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BRIEF19

A daily review of covid-19 research and policy

RESEARCH BRIEFING

Research ruminations: do we need a randomized clinical trial to prove masks are good?

A new paper by the Institute for Health Metrics and Evaluation in Seattle published in *Nature Medicine* uses mathematical and epidemiological modeling to show that universal masking (> 95 percent of the population) in conjunction with physical distancing mandates could save anywhere from 85,000 to 170,000 lives by February 2021. The methods of the paper have drawn scrutiny on social media. But it leads to a larger question:

Do we actually need a randomized clinical trial (RCT) showing the efficacy of masks in preventing or reducing the spread of SARS-CoV-2? RCTs are needed for medical interventions that are hoped or even believed might offer benefits *and* that those interventions are likely to be relatively modest in their benefits. RCTs are also needed for interventions that may report large benefits but are associated with significant adverse effects. In this way, RCTs help us either detect small benefits, or larger ones while comparing them to their potential harms.

On the other hand, there are times when RCTs are not needed. A famous illustration of this concept is parachutes. No one needs an RCT to know that parachutes save lives when used by skydivers. And in fact, a clever RCT has been devised in order to show that parachutes don't *always* save lives among people jumping out of planes (spoiler: the planes were not in the air; the devil is in the details, when it comes to RCTs). The exception proves the rule. There are some treatments that are so obviously beneficial that it would be silly to conduct an RCT. But research experts have compellingly written that most medical practices are not the equivalent of parachutes and do require RCTs to determine efficacy.

What does this have to do with masks? Using masks to prevent spread of viruses that are aerosolized or spread via droplets has "face validity," a fancy way of saying "it just makes sense." We've covered the research on masks previously in *Brief19*, and the totality of evidence-to-date (albeit there have been no high quality RCTs) suggests a benefit in preventing the spread of the SARS-CoV-2 virus. Masks are not a panacea, but they are likely to save *some* lives. They are also fairly inexpensive when compared to even the most cost-effective pharmaceuticals.

Nevertheless, some have argued that masks may somehow cause problems—for example, by encouraging people to lower their guard. Does mask wearing push people to engage in high-risk behaviors like going out more or congregating in small places, because they put too much faith in the effectiveness of masks? Cynics have made similar arguments about teaching safe sex over abstinence, the potential downfalls of prescribing pre-exposure prophylaxis to prevent HIV in high-risk groups, the use of buprenorphine versus symptomatic treatment or therapy for opioid use disorder. For the most part, none of those concerns have turned out to be warranted.

With a potential vaccine in the not-so-distant future, any life saved now is not just an inevitable covid-19 death temporarily prevented, but a life saved who may never contract covid-19 in the future.

So, do we need randomized clinical trials on the efficacy of population mask protocols? While many might say yes, I believe at this point any research on the efficacy of masks is likely not fruitful and actually just a waste of time and financial resources. If masks save even a small number of lives, they will have been worth the effort, whether or not a rigorous RCT is ever conducted.

Wear a mask. Maintain appropriate physical distance. Don't touch your face. Wash your hands. Maybe save a few lives along the way. *—Joshua Niforatos, MD*

POLICY BRIEFING

Supreme Court signals that is may uphold Affordable Care Act.

Amid rising coronavirus cases and hospitalizations, the Trump Administration argued on Tuesday, November 10th that the entirety of the Affordable Care Act (ACA), including its protections for the millions living with preexisting conditions, should be struck down as unconstitutional. This is particularly problematic now as the United States crosses 10 million coronavirus cases, such that many Americans have acquired preexisting conditions as a result of a poorly-controlled pandemic, and which could constitute grounds for insurance denial in the absence of the ACA's protections.

Stripping insurance from tens of millions of Americans during a deadly pandemic poses the additional challenge: even among those thus far not contracting coronavirus, many have had greater mental health needs amid the pandemic. Coverage for such services currently falls under the essential health benefits of the ACA.

How did the oral arguments unfold? Fortunately, the Supreme Court justices did not appear show much interest in being receptive to the arguments for its invalidation made by layers for the Trump Administration.

The case heard yesterday arose because the 2017 Tax Cuts and Jobs Act zeroed out the penalty for individuals who failed to enroll in health insurance. (The individual mandate component of the ACA was previously upheld by the Supreme Court based on Congress's power to tax). This new lawsuit, California v. Texas, hinges on two substantive questions: 1) Since the mandate penalty was upheld based on Congress's power to tax, is the a penalty-free mandate unconstitutional? And 2) If the current mandate is unconstitutional, can it be severed from the rest of the ACA, or must the entire law be struck down as unconstitutional?

During the arguments yesterday, Chief Justice John Roberts asked why there was a "bait and switch" from viewing the mandate as essential to the ACA to viewing the ACA as functional with the zeroed-out penalty. To this, Donald Verrilli, a lawyer working on behalf of Democrats in the House of Representatives responded that they had learned that the law seems to work anyway: "It turns out that carrots work without the stick." Justice Sonia Sotomayor commented that if Congress wanted the entirety of the Affordable Care Act to be struck down, they would have voted to do so but they did not, suggesting that Congress felt that the ACA could continue to exist even without the penalty in place. It was for these reasons that Justice Brett Kavanaugh commented that the case appears straightforward with respect to severability: that is, that the Court presumes that any portion of a law found to be unconstitutional is severable from the rest of the Act, rather than necessitating that the entire Act be struck down as invalid. Moreover, Chief Justice Roberts appealed to notions of judicial restraint, commenting that striking down the Affordable Care Act when Congress would not is "not our job."

While it is altogether possible that the mandate will be struck down as unconstitutional, it is likely from the oral arguments yesterday that the rest of the ACA will remain intact for the long run under a Biden presidential administration. Patients with preexisting conditions can breathe a sigh of relief

—Miranda Yaver, PhD