

From: Berger, Sherri (CDC/OD/OCS) <(b)(6)>
To: Pearlman, Aj (HHS/IOS) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b823159c628641fb89934ad67912edff-Pearlman, A <Aj.Pearlman@hhs.gov>; Despres, Sarah (HHS/IOS) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=15d1d64eacdf46b8a378310ae7caf6bd-Despres, Sa <Sarah.Despres@hhs.gov>; Sams, Ian (HHS/ASPA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=486e1c5f2f544391bfd4b50abc329b44-Sams, Ian <Ian.Sams@hhs.gov>
CC: Tumpey, Abigail (CDC/DDPHSS/CSELS/OD) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2137d2b90bd946d39c26add5d0ac9aa8-Tumpey, Abb <(b)(6)>; spe9 /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user40a67ecc <(b)(6)>
Subject: FYI
Date: 2021/11/16 13:51:22
Priority: Normal
Type: Note

this could be shared broadly, thanks

From: Michael Osterholm <(b)(6)>
Sent: Tuesday, November 16, 2021 8:41 AM
To: <(b)(6)>
Cc: Lisa Brosseau <(b)(6)>; Kevin Escandón <(b)(6)>; Angela Ulrich <(b)(6)>; Angela Rasmussen <(b)(6)>; Bix, Gregory J <(b)(6)>; Roy, Chad J <(b)(6)>; Saskia V Popescu <(b)(6)>; <(b)(6)> hlatshwayo-davism@stlouis-mo.gov; <(b)(6)> <(b)(6)> <(b)(6)> <(b)(6)> <(b)(6)> Daniel.p.mcquillen@lahey.org; Del Rio, Carlos (CDC emory.edu) <(b)(6)>; <(b)(6)> <(b)(6)> <(b)(6)> <(b)(6)> <(b)(6)> Adimora, Adaora (CDC med.unc.edu) <(b)(6)> <(b)(6)> <(b)(6)> <(b)(6)> <(b)(6)> Howard, John (CDC/NIOSH/OD) <(b)(6)>; Walensky, Rochelle (CDC/OD) <(b)(6)>
Subject: Errors in the CDC/IDSA Website "Masks and Face Coverings for the Public"

Dear Dr. Chida,

Please find attached a letter from six colleagues and me regarding serious errors in the website "Masks and Face Coverings for the Public" on the COVID-19 Real-Time Learning Network hosted by CDC and IDSA. We believe the information and recommendations as provided may actually put an individual at increased risk of becoming infected with SARS-CoV-2 and for them to experience a serious or even life-threatening infection.

We look forward to your review of the information included in our letter and how the IDSA and CDC will address it as soon as possible.

Thank you. The authors of the letter are happy to discuss this information with you at your earliest convenience.

Sincerely,
Mike

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November 15, 2021

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Dear Dr. Chida:

We urge you to address serious errors on the website "[Masks and Face Coverings for the Public](#)," on the COVID-19 Real-Time Learning Network hosted by the Centers for Disease Control and Prevention (CDC) and the Infectious Diseases Society of America (IDSA).

In particular, this website suggests, "Masking may reduce viral inoculum when transmission occurs, resulting in more mild disease" and cites a highly questionable and misleading commentary published by Monica Gandhi, Chris Beyrer, and Eric Goosby in the *Journal of General Internal Medicine (JGIM)*.¹ We recently authored an in-depth review addressing this hypothesis and the topics of SARS-CoV-2 infectious dose, viral load, and severity outcomes in *Clinical Infectious Diseases*,² in which we note that there is little and conflicting evidence to suggest a link between SARS-CoV-2 inoculum and disease severity. The infectious dose or inoculum received is very likely associated with the probability of infection, which is supported by animal data. However, once infection occurs, the disease outcomes that result are greatly dependent on host factors such as age, sex, cardiometabolic comorbidities, smoking, and pregnancy.

After Gandhi, Beyrer, and Goosby published that commentary on July 31, 2020, in *JGIM*, Gandhi and George W. Rutherford further proposed that masks could provide a means of "variolaion" in the absence of vaccines in a September 8, 2020, *New England Journal of Medicine* perspective article.³ In October 2020, six of us authored two letters to the editor strongly criticizing this perspective of masks.^{4,5} In particular, we noted, "Masks are used primarily to reduce SARS-CoV-2 transmission rather than reduce the dose of infectious particles or mitigate the severity of COVID-19. The suggestion that masks offer an alternative to vaccination without evidence that the benefits outweigh the great risks implicitly encourages reckless behavior." We also noted that the term "variolaion" should be avoided because it was inaccurate with respect to coronaviruses and described an obsolete and risky practice used for the iatrogenic inoculation of smallpox and that the importance of host factors in driving COVID-19 severity should not be neglected.

As of late 2021, there is still insufficient and controversial evidence supporting the variolaion inoculum-dependent hypothesis by which masks or any other interventions that potentially reduce the viral infectious dose

lead to reduced disease severity and induce protective immunity. We believe human epidemiological and animal experimental data have been misinterpreted in pieces that make such claims as well as in numerous other publications citing Gandhi's ideas.^{6,7,8,9} We are concerned that promotion of these pieces and their placement on well-trusted websites such as those of IDSA and the CDC not only damage the credibility of science and endanger public trust by misrepresenting the evidence, but also provide false expectations in terms of respiratory protection to the public.

We strongly urge IDSA to remove the suggestion that masking prevents severe disease from its webpage on Masks and Face Coverings for the Public. In addition, the podcast by Dr. Monica Gandhi where such irresponsible claims are made (<https://www.idsociety.org/multimedia/podcasts/covid-19-prevention-why-masking-is-our-best-weapon/>), should be removed from the website.

We also recommend that IDSA reconsider its statements about the efficacy of masks and face coverings for preventing transmission of SARS-CoV-2. We do not agree that the evidence for their efficacy has strengthened throughout the pandemic, as the website suggests. In fact, contrary to the conclusion on this website, the November 2020 Cochrane review cited states this: "Compared with wearing no mask, wearing a mask may make little to no difference in how many people caught a flu-like illness (9 studies; 3,507 people); and probably makes no difference in how many people have flu confirmed by a laboratory test (6 studies; 3,005 people). Unwanted effects were rarely reported, but included discomfort." Of note, although this review focused on respiratory viruses in general, it has been used to draw evidence and generalize it for COVID-19 prevention efforts.

We highly recommend that the living reviews, updated bimonthly throughout the pandemic, by Dr. Roger Chu and colleagues at the Pacific Northwest Evidence-based Practice Center at Oregon Health and Science University be used as an authoritative source for considering the effectiveness of masking. To date this ongoing review has found very limited evidence of mask efficacy in the community.¹⁰⁻¹⁶

We also call your attention to two recent commentaries published on the University of Minnesota Center for Infectious Disease Research and Policy (CIDRAP) website.^{17,18} The second of these pieces describes the important elements of a rigorous mask study and critiques several studies as examples of the shortcomings of most such studies to date. One of the critiqued studies is the randomized clinical trial of masks conducted in Bangladesh and released as a preprint by Jason Abaluck; this study is cited by IDSA in support of mask efficacy. This study has many significant shortcomings not described or recognized by the IDSA summary, which were highlighted in the CIDRAP commentary. Most important, this study did not consider or measure baseline seropositivity in the study population, but instead concluded that anyone seropositive at the end of the study must have been infected during the study period. The time period of the study – late 2020 to early 2021 — does not lend itself to this conclusion. The masks were not described, so we lack details on their filter efficiency or fit. The confidence intervals for the outcome variables were very wide and included 1.0, suggesting weak, if any, protection provided by masks.

The IDSA "Masks and Face Coverings for the Public" webpage appears to focus on the strengths of studies that support its conclusions while ignoring their shortcomings of study design; studies that do not support its perspective are similarly downplayed. For example, a summary of the Bundgaard study of masks in Denmark,¹⁹ which found no reduction in SARS-CoV-2 among mask wearers, declares in bold type, "**Overall, in this large population-based randomized controlled trial, recommending persons to wear masks in addition to social distancing was not associated with reduction in SARS-CoV-2 acquisition for mask wearers. The study is limited by a significant amount of mask nonadherence in participants recommended to wear them and by the**

fact that community caseload was low during the study. The results also cannot be extrapolated to determine the effectiveness of masks at reducing transmission of SARS-CoV-2, as the study was designed to assess protection of wearers, not transmission.” The last statement suggests that other studies of masks have focused on transmission and not protection of wearers, which is not true — in most cases, the direction of transmission (to or from a mask wearer) has not and generally cannot be ascertained and was not the outcome of interest. There are similar problems with most of the other studies cited by IDSA in support of mask efficacy.

We welcome the opportunity to assist IDSA in updating its review of the science that may support the use of masks by the public. We are not anti-mask, but rather we strongly support a more careful scientific review of the data that states the role that masks may play in preventing SARS-CoV-2 transmission, based on the best scientific evidence that exists.

Sincerely,

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¹ Gandhi M, Beyrer C, Goosby E. Masks do more than protect others during COVID-19: reducing the inoculum of SARS-CoV-2 to protect the wearer. *J Gen Intern Med* 35, 3063–3066 (2020). <https://doi.org/10.1007/s11606-020-06067-8>

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³ Gandhi M, Rutherford GW. (2020) Facial masking for Covid-19—potential for “variolaion” as we await a vaccine. *N Engl J Med* 383(18), e101. DOI: 10.1056/NEJMp2026913

⁴ Brosseau LM, Roy CJ, Osterholm MT. (2020) Facial masking for Covid-19. *N Engl J Med* 383(21), 2092-2093. DOI: 10.1056/NEJMc2030886

⁵ Rasmussen AL, Escandón K, Popescu SV. (2020) Facial masking for covid-19. *N Engl J Med* 383(21): 2092. DOI: 10.1056/NEJMc2030886

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⁷ Van Damme W, Dahake R, van de Pas R, Vanham G, Assefa Y. (2021) COVID-19: Does the infectious inoculum dose-response relationship contribute to understanding heterogeneity in disease severity and transmission dynamics? *Med Hypotheses* 146:110431. <https://doi.org/10.1016/j.mehy.2020.110431>.

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¹⁰ 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. *Ann Intern Med* 2020 Oct 6;173(7):542-55

¹¹ Chou R, Dana T, Jungbauer R, et al. Update alert: Masks for prevention of respiratory virus infections, including SARS-CoV-2, in health care and community settings. *Ann Intern Med* 2020 Sep 1;173(5):W86

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- ¹² Chou R, Dana T, Jungbauer R, et al. Update alert 2: Masks for prevention of respiratory virus infections, including SARS-CoV-2, in health care and community settings. *Ann Intern Med* 2020 Oct 6;173(7):132
- ¹³ Chou R, Dana T, Jungbauer R, et al. Update alert 3: Masks for prevention of respiratory virus infections, including SARS-CoV-2, in health care and community settings. *Ann Intern Med* 2020 Dec 15;173(12):169
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- ¹⁵ Chou R, Dana T, Jungbauer R, et al. Update alert 5: Masks for prevention of respiratory virus infections, including SARS-CoV-2, in health care and community settings. *Ann Intern Med* 2021 Apr;174(4):W47
- ¹⁶ Chou R, Dana T, Jungbauer R. Update alert 6: Masks for prevention of respiratory virus infections, including SARS-CoV-2, in health care and community settings. *Ann Intern Med* 2021 Sep;174(9):W68
- ¹⁷ Brosseau LM, Ulrich A, Escandon K, Anderson C, Osterholm MT. Commentary: What can masks do? Part 1: The science behind COVID-19 protection. Center for Infectious Disease Research and Policy. October 14, 2021. <https://www.cidrap.umn.edu/news-perspective/2021/10/commentary-what-can-masks-do-part-1-science-behind-covid-19-protection>
- ¹⁸ Brosseau LM, Ulrich A, Escandon K, Anderson C, Osterholm MT. Commentary: What can masks do? Part 2: What makes for a good mask study – and why most fail. Center for Infectious Disease Research and Policy. October 15, 2021. <https://www.cidrap.umn.edu/news-perspective/2021/10/commentary-what-can-masks-do-part-2-what-makes-good-mask-study-and-why-most>
- ¹⁹ Bundgaard H, Bundgaard JS, Raaschou-Pedersen DET, von Buchwald C, Todsén T, Norsk JB, Pries-Heje MM, Vissing CR, Nielsen PB, Winsløw UC, Fogh K, Hasselbalch R, Kristensen JH, Ringgaard A, Porsborg Andersen M, Goecke NB, Trebbien R, Skovgaard K, Benfield T, Ullum H, Torp-Pedersen C, Iversen K. 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*. 2021 Mar;174(3):335-343. doi: 10.7326/M20-6817.