

This is an Accepted Manuscript for *Infection Control & Hospital Epidemiology* as part of the Cambridge Coronavirus Collection.

DOI: 10.1017/ice.2021.35

Article Type: Letter to the Editor

Mask Mandates in Light of DANMASK-19

Sajith Matthews, MD

Department of Internal Medicine

Division of General Medicine

Wayne State University

4201 St. Antoine Street, UHC 5C

Detroit, MI 48201

smatthew@med.wayne.edu

313-745-3795 (phone)

When public pressure mounted for the use of hydroxychloroquine (HCQ) for prophylaxis or treatment of Coronavirus disease 2019 (COVID-19), our nation's leading scientists exercised prudence and recommended awaiting the results of randomized controlled trials (RCTs) before considering its use. Such restraint proved to be invaluable as evidence from RCTs ultimately showed that there is no benefit, but rather harm with HCQ use in the treatment of COVID-19. (1,2) A similar focus on high quality evidence has not been taken for masks and effect on mitigating the spread of disease. Internationally, public health mandates for masks in the community, has varied from no masks, to mandatory masks when outside in crowds, to wearing

masks when symptomatic . (3-5) While acknowledging the lack of evidence from RCTs of masks having any additive effects on mitigating the transmission of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), (5) public mask use was recommended by the Center for Disease Control (CDC) for protective effect (among healthy individuals) and not just source control (among symptomatic individuals).

The DANMASK-19 was a well powered randomized controlled trial (6000 participants) with 46% proper and 47% predominantly proper adherence to masks in a setting of uncommon mask use, moderate spread of infection, and reasonable adherence to social distancing and handwashing (6). The DANMASK-19 trial was consistent with the 12 previous RCTs (7) which showed, with moderate certainty evidence, there were negligible additive effects from masks in the prevention of respiratory infections. The DANMASK-19 trial showed the mask's protective effect to be inconclusive and difference between the two groups to not be statistically significant in the community setting. Despite the evidence from previous RCTs on influenza and other respiratory viral infections, there was suspicion from observational studies (8) that severe acute respiratory syndrome SARS-CoV-2 behaved differently and droplet transmission could be mitigated by mask use in the presymptomatic phase. (5) Therefore, the implementation of universal mask use was justified, while awaiting the results DANMASK 19. In light of the inconclusive evidence from DANMASK 19 and the previous RCTs, the case for a protective effect from COVID 19 lacks evidence and requires modification from public health officials.

While this study did not assess for source control, the effect of masks is compelling, when restricted to contacts of index cases receiving intervention within 36 hours of symptom onset. (9) Hence, mask use among symptomatic individuals and their contacts is evidence based. On the contrary, longterm effects of mask use among health individuals is unknown (3) and short term effects include breathing difficulties, self infection through touching eyes due to irritation from exhaled air from masks, and a false sense of security from mask while neglecting social distancing (10). The argument for masks having a variolation effect in COVID-19, is compelling (11), but lacking in evidence from cohort studies. Hence, with the current data available, the best case for masks appears to be in symptomatic patients and recommended (not mandatory) use in crowded settings. Wisdom to use measured language in what we “mandate” and “recommend” would be advised. We must decide with prudence as we did with HCQ what we choose to be

“absolutely essential” measures and we must decide these based upon robust evidence. In the haste of establishing “life saving” measures, we may be instead be losing the public’s trust by not having the supportive evidence and unintentionally placing the lives of the community and health care workers at risk.

Word Count: 569

Acknowledgements:

The corresponding author’s affiliation center belongs to the Integrative Biosciences Center, Wayne State University, Detroit, Michigan. The funders had no role in the decision to publish or preparation of the manuscript.

References

1. Boulware DR, Pullen MF, Bangdiwala AS et al A Randomized Trial of Hydroxychloroquine as Postexposure Prophylaxis for Covid-19. *N Engl J Med*. 2020 Aug 6;383(6):517-525. doi: 10.1056/NEJMoa2016638. Epub 2020 Jun 3. PMID: 32492293; PMCID: PMC7289276.
2. RECOVERY Collaborative Group, Horby P, Mafham M, Linsell L, Bell JL, Effect of Hydroxychloroquine in Hospitalized Patients with Covid-19. *N Engl J Med*. 2020 Nov 19;383(21):2030-2040. doi: 10.1056/NEJMoa2022926. Epub 2020 Oct 8. PMID: 33031652; PMCID: PMC7556338.
3. Javid B, Weekes MP, Matheson NJ. Covid-19: should the public wear face masks? *BMJ*. 2020 Apr 9;369:m1442. doi: 10.1136/bmj.m1442. PMID: 32273278.
4. Bundgaard H, Bundgaard JS, Raaschou-Pedersen DET et al. Face masks for the prevention of COVID-19 - Rationale and design of the randomised controlled trial DANMASK-19. *Dan Med J*. 2020 Aug 18;67(9):A05200363. PMID: 32829745.
5. World Health Organization. Advice on the use of masks in the context of COVID-19: interim guidance. *WHO Global: World Health Organization*, 2020;(5 June):1-5.
[https://www.who.int/publications/i/item/advice-on-the-use-of-masks-in-the-community-during-home-care-and-in-healthcare-settings-in-the-context-of-the-novel-coronavirus-\(2019-ncov\)-outbreak](https://www.who.int/publications/i/item/advice-on-the-use-of-masks-in-the-community-during-home-care-and-in-healthcare-settings-in-the-context-of-the-novel-coronavirus-(2019-ncov)-outbreak)
6. Bundgaard H, Bundgaard JS, Raaschou-Pedersen DET, et al. Effectiveness of Adding a Mask Recommendation to Other Public Health Measures to Prevent SARS-CoV-2 Infection in Danish Mask Wearers : A Randomized Controlled Trial. *Ann Intern Med*. 2020 Nov 18:M20-6817. doi: 10.7326/M20-6817. Epub ahead of print. PMID: 33205991; PMCID: PMC7707213.
7. Chou R, Dana T, Jungbauer R, et al. Masks for Prevention of Respiratory Virus Infections, Including SARS-CoV-2, in Health Care and Community Settings : A Living Rapid Review. *Ann Intern Med*. 2020 Oct 6;173(7):542-555. doi: 10.7326/M20-3213. Epub 2020 Jun 24. PMID: 32579379; PMCID: PMC7322812.

8. Chu DK, Akl EA, Duda S, et al.; COVID-19 Systematic Urgent Review Group Effort (SURGE) study authors. Physical distancing, face masks, and eye protection to prevent person-to-person transmission of SARS-CoV-2 and COVID-19: a systematic review and meta-analysis. *Lancet*. 2020 Jun 27;395(10242):1973-1987. doi: 10.1016/S0140-6736(20)31142-9. Epub 2020 Jun 1. PMID: 32497510; PMCID: PMC7263814.
9. Cowling BJ, Chan KH, Fang VJ, et al. Facemasks and hand hygiene to prevent influenza transmission in households: a cluster randomized trial. *Ann Intern Med*. 2009 Oct 6;151(7):437-46. doi: 10.7326/0003-4819-151-7-200910060-00142. Epub 2009 Aug 3. PMID: 19652172.
10. Lazzarino AI, Steptoe A, Hamer M, et al. Covid-19: Important potential side effects of wearing face masks that we should bear in mind. *BMJ*. 2020 May 21;369:m2003. doi: 10.1136/bmj.m2003. PMID: 32439689.
11. Gandhi M, Rutherford GW. Facial Masking for Covid-19 - Potential for "Variolation" as We Await a Vaccine. *N Engl J Med*. 2020 Oct 29;383(18):e101. doi: 10.1056/NEJMp2026913. Epub 2020 Sep 8. PMID: 32897661.