to receive payments without the cuts backdated to the beginning of April. The House of Representatives had initially passed a similar bill which would have also suspended a 4 percent Medicare cut currently slated to go into effect next year, however this provision was not able to pass the narrowly divided Senate. It is expected that the 4 percent payment reduction will be the subject of negotiations later this year. [15 April 2021](#).

—Jordan M. Warchol, MD MPH

US approaching full vaccine eligibility.

Last week President Biden [pushed](#) the deadline for vaccinating all Americans forward, a landmark date in the ongoing struggle to overcome the pandemic. Initially set for May 1st, he has now targeted April 17th, given the success of having vaccinated one hundred and sixty million Americans along with many doses waiting to be shot into arms.

Recall that while the National Academies of Science, Engineering, and Medicine (NAEM) [published](#) their recommended eligibility schedule as the vaccine candidates were still applying for authorization, it was left to the [states](#) to determine their own distribution plans, which led to regional [inconsistencies](#) due to differing timelines.

Many states have had an accelerated plan that has allowed them to offer vaccines to everyone sixteen years and older, though such efforts have not been entirely successful. A recent report [covered](#) by *Brief19* showed that the number of doses could not keep up with the expanded pool, resulting in regional shortages that largely mitigated any progression to wider eligibility. The people who have suffered the most when this happens are the most at-risk, like those in the correctional [system](#). With supplies stretched thin, there is no clear solution about how to ensure vulnerable populations don't get left behind. *Various*. [14 April 2021](#).
—*Brief19 Policy Team*

Supreme Court blocks California's restrictions on religious gatherings in private homes.

Last Friday, in a 5-4 vote, the United States Supreme Court blocked California's restrictions on religious gatherings in private homes. This decision marks the fifth time that the Supreme Court has sided with religious adherents against California's covid-19 restrictions. California's policy limited both religious and non-religious gatherings in homes to no more than three households in an effort to limit transmission of SARS-CoV-2. A pastor and others asked the court to allow them to hold Bible study and prayer meetings in their homes without limits on the number of households that could attend.

A Ninth Circuit Court of Appeals panel had previously ruled that because the state treated secular and non-secular groups alike with respect to restrictions on home gatherings, the state restriction was constitutional. The Supreme Court's majority challenged the neutrality of these laws, writing that "regulations are not neutral and generally applicable, and therefore trigger strict scrutiny under the Free Exercise Clause (i.e. freedom to practice religion), whenever they treat any comparable secular activity more favorably than religious exercise" and that "[i]t is no answer that a State treats some comparable secular businesses or other activities as poorly as or even less favorably than the religious exercise at issue."

In her dissent, Justice Kagan (joined by Justices Breyer and Sotomayor) argued that "[i]f the State also limits all secular gatherings in homes to three households, it has complied with the First Amendment. And the State does exactly that..." Kagan noted further that California's law does not single out religious gatherings but simply treats all at-home gatherings differently than it does commercial spaces. Kagan wrote that the reason for the distinction between at-home gatherings and commercial spaces is that gatherings in private homes are riskier because of the more intimate and prolonged way people gather in them, thus raising the possibility of viral transmission.

Up until early 2021, after the arrival of Justice Amy Coney Barrett, the Supreme Court had generally (by 5-4 votes) deferred to the judgments of health departments and scientists when ruling on covid-19 restrictions. For example, prior to Justice Ruth Bader Ginsburg's death in fall 2020, the Supreme Court had allowed California and Nevada to restrict religious attendance, with Chief Justice Roberts siding with the then-four liberal justices. That pattern shifted with Barrett's arrival. Since then, the Supreme Court has also blocked New York's covid-19-related restrictions on religious services.

Many Conservatives have hailed the New York and California rulings by the Supreme Court ruling as a victory for freedom to worship. However, these wins comes amid an effort to curb viral transmission as the nation continues to expand its vaccination rollout in the midst of increasing concerns about the spread of new coronavirus variants of concern, some of which have the potential to extend this crisis even further. [13 April 2021](#).
—*Miranda Yaver, PhD*

An end to mask reuse? CDC and FDA move away from recycling guidance, as shortages end.

One of the earliest and most preventable failures of the coronavirus pandemic was the shortage of personal protective equipment (PPE). The distribution system was so convoluted that mere weeks into the pandemic, grassroots organizations were [created](#) to source and share even the most basic of supplies. Beyond competition for ready-to-ship PPE, the supply chain of materials was quickly [overwhelmed](#), leading to global scarcity. Even the US Strategic National Stockpile's [viability](#) was at times in doubt.

To combat this, significant time and resources were poured into evaluating reuse and [recycling](#) of respirators (N95 in particular). A wide range of degradation of efficacy was reported, but given masks that *mostly* worked or *no masks at all*, reuse was the least bad option available.

It seems we may have finally turned a corner on this. On Friday, the US Centers for Disease Control and Prevention (CDC) and the US Food and Drug Administration (FDA) issued joint guidance on pivoting away from strategy of crisis conservation due to increased availability of respirators. The FDA's website [emphasizes](#) acquiring more National Institute for Occupational Safety and Health (NIOSH)-approved devices, which have finally become more readily available, and reserving decontamination and reuse for crisis situations only. Similarly, the CDC's website [outlines](#) strategies for conventional, contingency, and crisis situations with regards to respirator use. *Various. 12 April 2021.*

—*Brief19 Policy Team*

Kimi Chernoby, MD, JD, Policy Section Editor.

Kane Elfman PhD, Publishing and design.

Anna Fang, Week in Review.

Jeremy Samuel Faust MD MS, Editor-in-Chief.

<http://www.brief19.com/>

Twitter: [@brief_19](#)

submissions@brief19.com

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.