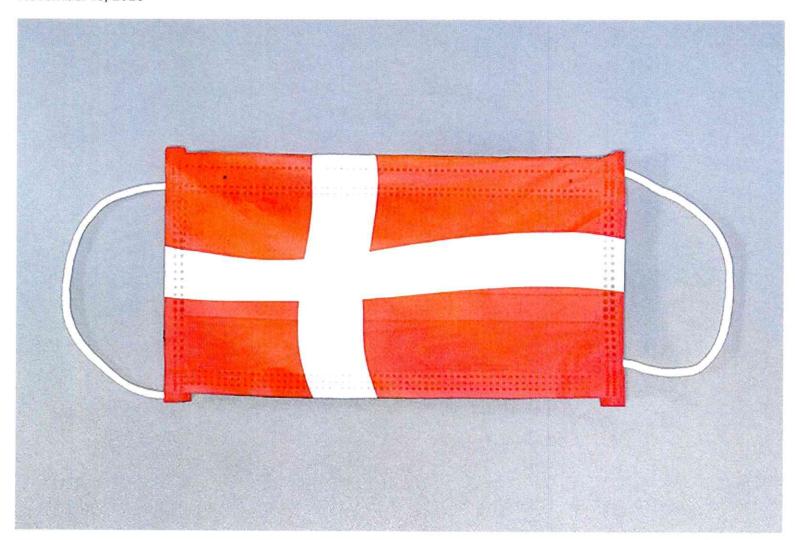
MEDPAGE TODAY°

Here's How to Think About the Danish Mask Study

 What the DANMASK-19 trial showed and didn't show about mask use and COVID-19

by Vinay Prasad, MD, MPH November 18, 2020



I was drawn to science and medicine because of all human endeavors, ours is one where smart people can say, "I don't know." We don't stop there. We run a study or experiment that helps us know more. That is what makes what we do different than other human endeavors.

I start then with a humility as I take on the Danish Mask Study, published on Wednesday in the *Annals of Internal Medicine*. This is a 4,800-person randomized trial that took place in the spring and early summer in Denmark. The trial was run at a time where most Danes did not wear masks when they left their house. It told participants to practice social distancing and randomly assigned them with the advice to wear a mask (and even gave them 50 surgical masks), advising them to change it after every 8 hours of use, or gave them no advice to wear mask, and followed them to see how many acquired SARS-CoV-2 by PCR or antibody testing. The answer was a nearly identical proportion -- 42 of 2,393 people (1.8%) in the mask group and 53 of 2,470 (2.1%) in the no-mask group. The difference was not statistically significant.

Before I tell you what the study showed and didn't, we have to consider some criticism that is rapidly emerging.

Was the trial underpowered? The trial was powered to test its hypothesis of a 50% reduction in SARS-CoV-2 from mask wearing in a setting where the baseline risk was approximately 2%. The trial anticipated a 20% loss to follow-up. By these measures the trial was adequately powered to test its hypothesis, but let's be honest, the authors could not possibly have known at the outset the exact rate of COVID-19. While 2% was a terrific guess, it so easily could have been 22%. SARS-CoV-2 is a fat-tail probability event: meaning that it is possible for extremely bad scenarios to occur. Instead of California, Denmark could have been South Dakota! For this reason, I don't judge them harshly for power.

Was adherence poor? Among participants, 46% wore the mask as recommended and 47% wore it "predominantly as recommended," for a total of 93%. Anyone who has walked around any city or store in America can attest: that is actually pretty good! To

my eye, one in four noses are seen protruding, and one in eight masks are worn as a chin strap.

Even low adherence would not be a problem, as it's part of what is being tested. A cake is both the batter and the temperature of the oven, and a public health recommendation is both the recommendation itself and whether people follow it. You should be judged for both things.

What does the trial show exactly? The Danish trial shows that this specific mask recommendation (plus a box of masks) made during the SARS-CoV-2 pandemic, with background rates of 2% PCR acquisition, failed to show that mask wearing reduces risk by 50%. In places where there is modest SARS-CoV-2 transmission (like Denmark during these months), there is insufficient evidence to suggest wearing a mask as you go about daily errands will protect you from infection. That is good to know!

What doesn't the trial show? The trial is not able to assess the claim, "My mask protects you, not me." The way to test this claim would be to randomize clusters or groups of people. Perhaps by city or county, and ask if mask mandates slow spread across all folks who live in that area. To my knowledge there has never been such a study, and while this message is popular and plausible, we should be willing to say, "I don't know for sure if it is true." By the way, we have done so many cluster randomized controlled trials in medicine, that a colleague and I studied them here.

What the trial really means? Above all else, the Danish trial shows randomized trials are possible, and desperately needed. We need these studies now more than ever. Let's be honest. Masks have become a hot-button political issue. They are increasingly a badge symbolizing who one voted for. This is a terrible consequence of bad leadership and caustic, polarized social media posts -- yes, unfortunately, by both proponents and opponents of masks.

The trials we need right now are cluster randomized trials to test messaging strategies. Is SARS-CoV-2 transmission slowed in counties/cities where we (a) advise people to wear a cloth mask because it's the patriot thing to do (b) advise them to wear a cloth mask

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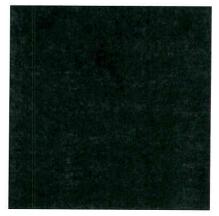
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