Plaintiff's Exhibit 51

UNITED STATES OF AMERICA
DEPARTMENT OF TRANSPORTATION
OFFICE OF THE SECRETARY
WASHINGTON, D.C.

NOTICE OF ENFORCEMENT POLICY: ACCOMMODATION BY CARRIERS OF PERSONS WITH DISABILITIES WHO ARE UNABLE TO WEAR OR SAFELY WEAR MASKS WHILE ON COMMERCIAL AIRCRAFT

The Office of Aviation Consumer Protection (OACP), a unit within the Office of the General Counsel of the U.S. Department of Transportation (DOT or the Department), is issuing this Notice of Enforcement Policy to remind U.S. and foreign air carriers of their legal obligation to accommodate the needs of passengers with disabilities when developing procedures to implement the Federal mandate on the use of masks to mitigate the public health risks associated with the Coronavirus Disease 2019 (COVID-19). OACP will exercise its prosecutorial discretion and provide airlines 45 days from the date of this notice to be in compliance with their obligation under the Air Carrier Access Act (ACAA)[1] and the Department's implementing regulation in 14 CFR Part 382 (Part 382) to provide reasonable accommodations to persons with disabilities who are unable to wear or safely wear masks, so long as the airlines demonstrate that they began the process of compliance as soon as this notice was issued.

To carry out the Executive Order on Promoting COVID-19 Safety in Domestic and International Travel (Executive Order),[2] the Centers for Disease Control and Prevention (CDC) issued an order on January 29, 2021 (CDC Order)[3] that, among other things, requires U.S. and foreign air carriers to use their best efforts to ensure that persons on flights to, within, or from[4] the United States wear a mask for the duration of travel, including when boarding and disembarking aircraft. The CDC Order exempts certain categories of persons from the mask-wearing mandate, including a person with a disability who cannot wear a mask, or who cannot safely wear a mask

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[1] The ACAA, signed into law in 1986, prohibits discrimination by airlines against individuals with disabilities in commercial air transportation. The Americans with Disabilities Act, signed into law after the ACAA in 1990, prohibits discrimination against individuals with disabilities in employment, state or local government, public accommodations, commercial facilities, telecommunications, and transportation other than by commercial airlines.

[2] Exec. Order No. 13998, 86 FR 7205 (Jan. 26, 2021).

[3] Order Under Section 361 of the Public Health Service Act (42 U.S.C. 264) and 42 Code of Federal Regulations 70.2, 71.31(b), 71.32(b): Requirement for Persons to Wear Masks While on Conveyances and at Transportation Hubs (CDC Order), *available at* https://www.cdc.gov/quarantine/pdf/Mask-Order-CDC_GMTF_01-29-21-p.pdf.

[4] CDC Order specifies that "[c]onveyance operators must also require all persons to wear masks on board conveyances departing from the United States and for the duration of their travel until the conveyance arrives at the foreign destination if at any time any of the persons onboard (passengers or conveyance operators) will return to the United States while this Order remains in effect." CDC Order at 9.

because of the disability.[5] However, it allows airlines to impose requirements or conditions for carriage on the categories of persons exempted from the mask mandate, whether the person is a child under the age of two, a person for whom wearing a mask would create a risk to workplace safety, health, or job duty, or a person with a disability who is unable to wear or safely wear a mask because of the disability. Additionally, on January 31, 2021, the Transportation Security Administration (TSA) issued a Security Directive (SD) to aircraft operators on face mask requirements to implement the Executive Order and to support enforcement of the CDC Order mandating masks.[6] The Department supports actions by the airline industry to have procedures in place requiring passengers to wear masks in accordance with the CDC Order, CDC guidance, and TSA SD. At the same time, the ACAA and Part 382, which are enforced by OACP, require airlines to make reasonable accommodations, based on individualized assessments, for passengers with disabilities who are unable to wear or safely wear a mask due to their disability. This Notice sets forth the enforcement policy that OACP will apply in determining, on a prospective basis, whether airlines are complying with the requirements of the ACAA and Part 382 when implementing procedures requiring mask-wearing by passengers.

Background

SARS-CoV-2, the virus that causes COVID-19, spreads most often when an infected person coughs, sneezes, or talks, and droplets from the infected individual's mouth or nose are spread through the air and come in contact with people nearby.[7] Persons with COVID-19 infection may have symptoms of fever, cough, or shortness of breath,[8] or they may be asymptomatic[9] or pre-symptomatic[10] but still able to spread the virus.[11] CDC has made clear that appropriately worn masks reduce the spread of COVID-19—particularly given the evidence of pre-symptomatic and asymptomatic transmission of COVID-19.[12]

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[5] CDC Order at 4 and 5 (noting that this is a narrow exception that includes a person with a disability who cannot wear a mask for reasons related to disability).

[6] TSA Security Directive 1544-21-02: Security Measures – Face Mask Requirements (January 31, 2021).

[7] *See* Ctrs. for Disease Control & Prevention, *How COVID Spreads*, CDC.gov (last updated Oct. 28, 2020), https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html; Ctrs. for Disease Control & Prevention, *Considerations for Wearing Masks*, CDC.gov (last updated Dec. 18, 2020), https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/cloth-face-cover-guidance.html.

[8] Ctrs. for Disease Control & Prevention, *Symptoms of Coronavirus*, CDC.gov (last updated Dec. 22, 2020), https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html.

[9] An asymptomatic case is an individual infected with SARS-CoV-2, who does not exhibit symptoms during the course of infection. Ctrs. for Disease Control & Prevention, *COVID-19 Pandemic Planning Scenarios*, CDC.gov (last updated Sept. 10, 2020), https://www.cdc.gov/coronavirus/2019-ncov/hcp/planning-scenarios.html.

[10] A pre-symptomatic case of COVID-19 is an individual infected with SARS-CoV-2, who has not exhibited symptoms at the time of testing, but who later exhibits symptoms during the course of the infection. *COVID-19 Pandemic Planning Scenarios*, *supra* note 8.

[11] *See How COVID Spreads* and *Considerations for Wearing Masks*, *supra* note 6.

[12] CDC Order at 6.

As of January 27, 2021, there have been over 99 million confirmed cases of COVID-19 globally and over 25 million confirmed cases of COVID-19 in the United States, with over 2 million deaths globally and over 400,000 deaths in the United States due to the disease.[13] To slow the spread of COVID-19, on January 21, 2021, President Biden issued Executive Order 13998, which directs the heads of certain Federal agencies to take immediate actions to require mask-wearing in domestic and international transportation. The Executive Order further provides that the heads of agencies may make categorical or case-by-case exceptions to policies developed under the order, consistent with applicable law, to the extent that doing so is necessary or required by law.

Pursuant to the Executive Order, on January 29, 2021, CDC issued an order directing conveyance operators, which includes airlines, to use best efforts to ensure that any person on the conveyance, such as an aircraft, wears a mask when boarding, disembarking, and for the duration of travel. Recognizing that there are specific instances when wearing a mask may not be feasible, the CDC Order exempts several categories of persons from the mask mandate, including "a person with a disability who cannot wear a mask, or who cannot safely wear a mask because of the disability as defined by the Americans with Disabilities Act (42 U.S.C. 12101 et seq.)." The Americans with Disabilities Act (ADA) defines a person with a disability to include a person who has a physical or mental impairment that substantially limits one or more major life activities.[14] To ensure that only qualified persons under the exemptions would be able to travel without a mask, the CDC Order permits operators of transportation conveyances, such as airlines, to impose requirements, or conditions for carriage, on persons requesting an exemption, including requiring a person seeking an exemption to request an accommodation in advance, submit to medical consultation by a third party, provide medical documentation by a licensed medical provider, and/or provide other information as determined by the operator. The CDC Order also permits operators to require protective measures, such as a negative result from a SARS-CoV-2 viral test or documentation of recovery from COVID-19 or seating or otherwise situating the individual in a less crowded section of the conveyance, e.g., aircraft.[15]

In response to COVID-19, U.S. and foreign air carriers generally have implemented policies requiring passengers to wear masks onboard aircraft even before the issuance of the Executive Order and the CDC Order. Some carriers have adopted policies that expressly allow "no exceptions" to the mask requirement other than for children under the age of two.[16] OACP has

[13] *Id.* at 5.

[14] 42 U.S.C. 12102(4). OACP notes that the definition of a person with a disability under the ADA is almost identical to the definition of a person with a disability under the Department's ACAA regulation. See also CDC Order at 4 and 5.

[15] CDC Order at 4. CDC definitions for SARS-CoV-2 viral test and documentation of recovery are available in the Frequently Asked Questions at https://www.cdc.gov/coronavirus/2019-ncov/travelers/testing-international-air-travelers.html.

[16] It would a violation of the ACAA to have an exemption for children under 2 on the basis that children that age cannot wear or safely wear a mask and not to have an exemption for the limited number of individuals with disabilities who similarly cannot wear or safely wear a mask when there is no evidence that these individuals with disabilities would pose a greater health risk to others. *See* Ctrs. for Disease Control & Prevention, *Information for Pediatric Healthcare Providers*, CDC.gov (last updated Dec. 30, 2020), https://www.cdc.gov/coronavirus/2019-

received complaints from persons who assert they have a disability that precludes their wearing a mask, and who contend that they were denied transport by an airline under a "no exceptions allowed" mask policy.

The CDC and other medical authorities recognize that individuals with certain medical conditions may have trouble breathing or other difficulties such as being unable to remove the mask without assistance if required to wear a mask that fits closely over the nose and mouth.[17] The CDC Order provides that a mask is not required in circumstances where an individual is "unconscious (for reasons other than sleeping), incapacitated, unable to be awakened, or otherwise unable to wear the mask without assistance."[18] The Order notes that individuals may remove masks "who are experiencing difficulty breathing or shortness of breath or are feeling winded may remove the mask temporarily until able to resume normal breathing with the mask"."[19] Also, individuals with acute illness may remove the mask if it "interferes with necessary medical care such as supplemental oxygen administered via an oxygen mask."[20] CDC will issue additional guidance regarding persons who cannot wear a mask on the basis of disability.[21] Individuals who have a physical or mental impairment that substantially limits one or more major life activities are individuals with a disability for purposes of the ACAA and Part 382.[22]

Legal Authority

The ACAA prohibits U.S. and foreign air carriers from denying air transportation to or otherwise discriminating in the provision of air transportation against a person with a disability by reason of the disability.[23] When a policy or practice adopted by a carrier has the effect of denying service to or otherwise discriminating against passengers because of their disabilities, the Department's disability regulations in Part 382 require the airline to modify the policy or practice as necessary to provide nondiscriminatory service to the passengers with disabilities, provided that the modifications would not constitute an undue burden or fundamentally alter the airline's program.[24]

Part 382 allows an airline to refuse to provide air transportation to an individual whom the airline determines presents a disability-related safety risk, provided that the airline can demonstrate that

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ncov/hcp/pediatric-hcp.html (stating that "[r]ecent evidence suggests that compared to adults, children likely have similar viral loads in their nasopharynx, similar secondary infections rates, and can spread the virus to others").

[17] Considerations for Wearing Masks, *supra* note 6.

[18] CDC Order at 4.

[19] CDC Order at 4 (footnote 7).

[20] CDC Order at 4 (footnote 7).

[21] CDC Order at 5 (footnote 9).

[22] 49 U.S.C. 41705(a); 14 CFR 382.3.

[23] 49 U.S.C. 41705(a); 14 CFR 382.11.

[24] 14 CFR 382.13.

the individual would pose a "direct threat" to the health or safety of others onboard the aircraft, and that a less restrictive option is not feasible.[25] To support a determination that an individual poses such a direct threat, the airline must make "an individualized assessment, based on reasonable judgment that relies on current medical knowledge or on the best available objective evidence," in order to ascertain "(i) [t]he nature, duration, and severity of the risk; (ii) [t]he probability that the potential harm to the health and safety of others will actually occur; and (iii) [w]hether reasonable modifications of policies, practices, or procedures will mitigate the risk."[26] If the airline has adequately determined, based on such an individualized assessment, that the passenger does pose a direct threat to the health or safety of others because of a disability-related condition, the airline "must select the least restrictive response from the point of view of the passenger, consistent with protecting the health and safety of others," and must, for example, "not refuse transportation to the passenger if [the airline] can protect the health and safety of others by means short of a refusal" to provide transportation.[27] Furthermore, the Department's regulations permit the airline to impose reasonable conditions, restrictions, or requirements on a passenger who has a "medical condition" that may cause the passenger to pose a risk to the health and safety of others.[28]

Enforcement Policy

The authority to pursue or not to pursue enforcement action against airlines with respect to air travel consumer protection and civil rights requirements, including compliance with the ACAA, lies with OACP.[29]

In accordance with the CDC Order, as conveyance operators, airlines are required to implement face mask policies that treat passengers presumptively as potential carriers of the SARS-CoV-2 virus and, therefore, as presenting a potential threat to the health and safety of other passengers and the crew.[30] Notably, however, the CDC Order exempts from the mask mandate a person with a disability who cannot wear a mask, or who cannot safely wear a mask because of the

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[25] 14 CFR 382.19(c)(1), (2).

[26] *Id.*

[27] 14 CFR 382.19(c)(2).

[28] 14 CFR 382.21(a)(3). The rule recognizes that a passenger with a communicable disease or infection, such as infection with the SARS-CoV-2 virus or other "medical condition," may pose a direct threat to the health and safety of others onboard an aircraft, and the airline may be justified in refusing to transport the passenger or in requiring protective measures to mitigate the risk, consistent with the directives of public health authorities. 14 CFR 382.21(a)–(b).

[29] 49 U.S.C. 41705(c), 46301. The CDC Order requiring aircraft operators to mandate mask use will be enforced by the Transportation Security Administration under its statutory and regulatory authorities, including 49 U.S.C. 106, 114, 44902, 44903, and 46301; and 49 CFR 1542.303, 1544.305, and 1546.105.

[30] CDC Order at 5 ("The virus that causes COVID-19 spreads very easily and sustainably between people who are in close contact with one another (within about 6 feet)."); *id.* at 7 ("Traveling on public conveyances increases a person's risk of getting and spreading COVID-19 by bringing persons in close contact with others, often for prolonged periods, and exposing them to frequently touched surfaces.").

disability. The Department also requires reasonable accommodations for persons with disabilities who are unable to wear masks or are unable to wear them safely.[31]

Airlines have expressed concerns to OACP that a significant number of passengers may claim medical exemption from the mask requirements without an apparent credible basis. The CDC Order permits airlines to impose requirements or conditions for carriage on a person requesting an exemption, including requiring a person seeking an exemption to request an accommodation in advance, submit to medical consultation by a third party, provide medical documentation by a licensed medical provider, and/or provide other information as determined by the airline.[32] Similarly, under the Department's disability regulation in 14 CFR Part 382, airlines may impose conditions, restrictions, or requirements on a passenger asserting that a medical condition prevents the passenger from wearing a face mask, because the passenger may pose a direct threat to the health or safety of others, as any passenger is a potential carrier of the SARS-CoV-2 virus.[33] In short, both the CDC Order and Part 382 permit airlines to require passengers to consult with the airline's medical expert and/or to provide medical evaluation documentation from the passenger's doctor sufficient to satisfy the airline that the passenger does, indeed, have a recognized medical condition precluding the wearing or safe wearing of a mask.

Airlines have also represented to OACP that, given the number of passengers making such claims, it is not practicable for airlines to make the required individualized assessment of appropriate mitigation measures at the airport on the day of the flight. Under the Department's disability regulation in Part 382, airlines must conduct an individualized assessment of the potential ways to mitigate the risk to others of allowing passengers with disabilities to fly without a mask.[34] However, Part 382, like the CDC Order, permits airlines to require passengers with disabilities who are unable to wear masks to request an accommodation in advance. Airlines may also require such passengers to check in early and to agree to undergo the required individualized assessment a reasonable period in advance of the scheduled flight, provided that the process is completed on the day of travel.

In addition, airlines may impose protective measures to reduce or prevent the risk to other passengers. For example, airlines may require protective measures, such as a negative result from a SARS-CoV-2 test,[35] taken at the passenger's own expense, during the days immediately

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[31] 14 CFR 382.13.

[32] *Id.*

[33] 14 CFR 382.21(a)(3).

[34] 14 CFR 382.19(c)(1).

[35] On January 12, 2021, CDC issued an order requiring any passenger flying into the United States from a foreign country to provide, before boarding the flight, proof of a negative pre-departure test result for SARS-CoV-2, the virus that causes COVID-19, or documentation of recovery from COVID-19 after a previous SARS-CoV-2 infection. This order became effective on January 26, 2021. Order Under Section 361 of the Public Health Service Act (42 U.S.C. 264) and 42 Code of Federal Regulations 70.2, 71.31(b): Requirement for Negative Pre-Departure COVID-19 Test Result or Documentation of Recovery From COVID-19 for All Airlines or Other Aircraft Passengers Arriving into the United States from Any Foreign Country, *available at* https://www.cdc.gov/quarantine/pdf/global-airline-testing-order_2021-01-2_R3-signed-encrypted-p.pdf.

prior to the scheduled flight.[36] Further, the airline may arrange for additional, appropriate mitigation measures, including arranging for the passenger to sit in a less crowded section of the plane, to take a flight at times when airports are less crowded, and/or scheduling the passenger on a less crowded flight.

To ensure travelers are aware of the face mask requirements, airlines should use their best efforts to make this information easily available. The Department requires airlines provide information on request, to individuals with disabilities, about any service-related or other limitations on the airline's ability to accommodate passengers with a disability.[37] Also, CDC and TSA require airlines to provide passengers with prominent and adequate notice to facilitate awareness and compliance with the requirement that masks must be worn, subject to certain limited exemptions, to mitigate the spread of COVID-19 during air travel.[38] Airlines' obligation to provide information on the face mask requirements includes updating airlines' face mask policies on their websites to ensure accuracy and consistency with the ACAA, CDC Order and TSA SD.[39]

In recognition of the CDC Order, as well as airlines' efforts to minimize the potential for transmission of the virus onboard aircraft by implementing policies requiring passengers to wear masks onboard aircraft even before the issuance of the CDC Order, OACP will exercise its prosecutorial discretion and provide airlines an opportunity to follow the steps described herein to become compliant before taking further action.[40] Airlines are expected to review their face mask policies immediately and to revise them as necessary to comply with the ACAA and Department's disability regulation in Part 382. OACP will refrain from taking enforcement action against an airline for a period of up to 45 days from the date of this notice, so long as the airline demonstrates that it began the process of compliance as soon as this notice was issued. This timeframe should provide airlines with adequate time to review and revise their mask procedures as needed to comply with the law.[41]

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[36] A positive test result for SARS-CoV-2, the virus that causes COVID-19, is a valid reason for an airline to deny transport to any individual, including an individual with a disability. CDC recommends isolation to separate people infected with SARS-CoV-2 from people who are not infected. *See* Ctrs. for Disease Control & Prevention, *Isolate if You are Sick*, CDC.gov (last updated Jan. 7, 2021), https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/isolation.html.

[37] 14 CFR 382.41.

[38] CDC Order at 1; TSA SD at 2.

[39] *See* 14 CFR 399.79 (b)(2) (defining an airline's practice as "deceptive" to consumers within the meaning of section 41712 if it is likely to mislead a consumer, acting reasonably under the circumstances, with respect to a material matter).

[40] Every day, we are learning more about how COVID-19 spreads and affects people and communities. OACP will continue to follow the data and information provided by public health authorities, such as CDC, on actions necessary to limit the spread or impact of SARS-CoV-2 and will make changes to this notice as necessary to be consistent with current medical knowledge and the best available objective evidence.

[41] This document is a temporary notice of enforcement discretion. Regulated entities may rely on this notice as a safeguard from Departmental enforcement as described herein. To the extent that this notice includes guidance on how regulated entities may comply with existing regulations, it does not have the force and effect of law and is not meant to bind the regulated entities in any way.

Questions regarding this Notice may be addressed to the Office of Aviation Consumer Protection (C-70), 1200 New Jersey Avenue, S.E., Washington, D.C. 20590.

By:

Blane A. Workie
Assistant General Counsel for
Office of Aviation Consumer Protection

Dated: February 5, 2021

An electronic version of this document is available at http://www.dot.gov/airconsumer

U.S. Department of Transportation
Federal Aviation Administration

SAFO

Safety Alert for Operators

SAFO 20009
DATE: 03/03/21

Flight Standards Service
Washington, DC

http://www.faa.gov/other_visit/aviation_industry/airline_operators/airline_safety/safo

A SAFO contains important safety information and may include recommended action. Besides the specific action recommended in a SAFO, an alternative action may be as effective in addressing the safety issue named in the SAFO. The contents of this document do not have the force and effect of law and are not meant to bind the public in any way. This document is intended only to provide clarity to the public regarding existing requirements under the law or agency policies.

Subject: COVID-19: Updated Interim Occupational Health and Safety Guidance for Air Carriers and Crews.

Purpose: This SAFO updates SAFO 20009 and provides updated interim occupational health and safety guidance by the Centers for Disease Control and Prevention (CDC) and the Federal Aviation Administration (FAA) for air carriers and crewmembers regarding Coronavirus Disease 2019 (COVID-19). The CDC and FAA are providing this additional occupational health and safety guidance for air carriers and their crews to reduce crewmembers' risk of exposure to COVID-19 and decrease the risk of transmission of COVID-19 on board aircraft and to destination communities through air travel.

Background: SARS-CoV-2, the virus that causes COVID-19, has spread throughout the world and to all States and territories of the United States (U.S.). Air carriers and crews conducting flight operations having a nexus to the United States, including both U.S. and foreign air carriers, should follow CDC's occupational health and safety guidance as outlined in the Appendix below.

Discussion: On January 30, 2020, the World Health Organization (WHO) declared that the outbreak of COVID-19 constituted a Public Health Emergency of International Concern (PHEIC). On January 31, 2020, the Secretary of Health and Human Services declared COVID-19 to be a public health emergency in the United States under section 319 of the Public Health Service Act.[1] On March 11, 2020, WHO characterized the outbreak of COVID-19 as a pandemic. On March 13, 2020, the President declared a national emergency concerning the COVID-19 outbreak.

Because air travel remains essential, including transportation of personnel and supplies necessary to support COVID-19 response and recovery efforts, it is critical to protect the health and safety of crews while ensuring that essential flight operations can continue. The FAA and CDC recommend that air carriers and crewmembers take precautions to avoid exposure of crewmembers to SARS-CoV-2. Crewmembers should not work while symptomatic with fever, cough, or shortness of breath, or other

[1] This public health emergency has been renewed several times since January, most recently on October 23, 2020.

Plaintiff's Exhibit 53

phe.gov

Renewal of Determination That A Public Health Emergency Exists

1 minute

As a result of the continued consequences of the Coronavirus Disease 2019 (COVID-19) pandemic, on this date and after consultation with public health officials as necessary, I, Xavier Becerra, Secretary of Health and Human Services, pursuant to the authority vested in me under section 319 of the Public Health Service Act, do hereby renew, effective October 18, 2021, the January 31, 2020, determination by former Secretary Alex M. Azar II, that he previously renewed on April 21, 2020, July 23, 2020, October 2, 2020, and January 7, 2021, and that I renewed on April 15, 2021 and July 19, 2021, that a public health emergency exists and has existed since January 27, 2020, nationwide.

October 15, 2021 ____________________ Date		/s/ ____________________ Xavier Becerra

- This page last reviewed: October 15, 2021

Plaintiff's Exhibit 54

whitehouse.gov

Executive Order on Promoting COVID-19 Safety in Domestic and International Travel | The White House

11-14 minutes

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Section 1. Policy. Science-based public health measures are critical to preventing the spread of coronavirus disease 2019 (COVID-19) by travelers within the United States and those who enter the country from abroad. The Centers for Disease Control and Prevention (CDC), the Surgeon General, and the National Institutes of Health have concluded that mask-wearing, physical distancing, appropriate ventilation, and timely testing can mitigate the risk of travelers spreading COVID-19. Accordingly, to save lives and allow all Americans, including the millions of people employed in the transportation industry, to travel and work safely, it is the policy of my Administration to implement these public health measures consistent with CDC guidelines on public modes of transportation and at ports of entry to the United States.

Sec. 2. Immediate Action to Require Mask-Wearing on Certain Domestic Modes of Transportation.

(a) Mask Requirement. The Secretary of Labor, the Secretary of Health and Human Services (HHS), the Secretary of Transportation (including through the Administrator of the Federal Aviation Administration (FAA)), the Secretary of Homeland Security (including through the Administrator of the Transportation Security Administration (TSA) and the Commandant of the United States Coast Guard), and the heads of any other executive departments and agencies (agencies) that have relevant regulatory authority (heads of agencies) shall immediately take action, to the extent appropriate and consistent with applicable law, to require masks to be worn in compliance with CDC guidelines in or on:

(i) airports;

(ii) commercial aircraft;

(iii) trains;

(iv) public maritime vessels, including ferries;

(v) intercity bus services; and

(vi) all forms of public transportation as defined in section 5302 of title 49, United States Code.

(b) Consultation. In implementing this section, the heads of agencies shall consult, as appropriate, with interested parties, including State, local, Tribal, and territorial officials; industry and union representatives from the transportation sector; and consumer representatives.

(c) Exceptions. The heads of agencies may make categorical or case-by-case exceptions to policies developed under this section, consistent with applicable law, to the extent that doing so is necessary or required by law. If the heads of agencies do make exceptions, they shall require alternative and appropriate safeguards, and shall document all exceptions in writing.

(d) Preemption. To the extent permitted by applicable law, the heads of agencies shall ensure that any action taken to implement this section does not preempt State, local, Tribal, and territorial laws or rules imposing public health measures that are more protective of public health than those required by the heads of agencies.

(e) Coordination. The Coordinator of the COVID-19 Response and Counselor to the President (COVID-19 Response Coordinator) shall coordinate the implementation of this section. The heads of agencies shall update the COVID-19 Response Coordinator on their progress in implementing this section, including any categorical exceptions established under subsection (c) of this section, within 7 days of the date of this order and regularly thereafter. The heads of agencies are encouraged to bring to the attention of the COVID-19 Response Coordinator any questions regarding the scope or implementation of this section.

Sec. 3. Action to Implement Additional Public Health Measures for Domestic Travel.

(a) Recommendations. The Secretary of Transportation (including through the Administrator of the FAA) and the Secretary of Homeland Security (including through the Administrator of the TSA and the Commandant of the Coast Guard), in consultation with the Director of CDC, shall promptly provide to the COVID-19 Response Coordinator recommendations concerning how their respective agencies may impose additional public health measures for domestic travel.

(b) Consultation. In implementing this section, the Secretary of Transportation and the Secretary of Homeland Security shall engage with interested parties, including State, local, Tribal, and territorial officials; industry and union representatives from the transportation sector; and consumer representatives.

Sec. 4. Support for State, Local, Tribal, and Territorial Authorities. The COVID-19 Response Coordinator, in coordination with the Secretary of Transportation and the heads of any other relevant agencies, shall promptly identify and inform agencies of options to incentivize, support, and encourage widespread mask-wearing and physical distancing on public modes of transportation, consistent with CDC guidelines and applicable law.

Sec. 5. International Travel.

(a) Policy. It is the policy of my Administration that, to the extent feasible, travelers seeking to enter the United States from a foreign country shall be:

(i) required to produce proof of a recent negative COVID-19 test prior to entry; and

(ii) required to comply with other applicable CDC guidelines concerning international travel, including recommended periods of self-quarantine or self-isolation after entry into the United States.

(b) Air Travel.

(i) The Secretary of HHS, including through the Director of CDC, and in coordination with the Secretary of Transportation (including through the Administrator of the FAA) and the Secretary of Homeland Security (including through the Administrator of the TSA), shall, within 14 days of the date of this order, assess the CDC order of January 12, 2021, regarding the requirement of a negative COVID-19 test result for airline passengers traveling into the United States, in light of subsection (a) of this section. Based on such assessment, the Secretary of HHS and the Secretary of Homeland Security shall take any further appropriate regulatory action, to the extent feasible and consistent with CDC guidelines and applicable law. Such assessment and regulatory action shall include consideration of:

(A) the timing and types of COVID-19 tests that should satisfy the negative test requirement, including consideration of additional testing immediately prior to departure;
(B) the proof of test results that travelers should be required to provide;
(C) the feasibility of implementing alternative and sufficiently protective public health measures, such as testing, self-quarantine, and self-isolation on arrival, for travelers entering the United States from countries where COVID-19 tests are inaccessible, particularly where such inaccessibility of tests would affect the ability of United States citizens and lawful permanent residents to return to the United States; and
(D) measures to prevent fraud.

(ii) The Secretary of HHS, in coordination with the Secretary of Transportation (including through the Administrator of the FAA) and the Secretary of Homeland Security (including through the Administrator of the TSA), shall promptly provide to the President, through the COVID-19 Response Coordinator, a plan for how the Secretary and other Federal Government actors could implement the policy stated in subsection (a) of this section with respect to CDC-recommended periods of self-quarantine or self-isolation after a flight to the United States from a foreign country, as he deems appropriate and consistent with applicable law. The plan shall identify agencies' tools and mechanisms to assist travelers in complying with such policy.

(iii) The Secretary of State, in consultation with the Secretary of HHS (including through the Director of CDC), the Secretary of Transportation (including through the Administrator of the FAA), and the Secretary of Homeland Security, shall seek to consult with foreign governments, the World Health Organization, the International Civil Aviation Organization, the International Air Transport Association, and any other relevant stakeholders to establish guidelines for public health measures associated with safe international travel, including on aircraft and at ports of entry. Any such guidelines should address quarantine, testing, COVID-19 vaccination, follow-up testing and symptom-monitoring, air filtration requirements, environmental decontamination standards, and contact tracing.

(c) Land Travel. The Secretary of State, in consultation with the Secretary of HHS, the Secretary of Transportation, the Secretary of Homeland Security, and the Director of CDC, shall immediately commence diplomatic outreach to the governments of Canada and Mexico regarding public health protocols for land ports of entry. Based on this diplomatic engagement, within 14 days of the date of this order, the Secretary of HHS (including through the Director of CDC), the Secretary of Transportation, and the Secretary of Homeland Security shall submit to the President a plan to implement appropriate public health measures at land ports of entry. The plan should implement CDC guidelines, consistent with applicable law, and take into account the operational considerations relevant to the different populations who enter the United States by land.

(d) Sea Travel. The Secretary of Homeland Security, through the Commandant of the Coast Guard and in consultation with the Secretary of HHS and the Director of CDC, shall, within 14 days of the date of this order, submit to the President a plan to implement appropriate public health measures at sea ports. The plan should implement CDC guidelines, consistent with applicable law, and take into account operational considerations.

(e) International Certificates of Vaccination or Prophylaxis. Consistent with applicable law, the Secretary of State, the Secretary of HHS, and the Secretary of Homeland Security (including through the Administrator of the TSA), in coordination with any relevant international organizations, shall assess the feasibility of linking COVID-19 vaccination to International Certificates of Vaccination or Prophylaxis (ICVP) and producing electronic versions of ICVPs.

(f) Coordination. The COVID-19 Response Coordinator, in consultation with the Assistant to the President for National Security Affairs and the Assistant to the President for Domestic Policy, shall coordinate the implementation of this section. The Secretary of State, the Secretary of HHS, the Secretary of Transportation, and the Secretary of Homeland Security shall update the COVID-19 Response Coordinator on their progress in implementing this section within 7 days of the date of this order and regularly thereafter. The heads of all agencies are encouraged to bring to the attention of the COVID-19 Response Coordinator any questions regarding the scope or implementation of this section.

Sec. 6. General Provisions. (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

JOSEPH R. BIDEN JR.

THE WHITE HOUSE,
January 21, 2021.

washingtonpost.com

Sneezed on, cussed at, ignored: Airline workers battle mask resistance with scant government backup

Michael Laris

13-17 minutes

Other passengers have verbally abused and taunted flight attendants trying to enforce airline mask requirements, treating the potentially lifesaving act as a pandemic game of cat-and-mouse. A loophole allowing the removal of masks while consuming food and beverages is a favorite dodge.

Asked to mask up, one passenger pulled out a large bag of popcorn and nibbled her way through it, kernel by kernel, stymieing the cabin crew for the length of the flight. Others blew off requests by chomping leisurely on apple slices, between occasional coughs, or lifting an empty plastic cup and declaring: "I am drinking!"

The displays of rule-bucking intransigence are described in more than 150 aviation safety reports filed with the federal government since the start of the pandemic and reviewed by The Washington Post. The reports provide an unguarded accounting of bad behavior by airline customers, something executives hit by a steep drop in travel and billions in pandemic-related losses are loath to share themselves.

Some reports raise safety concerns beyond the risk of coronavirus infection. A flight attendant reported being so busy seeking mask compliance that the employee couldn't safely reach a seat in time for landing.

One airline captain, distracted by mask concerns, descended to the wrong altitude. The repeated talk of problem passengers in Row 12 led the captain to mistakenly head toward 12,000 feet, not a higher altitude given by air traffic control to keep planes safely apart. The error was caught, and "there was no conflicting traffic," the captain wrote.

The Boeing 737 Max was grounded for 20 months following two crashes that killed 346 people. Now, after design changes, the aircraft is returning to service. (The Washington Post)

Some passengers are portrayed as oblivious, obstinate, foul-mouthed and, at times, dangerous. One called a flight attendant a "Nazi." Another "started to rant how the virus is a political hoax and that she doesn't wear a mask," a flight attendant reported.

With millions of passengers ignoring warnings from the Centers for Disease Control and Prevention to refrain from holiday travel, the reports offer an X-ray into the country's deeper failures against the coronavirus — and insights into the pitfalls and possibilities facing a new presidential administration.

While the White House under President Trump has, at times, been dismissive or hostile toward masks, President-elect Joe Biden is making a patriotic appeal to “mask up for 100 days,” whatever people’s politics. Biden has said he will sign an order on his first day requiring masks for “interstate travel on planes, trains and buses.” How well those efforts will work remains to be seen.

Experts in psychology and decision-making say hostility toward wearing masks, even within the shared confines of a passenger jet, has been fueled by politicization — but also by skewed incentives and inconsistent messaging.

“The reinforcement principles are backward,” said Paul Slovic, who studies the psychology of risk at the University of Oregon.

The usual signs of danger, and rewards for following potentially bothersome rules, are thrown off by a virus that is spread easily by people who don’t know they have it, Slovic said.

“You get an immediate benefit for not following the guidelines because you get to do what you want to do,” Slovic said. “And you don’t get punished for doing the wrong thing” because it’s not immediately clear who is being harmed.

The “squishiness of the requirement” to wear masks on planes also undermines the message that they are critical for public health, Slovic said. In contrast, he cites the rigid clarity of the ban on flying with a firearm. “It’s not, ‘You can carry it as long as you don’t use it,’ ” Slovic said.

But passengers are allowed to drop their masks to snack and sip beverages. “When you start opening it up to eating, the whole thing kind of weakens,” Slovic said.

Applying mask rules also worsens the already strained position of flight attendants, who are front-line enforcers even as they keep their usual safety responsibilities, experts said.

“Flight attendants are dealing with mask compliance issues on every single flight they work right now,” said Taylor Garland, spokeswoman for the Association of Flight Attendants-CWA, noting that those efforts range from friendly reminders to facing passengers “actively challenging the flight attendants’ authority.”

The Department of Transportation in October rejected a petition to require masks on airplanes, subways and other forms of transportation, with Secretary Elaine Chao’s general counsel saying the department “embraces the notion that there should be no more regulations than necessary.”

The nation’s aviation regulator has deferred to airlines on masks, with Federal Aviation Administration chief Stephen Dickson telling senators at a June hearing “we do not plan to provide an enforcement specifically on that issue.”

Such matters are more appropriately left to federal health authorities, Dickson argued. “As Secretary Chao has said, we believe that our space is in aviation safety, and their space is in public health,” Dickson said, referring to the CDC and other health officials.

Airline representatives say they take mask usage seriously and the overwhelming majority of customers comply. Some airlines have banned passengers for the length of the pandemic for refusing to mask up. Many have eliminated medical exemptions in their mask requirements.

“Of the hundreds of thousands of passengers who have flown with us, we have only needed to ban about 370 customers for not complying," United Airlines spokeswoman Leslie Scott said. Delta said its mask-related no-fly list includes about 600 people, despite carrying about 1 million people each week.

Resistance by some passengers prompted Alaska Airlines to begin issuing yellow cards, akin to the warnings in soccer, to problem passengers.

The initial yellow card said employees would file a report that could result in a passenger being suspended. A later version was more aggressive, saying continued defiance would lead to a flight ban "immediately upon landing," even if the customer had a connecting flight.

Alaska Airlines has barred 237 passengers since August, and "in more than half of these incidents we also canceled onward or returning travel," spokeswoman Cailee Olson said.

American Airlines declined to release numbers of banned customers, as did Southwest, which said in a statement it appreciates "the ongoing spirit of cooperation among customers and employees as we collectively take care of each other while striving to prevent the spread of COVID-19."

Yet a small, uncooperative minority can wreak outsize havoc, safety reports show.

The anonymous reports are collected in a National Aeronautics and Space Administration database, part of a program meant to increase aviation safety by encouraging employees to provide candid descriptions of emerging problems without fear of reprisal. Names of people filing the reports, and their airlines, are removed by NASA before they are made available to regulators at the FAA and the public.

NASA analysts screen the reports to weed out irrelevant filings and may call back filers to clarify safety points. But its analysts do not try to verify people's identities or the accuracy of the reports.

The database shows some fliers treat airline mask requirements as a seemingly asinine rule to evade, akin to sneaking a late look at text messages after phones are supposed to be in airplane mode. Passengers berate flight attendants about their noncompliant cabin mates. Some reports read like cries for help.

"It all has to stop," pleaded one flight attendant.

"In the future I would like to feel safe while doing my job," said another.

● A woman refused to wear her mask as the plane rolled away from the terminal, saying it made her ill, and the pilot pulled over temporarily to try to avoid returning to the gate. She continued to resist but finally agreed.

"As soon as we took off, she took it off again and kept it off the entire flight," the flight attendant reported.

● A man started down the aisle, pausing about 18 inches from a flight attendant.

"He sneezed directly in my face, making no attempt to cover his mouth, pull up his mask or turn towards the row 1 window," the employee wrote. The flight attendant, who was wearing a face covering, judged the act unintentional and tried to blot away the remnants.

● A woman propped her foot up and painted her toenails with her mask below her chin, despite several requests to wear it properly. After another passenger appealed for more to be done, the woman acquiesced, then loudly instructed the flight attendant to “go away!”

After landing, she cut in line to rush off the plane. “Although we understand the importance of wanting to retain customer loyalty, this kind of behavior should not be tolerated for the sake of one over an entire cabin of guests and employees,” the flight attendant wrote.

● An immunocompromised passenger was furious at the lack of enforcement as another customer snacked incessantly on chocolate. The concerned passenger then removed his mask to complain to the flight attendant.

● A passenger claimed discrimination, arguing he was singled out for enforcement because of his tattoos. “He said ‘I am complying, #%$^!’ His nostrils were clearly visible,” the flight attendant wrote.

● A pilot flouted the mask requirement with what appeared to be a passive-aggressive display, donning a flimsy, see-through veil described as useless for containing airborne particles.

● Flight attendants made an exception and allowed a distraught mother, whose daughter may have had a disability and screamed about the mask requirement, to remain on the plane. They tried cookies, which didn’t help, then moved the family to seats three rows from other passengers, who were supportive.

● A customer, after earlier warnings, stuck his mask-free head in the aisle during the safety demonstration, “making a total mockery out of me,” a flight attendant wrote. He repeated his taunt when the plane was fourth in line for takeoff. The captain turned around, and the man was taken off the plane.

The obstinacy cuts against basic health precautions. Experts in cabin air say masks are critical tools for safety. Cabin air is run through powerful filters, mixed with outside air and recirculated. But it takes several minutes for all air to be vented out of the cabin, giving the coronavirus and other viruses the opportunity to spread.

A Harvard study funded by the aviation industry said flying can be done with a relatively low risk of coronavirus infection if precautions are followed. It said masks are “perhaps the most essential layer” among measures to reduce transmission.

The study said removing masks to eat should be kept to an “absolute minimum,” and straws should be used when feasible. “When one passenger briefly removes a mask to eat or drink, other passengers in close proximity should keep their masks on,” researchers said.

Trump and some of his advisers, meanwhile, have stoked divisions over masks.

The president mocked Biden’s frequent mask use, presided over White House events that flouted mask guidelines and relied on a former pandemic adviser who wrongly argued masks were ineffective. The White House also blocked a nationwide order, drafted by the CDC, that would have required masks on all forms of public transportation.

“Masks have been made a political issue from the start of the pandemic, and people don’t believe they need to wear them,” said Garland, whose union represents about 50,000 flight attendants.

“We do not have a president who tells people to wear a mask, and the federal government, not just in aviation but across the board, has declined to mandate it in any way, shape or form,” she added, saying her members are eager to see a Biden administration set a different tone.

An FAA spokesman declined to answer questions about the risks involved with passengers refusing to wear masks.

After inquiries from The Post about enforcement, the agency distributed a news release touting its role in pursuing civil penalties in two assault cases but reiterated that “the failure to wear a face covering is not itself a federal violation.”

The cases show how mask disputes can escalate.

On an Allegiant Air flight in August, a passenger hit a flight attendant, yelled obscenities at him and grabbed his phone as he described a mask-related dispute to the captain, according to the FAA. The agency said it is pursuing a $15,000 civil penalty for assault and interfering with a flight attendant.

Allegiant declined to say whether anyone was arrested or charged.

On a SkyWest Airlines flight to Chicago in August, a passenger took off a mask, “continually bothered” fellow customers and “at one point, grabbed a flight attendant’s buttock as she walked by the passenger’s row of seats,” according to the FAA, which is seeking a $7,500 penalty.

Beyond addressing such extreme cases, some outside experts say federal and corporate leaders have fallen short.

“Both industry and government have failed the people on the front line who need to administer these rules,” said Baruch Fischhoff, a psychologist and professor at Carnegie Mellon University who researches decision-making.

Politics often has driven responses to the pandemic, while critical public health communication on things like masks has not been tested to make sure it hits the right notes or is convincing, Fischhoff said. “Neither have fulfilled that responsibility for clear, consistent, tested communications,” he said.

Fischhoff said that with 330 million people in the United States, it’s not surprising the safety reports received by NASA reveal examples of poor behavior.

“Part of the reason they stand out is, I think, the vast majority of people are polite and civil to one another,” Fischhoff said. Still, the reports probably represent a dramatic undercount because it takes time and initiative for busy employees to file them.

“If you see 100, there are probably 1,000 or 10,000. This is a widespread enough phenomenon that it needs to be taken seriously,” he said. “You have to give credit to people who lodge just complaints and recognize they’re just a fraction of the people who are observing things that threaten our health and our economy.”

Plaintiff's Exhibit 56

Determination of a National Emergency Requiring Actions to Protect the Safety of Americans Using and Employed by the Transportation System

As reflected in numerous determinations by the Executive Branch, including the President's March 13, 2020 determination that the outbreak of Coronavirus Disease 2019 (COVID-19) constitutes a "national emergency" under the National Emergencies Act and the nationwide public health emergency declared by the Secretary of Health and Human Services on January 31, 2020, the COVID-19 pandemic continues to pose a threat to our health and security. On January 15, 2021, the Centers for Disease Control and Prevention (CDC) updated their information to account for several new strains of COVID-19, including variant B.1.1.7 from the United Kingdom, variant B.1.351 from South Africa, and variant B.1.1.28.1 from Brazil. As of January 20, 2021, the United States has experienced more than 24 million confirmed COVID-19 cases and more than 400,000 COVID-19 deaths. The CDC, the Surgeon General, and the National Institutes of Health have concluded that mask-wearing, physical distancing, appropriate ventilation, and timely testing can mitigate the risk of travelers spreading COVID-19. On January 21, 2021, the President issued the *Executive Order on Promoting COVID-19 Safety in Domestic and International Travel*. The purpose of this Executive Order is to save lives and allow all Americans, including the millions of people employed in the transportation industry, to travel and work safely. Further, on January 25, 2021 the President issued a *Proclamation on the Suspension of Entry as Immigrants and Non-Immigrants of Certain Additional Persons Who Pose a Risk of Transmitting Coronavirus Disease* whereby he reinstituted travel restriction for individuals traveling to the United States from the United Kingdom, Ireland, the Schengen Area, and instituted restrictions for South Africa.

In the light of these circumstances and direction from the President, and after consultation with public health officials, I, David P. Pekoske, Acting Secretary of Homeland Security, pursuant to the authority vested in me under section 101 of the Aviation and Transportation Security Act (ATSA), as codified at section 114(g) of title 49, United States Code (U.S.C.) do hereby determine that a national emergency exists and am directing the Transportation Security Administration to take actions consistent with the authorities in ATSA as codified at 49 U.S.C. sections 106(m) and 114(f), (g), (l), and (m) to implement the Executive Order to promote safety in and secure the transportation system. This includes supporting the CDC in the enforcement of any orders or other requirements necessary to protect the transportation system, including passengers and employees, from COVID-19 and to mitigate the spread of COVID-19 through the transportation system, to the extent appropriate and consistent with applicable law. I specifically direct the Transportation Security Administration to use its authority to accept the services of, provide services to, or otherwise cooperate with other federal agencies, including through the implementation of countermeasures with appropriate departments, agencies, and instrumentalities of the United States in order to address a threat to transportation, recognizing that such threat may involve passenger and employee safety.

David P. Pekoske 1/27/2021

David P. Pekoske

Acting Secretary

Department of Homeland Security

Plaintiff's Exhibit 57

The rapidly changing nature of the pandemic requires not only that CDC act swiftly, but also deftly to ensure that its actions are commensurate with the threat. This necessarily involves assessing evolving conditions that inform CDC's determinations.

The conditions that existed on September 4, 2020 have only worsened. As of January 21, 2021, there have been over 24,400,000 cases and over 400,000 deaths. Data collected by Princeton University show that eviction filings are occurring; it is therefore expected that large numbers of evictions would be processed if the Order were to expire. [*https://evictionlab.org/eviction-tracking*]. Without this Order, there is every reason to expect that evictions will increase significantly, resulting in further spread of COVID–19. It is imperative is to act quickly to protect the public health, and it would be impracticable and contrary to the public interest to delay the issuance and effective date of the Order pending notice-and-comment rulemaking.

Similarly, if this Order qualifies as a rule under the APA, the Office of Information and Regulatory Affairs (OIRA) has determined that it would be a major rule under the Congressional Review Act (CRA). But there would not be a delay in its effective date. The agency has determined that for the same reasons, there would be good cause under the CRA to make the requirements herein effective immediately

If any provision of this Order, or the application of any provision to any persons, entities, or circumstances, shall be held invalid, the remainder of the provisions, or the application of such provisions to any persons, entities, or circumstances other than those to which it is held invalid, shall remain valid and in effect.

This Order shall be enforced by federal authorities and cooperating state and local authorities through the provisions of 18 U.S.C. 3559, 3571; 42 U.S.C. 243, 268, 271; and 42 CFR 70.18. However, this Order has no effect on the contractual obligations of renters to pay rent and shall not preclude charging or collecting fees, penalties, or interest as a result of the failure to pay rent or other housing payment on a timely basis, under the terms of any applicable contract.

Criminal Penalties

Under 18 U.S.C. 3559, 3571; 42 U.S.C. 271; and 42 CFR 70.18, a person violating this Order may be subject to a fine of no more than $100,000 if the violation does not result in a death, or a fine of no more than $250,000 if the violation results in a death, or as otherwise provided by law. An organization violating this Order may be subject to a fine of no more than $200,000 per event if the violation does not result in a death or $500,000 per event if the violation results in a death or as otherwise provided by law. The U.S. Department of Justice may initiate criminal proceedings as appropriate seeking imposition of these criminal penalties.

Notice to Cooperating State and Local Officials

Under 42 U.S.C. 243, the U.S. Department of Health and Human Services is authorized to cooperate with and aid state and local authorities in the enforcement of their quarantine and other health regulations and to accept state and local assistance in the enforcement of Federal quarantine rules and regulations, including in the enforcement of this Order.

Notice of Available Federal Resources

While this Order to prevent eviction is effectuated to protect the public health, the states and units of local government are reminded that the Federal Government has deployed unprecedented resources to address the pandemic, including housing assistance.

The Department of Housing and Urban Development (HUD) has informed CDC that all HUD grantees—states, cities, communities, and nonprofits—who received Emergency Solutions Grants (ESG) or Community Development Block Grant (CDBG) funds under the CARES Act may use these funds to provide temporary rental assistance, homelessness prevention, or other aid to individuals who are experiencing financial hardship because of the pandemic and are at risk of being evicted, consistent with applicable laws, regulations, and guidance.

HUD has further informed CDC that:

HUD's grantees and partners play a critical role in prioritizing efforts to support this goal. As grantees decide how to deploy CDBG–CV and ESG–CV funds provided by the CARES Act, all communities should assess what resources have already been allocated to prevent evictions and homelessness through temporary rental assistance and homelessness prevention, particularly to the most vulnerable households.

HUD stands at the ready to support American communities take these steps to reduce the spread of COVID–19 and maintain economic prosperity. Where gaps are identified, grantees should coordinate across available Federal, non-Federal, and philanthropic funds to ensure these critical needs are sufficiently addressed and utilize HUD 's technical assistance to design and implement programs to support a coordinated response to eviction prevention needs. For program support, including technical assistance, please visit *www.hudexchange.info/program-support.* For further information on HUD resources, tools, and guidance available to respond to the COVID–19 pandemic, state and local officials are directed to visit *https://www.hud.gov/coronavirus.* These tools include toolkits for Public Housing Authorities and Housing Choice Voucher landlords related to housing stability and eviction prevention, as well as similar guidance for owners and renters in HUD-assisted multifamily properties.

Similarly, the Department of the Treasury has informed CDC that the funds allocated through the Coronavirus Relief Fund and the Emergency Rental Assistance Program may be used to fund rental assistance programs to prevent eviction. Visit *https://home.treasury.gov/policy-issues/cares/state-and-local-governments* for more information about the Coronavirus Relief Fund and *https://home.treasury.gov/policy-issues/cares/emergency-rental-assistance-program* for more information about the Emergency Rental Assistance Program..

Effective Date

This Order is effective on January 31, 2021 and will remain in effect, unless extended, modified, or rescinded, through March 31, 2021.

Authority

The authority for this Order is Section 361 of the Public Health Service Act (42 U.S.C. 264) and 42 CFR 70.2.

Dated: January 29, 2021.

Sherri Berger

Acting Chief of Staff, Centers for Disease Control and Prevention.

[FR Doc. 2021–02243 Filed 1–29–21; 4:15 pm]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Requirement for Persons To Wear Masks While on Conveyances and at Transportation Hubs

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of Agency Order.

SUMMARY: The Centers for Disease Control and Prevention (CDC), a component of the U.S. Department of Health and Human Services (HHS), announces an Agency Order requiring persons to wear masks over the mouth and nose when traveling on any conveyance (*e.g.,* airplanes, trains, subways, buses, taxis, ride-shares, ferries, ships, trolleys, and cable cars) into or within the United States. A person must also wear a mask on any conveyance departing from the United States until the conveyance reaches its foreign destination. Additionally, a person must wear a mask while at any transportation hub within the United States (*e.g.,* airport, bus terminal, marina, train station, seaport or other port, subway station, or any other area that provides transportation within the United States). Furthermore, operators of conveyances and transportation hubs must use best efforts to ensure that persons wear masks as required by this Order.

DATES: This Order takes effect at 11:59 p.m. Monday February 1, 2021.

FOR FURTHER INFORMATION CONTACT: Jennifer Buigut, Division of Global Migration and Quarantine, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H16–4, Atlanta, GA 30329. Email: *dgmqpolicyoffice@cdc.gov.*

SUPPLEMENTARY INFORMATION: The virus that causes COVID–19 spreads very easily and sustainably between people who are in close contact with one another (within about 6 feet) mainly through respiratory droplets produced when an infected person coughs, sneezes, or talks. These droplets can land in the mouths, eyes, or noses of people who are nearby and possibly be inhaled into the lungs. Some people without symptoms also spread the virus. In general, the more closely a person interacts with others and the longer that interaction, the higher the risk of COVID–19 spread.

This Order is issued to preserve human life; maintain a safe and operating transportation system; mitigate the further introduction, transmission, and spread of COVID–19 into the United States and from one state or territory into any other state or territory; and support response efforts to COVID–19 at the Federal, state, local, territorial, and tribal level.

Appropriately worn masks reduce the spread of COVID–19—particularly given the evidence of pre-symptomatic and asymptomatic transmission of COVID–19. Masks are most likely to reduce the spread of COVID–19 when they are widely used by people in public settings. Using masks along with other preventive measures, including social distancing, frequent handwashing, and cleaning and disinfecting frequently touched surfaces, is one of the most effective strategies available for reducing COVID–19 transmission.

This Order will remain in effect unless modified or rescinded based on specific public health or other considerations, or until the Secretary of Health and Human Services rescinds the determination under section 319 of the Public Health Service Act (42 U.S.C. 247d) that a public health emergency exists.

A copy of the Order is provided below and a copy of the signed order can be found at *https://www.cdc.gov/quarantine/masks/mask-travel-guidance.html*

CENTERS FOR DISEASE CONTROL AND PREVENTION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

ORDER UNDER SECTION 361

OF THE PUBLIC HEALTH SERVICE ACT (42 U.S.C. 264)

AND 42 CODE OF FEDERAL REGULATIONS 70.2, 71.31(b), 71.32(b)

REQUIREMENT FOR PERSONS TO WEAR MASKS

WHILE ON CONVEYANCES AND AT TRANSPORTATION HUBS

SUMMARY:

Notice and Order; and subject to the limitations under ''Applicability,'' pursuant to 42 U.S.C. 264(a) and 42 CFR 70.2, 71.31(b), and 71.32(b):

(1) Persons [1] must wear [2] masks over the mouth and nose when traveling on conveyances into and within the United States. Persons must also wear masks at transportation hubs as defined in this Order.

(2) A conveyance operator transporting persons into and within the United States [3] must require all persons onboard to wear masks for the duration of travel.

(3) A conveyance operators operating a conveyance arriving at or departing from a U.S. port of entry must require all persons on board to wear masks for the duration of travel as a condition of controlled free pratique.[4]

(4) Conveyance operators must use best efforts to ensure that any person on the conveyance wears a mask when boarding, disembarking, and for the duration of travel. Best efforts include:

• Boarding only those persons who wear masks;

• instructing persons that Federal law requires wearing a mask on the conveyance and failure to comply constitutes a violation of Federal law;

• monitoring persons onboard the conveyance for anyone who is not wearing a mask and seeking compliance from such persons;

• at the earliest opportunity, disembarking any person who refuses to comply; and

• providing persons with prominent and adequate notice to facilitate awareness and compliance of the requirement of this Order to wear a mask; best practices may include, if feasible, advance notifications on digital platforms, such as on apps, websites, or email; posted signage in multiple languages with illustrations; printing the requirement on transit tickets; or other methods as appropriate.

(5) Operators of transportation hubs must use best efforts to ensure that any person entering or on the premises of the transportation hub wears a mask. Best efforts include:

• Allowing entry only to those persons who wear masks;

• instructing persons that Federal law requires wearing a mask in the transportation hub and failure to comply constitutes a violation of Federal law;

• monitoring persons on the premises of the transportation hub for anyone who is not wearing a mask and seeking compliance from such persons;

• at the earliest opportunity, removing any person who refuses to comply from the premises of the transportation hub; and

• providing persons with prominent and adequate notice to facilitate awareness and compliance with the requirement of this Order to wear a mask; best practices may include, if feasible, advance notifications on digital platforms, such as on apps, websites, or

[1] As used in this Order, ''persons'' includes travelers (*i.e.,* passengers and crew), conveyance operators, and any workers or service providers in the transportation hub.

[2] To ''wear a mask'' means to wear a mask over the nose and mouth.

[3] This includes international, interstate, or intrastate waterways, subject to the jurisdiction of the United States.

[4] As a condition of this controlled free pratique to commence or continue operations in the United States, conveyance operators must additionally require all persons to wear masks on board conveyances departing from the United States and for the duration of their travel until the conveyance arrives at the foreign destination if at any time any of the persons on the conveyance (passengers, crew, or conveyance operators) will return to the United States while this Order remains in effect. This precaution must be followed regardless of scheduled itinerary.

email; posted signage in multiple languages with illustrations; printing the requirement on transit tickets; or other methods as appropriate.

DEFINITIONS:

Controlled free pratique shall have the same definition as under 42 CFR 71.1, meaning ''permission for a carrier to enter a U.S. port, disembark, and begin operation under certain stipulated conditions.''

Conveyance shall have the same definition as under 42 CFR 70.1, meaning ''an aircraft, train, road vehicle,[5] vessel . . . or other means of transport, including military.'' Included in the definition of ''conveyance'' is the term ''carrier'' which under 42 CFR 71.1 has the same definition as conveyance under 42 CFR 70.1.

Conveyance operator means an individual operating a conveyance and an individual or organization causing or authorizing the operation of a conveyance.

Mask means a material covering the nose and mouth of the wearer, excluding face shields.[6]

Interstate traffic shall have the same definition as under 42 CFR 70.1, meaning

''(1):

(i) The movement of any conveyance or the transportation of persons or property, including any portion of such movement or transportation that is entirely within a state or possession—

(ii) From a point of origin in any state or possession to a point of destination in any other state or possession; or

(iii) Between a point of origin and a point of destination in the same state or possession but through any other state, possession, or contiguous foreign country.

(2) Interstate traffic does not include the following:

(i) The movement of any conveyance which is solely for the purpose of unloading persons or property transported from a foreign country or loading persons or property for transportation to a foreign country.

(ii) The movement of any conveyance which is solely for the purpose of effecting its repair, reconstruction, rehabilitation, or storage.''

Intrastate traffic means the movement of any conveyance or the transportation or movement of persons occurring solely within the boundaries of a state or territory, or on tribal land.

Possession shall have the same definition as under 42 CFR 70.1 and 71.1, meaning a ''U.S. territory.''

State shall have the same definition as under 42 CFR 70.1, meaning ''any of the 50 states, plus the District of Columbia.''

Territory shall have the same definition as ''U.S. territory'' under 42 CFR 70.1 and 71.1, meaning ''any territory (also known as possessions) of the United States, including American Samoa, Guam, the [Commonwealth of the] Northern Mariana Islands, the Commonwealth of Puerto Rico, and the U.S. Virgin Islands.''

Transportation hub means any airport, bus terminal, marina, seaport or other port, subway station, terminal (including any fixed facility at which passengers are picked-up or discharged), train station, U.S. port of entry, or any other location that provides transportation subject to the jurisdiction of the United States.

Transportation hub operator means an individual operating a transportation hub and an individual or organization causing or authorizing the operation of a transportation hub.

U.S. port shall have the same definition as under 42 CFR 71.1, meaning any ''seaport, airport, or border crossing point under the control of the United States.''

STATEMENT OF INTENT:

This Order shall be interpreted and implemented in a manner as to achieve the following objectives:

- Preservation of human life;
- Maintaining a safe and secure operating transportation system;
- Mitigating the further introduction, transmission, and spread of COVID–19 into the United States and from one state or territory into any other state or territory; and
- Supporting response efforts to COVID–19 at the Federal, state, local, territorial, and tribal levels.

APPLICABILITY:

This Order shall not apply within any state, locality, territory, or area under the jurisdiction of a Tribe that (1) requires a person to wear a mask on conveyances; (2) requires a person to wear a mask at transportation hubs; and (3) requires conveyances to transport only persons wearing masks. Such requirements must provide the same level of public health protection as—or greater protection than—the requirements listed herein.

In addition, the requirement to wear a mask shall not apply under the following circumstances:

- While eating, drinking, or taking medication, for brief periods;
- While communicating with a person who is hearing impaired when the ability to see the mouth is essential for communication;
- If, on an aircraft, wearing of oxygen masks is needed because of loss of cabin pressure or other event affecting aircraft ventilation;
- If unconscious (for reasons other than sleeping), incapacitated, unable to be awakened, or otherwise unable to remove the mask without assistance;[7] or
- When necessary to temporarily remove the mask to verify one's identity such as during Transportation Security Administration screening or when asked to do so by the ticket or gate agent or any law enforcement official.

This Order exempts the following categories of persons:[8]

- A child under the age of 2 years;
- A person with a disability who cannot wear a mask, or cannot safely wear a mask, because of the disability as defined by the Americans with Disabilities Act (42 U.S.C. 12101 *et seq.*).[9]

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[5] This includes rideshares meaning arrangements where passengers travel in a privately owned road vehicle driven by its owner in connection with a fee or service.

[6] A properly worn mask completely covers the nose and mouth of the wearer. A mask should be secured to the head, including with ties or ear loops. A mask should fit snugly but comfortably against the side of the face. Masks do not include face shields. Masks can be either manufactured or homemade and should be a solid piece of material without slits, exhalation valves, or punctures. Medical masks and N–95 respirators fulfill the requirements of this Order. CDC guidance for attributes of acceptable masks in the context of this Order is available at: *https://www.cdc.gov/quarantine/masks/mask-travel-guidance.html*.

[7] Persons who are experiencing difficulty breathing or shortness of breath or are feeling winded may remove the mask temporarily until able to resume normal breathing with the mask. Persons who are vomiting should remove the mask until vomiting ceases. Persons with acute illness may remove the mask if it interferes with necessary medical care such as supplemental oxygen administered via an oxygen mask.

[8] Operators of conveyances or transportation hubs may impose requirements, or conditions for carriage, on persons requesting an exemption from the requirement to wear a mask, including medical consultation by a third party, medical documentation by a licensed medical provider, and/or other information as determined by the operator, as well as require evidence that the person does not have COVID–19 such as a negative result from a SARS–CoV–2 viral test or documentation of recovery from COVID–19. CDC definitions for SARS-CoV–2 viral test and documentation of recovery are available in the Frequently Asked Questions at: *https://www.cdc.gov/coronavirus/2019-ncov/travelers/testing-international-air-travelers.html.* Operators may also impose additional protective measures that improve the ability of a person eligible for exemption to maintain social distance (separation from others by 6 feet), such as scheduling travel at less crowded times or on less crowded conveyances, or seating or otherwise situating the individual in a less crowded section of the conveyance or transportation hub. Operators may further require that persons seeking exemption from the requirement to wear a mask request an accommodation in advance.

[9] This is a narrow exception that includes a person with a disability who cannot wear a mask

Continued

• A person for whom wearing a mask would create a risk to workplace health, safety, or job duty as determined by the relevant workplace safety guidelines or federal regulations.

This Order exempts the following categories of conveyances, including persons on board such conveyances:

• Private conveyances operated solely for personal, non-commercial use;

• Commercial motor vehicles or trucks as these terms are defined in 49 CFR 390.5, if the driver is the sole occupant of the vehicle or truck;

• Conveyances operated or chartered by the U.S. military services provided that such conveyance operators observe Department of Defense precautions to prevent the transmission of COVID–19 that are equivalent to the precautions in this Order.

This Order applies to persons on conveyances and at transportation hubs directly operated by U.S. state, local, territorial, or tribal government authorities, as well as the operators themselves. U.S. state, local, territorial, or tribal government authorities directly operating conveyances and transportation hubs may be subject to additional federal authorities or actions, and are encouraged to implement additional measures enforcing the provisions of this Order regarding persons traveling onboard conveyances and at transportation hubs operated by these government entities.

To the extent permitted by law, and consistent with President Biden's Executive Order of January 21, 2021 (Promoting COVID–19 Safety in Domestic and International Travel),[10] Federal agencies are required to implement additional measures enforcing the provisions of this Order.

BACKGROUND:

There is currently a pandemic of respiratory disease (coronavirus disease 2019 or ''COVID–19'') caused by a novel coronavirus (SARS–COV–2). As of January 27, 2021, there have been 99,638,507 confirmed cases of COVID–19 globally, resulting in more than 2,141,000 deaths. As of January 27, 2021, there have been over 25,000,000 cases identified in the United States and over 415,000 deaths due to the disease. New SARS–CoV–2 variants have emerged in recent weeks, including at least one with evidence of increased transmissibility.[11]

The virus that causes COVID–19 spreads very easily and sustainably between people who are in close contact with one another (within about 6 feet) mainly through respiratory droplets produced when an infected person coughs, sneezes, or talks. These droplets can land in the mouths, eyes, or noses of people who are nearby and possibly be inhaled into the lungs. Infected people without symptoms (asymptomatic) and those in whom symptoms have not yet developed (pre-symptomatic) can also spread the virus. In general, the more closely an infected person interacts with others and the longer those interactions, the higher the risk of COVID–19 spread. COVID–19 may be transmitted by touching surfaces or objects that have the virus on them and then touching one's own or another person's eyes, nose, or mouth.

Masks help prevent people who have COVID–19, including those who are pre-symptomatic or asymptomatic, from spreading the virus to others.[12] Masks are primarily intended to reduce the emission of virus-laden droplets, *i.e.,* they act as source control by blocking exhaled virus.[13] This is especially relevant for asymptomatic or pre-symptomatic infected wearers who feel well and may be unaware of their infectiousness to others, and who are estimated to account for more than 50% of transmissions.[14 15] Masks also provide personal protection to the wearer by reducing inhalation of these droplets, *i.e.,* they reduce wearers' exposure through filtration.[16] The community benefit of wearing masks for SARS–CoV–2 control is due to the combination of these effects; individual prevention benefit increases with increasing numbers of people using masks consistently and correctly.

Appropriately worn masks reduce the spread of COVID–19—particularly given the evidence of pre-symptomatic and asymptomatic transmission of COVID–19. Seven studies have confirmed the benefit of universal masking in community level analyses: in a unified hospital system,[17] a German city,[18] a U.S. State,[19] a panel of 15 U.S. States and Washington, DC,[20 21] as well as both Canada [22] and the United States [23] nationally. Each analysis demonstrated that, following directives from organizational and political leadership for universal masking, new infections fell significantly. Two of these studies [24 25] and an additional analysis of data from 200 countries that included localities within the United States [26] also demonstrated reductions in

for reasons related to the disability. CDC will issue additional guidance regarding persons who cannot wear a mask under this exemption. *https://www.cdc.gov/quarantine/masks/mask-travel-guidance.html.*

[10] *https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/21/executive-order-promoting-covid-19-safety-in-domestic-and-international-travel/.*

[11] *https://www.cdc.gov/coronavirus/2019-ncov/more/science-and-research/scientific-brief-emerging-variants.html.*

[12] *https://www.cdc.gov/coronavirus/2019-ncov/more/masking-science-sars-cov2.html.*

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[14] Moghadas SM, Fitzpatrick MC, Sah P, et al. The implications of silent transmission for the control of COVID–19 outbreaks. *Proc Natl Acad Sci U S A.* 2020;117(30):17513–17515.10.1073/pnas.2008373117. *https://www.ncbi.nlm.nih.gov/pubmed/32632012.*

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[22] Karaivanov A., Lu SE, Shigeoka H., Chen C., Pamplona S. *Face Masks, Public Policies and Slowing the Spread of Covid–19: Evidence from Canada* National Bureau of Economic Research 2020. Working Paper 27891. *http://www.nber.org/papers/w27891.*

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[26] Leffler CT, Ing EB, Lykins JD, Hogan MC, McKeown CA, Grzybowski A. Association of country-wide coronavirus mortality with demographics, testing, lockdowns, and public wearing of masks. Am J Trop Med Hyg. 2020 Dec;103(6):2400–2411. doi: 10.4269/ajtmh.20–1015. Epub 2020 Oct 26.

mortality. An economic analysis using U.S. data found that, given these effects, increasing universal masking by 15% could prevent the need for lockdowns and reduce associated losses of up to $1 trillion or about 5% of gross domestic product.[27]

Wearing a mask especially helps protect those at increased risk of severe illness from COVID–19 [28] and workers who frequently come into close contact with other people (*e.g.,* at transportation hubs). Masks are most likely to reduce the spread of COVID–19 when they are widely used by people in public settings. Using masks along with other preventive measures, including social distancing, frequent handwashing, and cleaning and disinfecting frequently touched surfaces, is one of the most effective strategies available for reducing COVID–19 transmission.

Traveling on multi-person conveyances increases a person's risk of getting and spreading COVID–19 by bringing persons in close contact with others, often for prolonged periods, and exposing them to frequently touched surfaces. Air travel often requires spending time in security lines and crowded airport terminals. Social distancing may be difficult if not impossible on flights. People may not be able to distance themselves by the recommended 6 feet from individuals seated nearby or those standing in or passing through the aircraft's aisles. Travel by bus, train, vessel, and other conveyances used for international, interstate, or intrastate transportation pose similar challenges.

Intrastate transmission of the virus has led to—and continues to lead to—interstate and international spread of the virus, particularly on public conveyances and in travel hubs, where passengers who may themselves be traveling only within their state or territory commonly interact with others traveling between states or territories or internationally. Some states, territories, Tribes, and local public health authorities have imposed mask-wearing requirements within their jurisdictional boundaries to protect public health.[29] Any state or territory without sufficient mask-wearing requirements for transportation systems within its jurisdiction has not taken adequate measures to prevent the spread of COVID–19 from such state or territory to any other state or territory. That determination is based on, *inter alia,* the rapid and continuing transmission of the virus across all states and territories and across most of the world. Furthermore, given how interconnected most transportation systems are across the nation and the world, local transmission can grow even more quickly into interstate and international transmission when infected persons travel on non-personal conveyances without wearing a mask and with others who are not wearing masks.

Therefore, I have determined that the mask-wearing requirements in this Order are reasonably necessary to prevent the further introduction, transmission, or spread of COVID–19 into the United States and among the states and territories. Individuals traveling into or departing from the United States, traveling interstate, or traveling entirely intrastate, conveyance operators that transport such individuals, and transportation hub operators that facilitate such transportation, must comply with the mask-wearing requirements set forth in this Order.

America's transportation systems are essential. Not only are they essential for public health, they are also essential for America's economy and other bedrocks of American life. Those transportation systems carry life-saving medical supplies and medical providers into and across the nation to our hospitals, nursing homes, and physicians' offices. Trains, planes, ships, and automobiles bring food and other essentials to our communities and to our homes. Buses bring America's children and teachers to school. Buses, trains, and subways, bring America's workforce to their jobs.

Requiring masks on our transportation systems will protect Americans and provide confidence that we can once again travel safely even during this pandemic. Therefore, requiring masks will help us control this pandemic and aid in re-opening America's economy.

The United States and countries around the world are currently embarking on efforts to vaccinate their populations, starting with healthcare personnel and other essential workers at increased risk of exposure to SARS–CoV–2 and people at increased risk for severe illness from the virus. While vaccines are highly effective at preventing severe or symptomatic COVID–19, at this time there is limited information on how much the available COVID–19 vaccines may reduce transmission in the general population and how long protection lasts.[30] Therefore, this mask requirement, as well as CDC recommendations to prevent spread of COVID–19,[31] additionally apply to vaccinated persons. Similarly, CDC recommends that people who have recovered from COVID–19 continue to take precautions to protect themselves and others, including wearing masks; [32] therefore, this mask requirement also applies to people who have recovered from COVID–19.

ACTION:

Until further notice, under 42 U.S.C. 264(a) and 42 CFR 70.2, 71.31(b), and 71.32(b), unless excluded or exempted as set forth in this Order, a person must wear a mask while boarding, disembarking, and traveling on any conveyance into or within the United States. A person must also wear a mask at any transportation hub that provides transportation within the United States.

Conveyance operators traveling into or within the United States may transport only persons wearing masks and must use best efforts to ensure that masks are worn when embarking, disembarking, and throughout the duration of travel. Operators of transportation hubs must use best efforts to ensure that any person entering or on the premises of the transportation hub wears a mask.

As a condition of receiving controlled free pratique under 42 CFR 71.31(b) to enter a U.S. port, disembark passengers, and begin operations at any U.S. port of entry, conveyances arriving into the United States must require persons to wear masks while boarding, disembarking, and for the duration of travel. Conveyance operators must also require all persons to wear masks while boarding and for the duration of their travel on board conveyances departing from the United States until the conveyance arrives at the foreign destination, if at any time any of the persons onboard (passengers, crew, or conveyance operators) will return to the United States while this Order remains in effect. These travel conditions are

[27] Hatzius J, Struyven D, Rosenberg I. Face Masks and GDP. *Goldman Sachs Research https://www.goldmansachs.com/insights/pages/face-masks-and-gdp.html.* Accessed January 20, 2021.

[28] *https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/index.html.*

[29] Based on internet sources, 37 states plus DC and Puerto Rico mandate the wearing of masks in public. Among the jurisdictions that have imposed mask mandates, variations in requirements exist. For example, exemptions for children range in cutoff age from 2 to 12, but masks are generally required in indoor public spaces such as restaurants and stores, on public transit and ride-hailing services, and outdoors when unable to maintain 6 feet of distance from others. *See https://www.aarp.org/health/healthy-living/info-2020/states-mask-mandates-coronavirus.html* (accessed January 28, 2021).

[30] *https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html.*

[31] *https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html.*

[32] *https://www.cdc.gov/coronavirus/2019-ncov/hcp/duration-isolation.html.*

necessary to mitigate the harm of further introduction of COVID–19 into the United States.

Requiring a properly worn mask is a reasonable and necessary measure to prevent the introduction, transmission and spread of COVID–19 into the United States and among the states and territories under 42 U.S.C. 264(a) and 42 CFR 71.32(b). Among other benefits, masks help prevent dispersal of an infected person's respiratory droplets that carry the virus. That precaution helps prevent droplets from landing in the eye, mouth, or nose or possibly being inhaled into the lungs of an uninfected person, or from landing on a surface or object that an uninfected person may then touch and then touch his or her own or another's eyes, nose, or mouth. Masks also provide some protection to the wearer by helping reduce inhalation of respiratory droplets.

This Order shall not apply within any state, locality, territory, or area under the jurisdiction of a Tribe, where the controlling governmental authority: (1) Requires a person to wear a mask on conveyances; (2) requires a person to wear a mask at transportation hubs; and (3) requires conveyances to transport only persons wearing masks. Those requirements must provide the same level of public health protection as—or greater protection than—the requirements listed herein.

In accordance with 42 U.S.C. 264(e), state, local, territorial, and tribal authorities may impose additional requirements that provide greater public health protection and are more restrictive than the requirements in this Order. Consistent with other federal, state, or local legal requirements, this Order does not preclude operators of conveyances or transportation hubs from imposing additional requirements, or conditions for carriage, that provide greater public health protection and are more restrictive than the requirements in this Order (*e.g.,* requiring a negative result from a SARS–CoV–2 viral test or documentation of recovery from COVID–19 or imposing requirements for social distancing or other recommended protective measures).

This Order is not a rule within the meaning of the Administrative Procedure Act (''APA'') but rather is an emergency action taken under the existing authority of 42 U.S.C. 264(a) and 42 CFR 70.2, 71.31(b), 71.32(b). In the event that a court determines this Order qualifies as a rule under the APA, notice and comment and a delay in effective date are not required because there is good cause to dispense with prior public notice and comment and the opportunity to comment on this Order and the delay in effective date. Considering the public health emergency caused by COVID–19, it would be impracticable and contrary to the public's health, and by extension the public's interest, to delay the issuance and effective date of this Order. Similarly, the Office of Information and Regulatory Affairs has determined that if this Order were a rule, it would be a major rule under the Congressional Review Act, but there would not be a delay in its effective date as the agency has determined that there would be good cause to make the requirements herein effective immediately under the APA.

This order is also an economically significant regulatory action under Executive Order 12866 and has therefore been reviewed by the Office of Information and Regulatory Affairs of the Office of Management and Budget. The agency is proceeding without the complete analysis required by Executive Order 12866 under the emergency provisions of 6(a)(3)(D) of that Order.

If any provision of this Order, or the application of any provision to any carriers, conveyances, persons, or circumstances, shall be held invalid, the remainder of the provisions, or the application of such provisions to any carriers, conveyances, persons, or circumstances other than those to which it is held invalid, shall remain valid and in effect.

To address the COVID–19 public health threat to transportation security, this Order shall be enforced by the Transportation Security Administration under appropriate statutory and regulatory authorities including the provisions of 49 U.S.C. 106, 114, 44902, 44903, and 46301; and 49 CFR part 1503, 1540.105, 1542.303, 1544.305 and 1546.105.

This Order shall be further enforced by other federal authorities and may be enforced by cooperating state and local authorities through the provisions of 18 U.S.C. 3559, 3571; 42 U.S.C. 243, 268, 271; and 42 CFR 70.18 and 71.2.[33]

EFFECTIVE DATE:

This Order shall enter into effect on February 1, 2021, at 11:59 p.m. and will remain in effect unless modified or rescinded based on specific public health or other considerations, or until the Secretary of Health and Human Services rescinds the determination under section 319 of the Public Health Service Act (42 U.S.C. 247d) that a public health emergency exists.

Dated: February 1, 2021.

Sherri Berger,

Acting Chief of Staff, Centers for Disease Control and Prevention.

[FR Doc. 2021–02340 Filed 2–1–21; 4:15 pm]

BILLING CODE 4163–18–P

[33] While this Order may be enforced and CDC reserves the right to enforce through criminal penalties, CDC does not intend to rely primarily on these criminal penalties but instead strongly encourages and anticipates widespread voluntary compliance as well as support from other federal agencies in implementing additional civil measures enforcing the provisions of this Order, to the extent permitted by law and consistent with President Biden's Executive Order of January 21, 2021 (Promoting COVID–19 Safety in Domestic and International Travel).

DEPARTMENT OF THE INTERIOR

Geological Survey

[GX20EG31DW50100; OMB Control Number 1028-New]

Agency Information Collection Activities; Hydrography Addressing tool

AGENCY: U.S. Geological Survey, Interior.

ACTION: Notice of Information Collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the U.S. Geological Survey (USGS) are proposing a new information collection.

DATES: Interested persons are invited to submit comments on or before April 5, 2021.

ADDRESSES: Send your comments on this information collection request (ICR) by mail to U.S. Geological Survey, Information Collections Officer, 12201 Sunrise Valley Drive MS 159, Reston, VA 20192; or by email to *gs-info_collections@usgs.gov.* Please reference OMB Control Number 1028–xxxx in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Michael Tinker by email at *mdtinker@usgs.gov* or by telephone at 303–202–4476.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995, we provide the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

We are soliciting comments on the proposed ICR that is described below.

WHO stands by recommendation to not wear masks if you are not sick or not caring for someone who is sick

By Jacqueline Howard, CNN

Updated 2:24 AM ET, Tue March 31, 2020

(CNN) — World Health Organization officials Monday said they still recommend people not wear face masks unless they are sick with Covid-19 or caring for someone who is sick.

Related Article: Masks may actually increase your coronavirus risk if worn improperly, surgeon general warns

"There is no specific evidence to suggest that the wearing of masks by the mass population has any potential benefit. In fact, there's some evidence to suggest the opposite in the misuse of wearing a mask properly or fitting it properly," Dr. Mike Ryan, executive director of the WHO health emergencies program, said at a media briefing in Geneva, Switzerland, on Monday.

"There also is the issue that we have a massive global shortage," Ryan said about masks and other medical supplies. "Right now the people most at risk from this virus are frontline health workers who are exposed to the virus every second of every day. The thought of them not having masks is horrific."

Dr. Maria Van Kerkhove, an infectious disease epidemiologist with the WHO, also said at Monday's briefing that it is important "we prioritize the use of masks for those who need it most," which would be frontline health care workers.

"In the community, we do not recommend the use of wearing masks unless you yourself are sick and as a measure to prevent onward spread from you if you are ill," Van Kerkhove said.

"The masks that we recommend are for people who are at home and who are sick and for those individuals who are caring for those people who are home that are sick," she said.

World Health Organization officials warned at a media briefing last week that globally there is a "significant shortage" of medical supplies, including personal protective gear or PPE, for doctors.

"We need to be clear," Van Kerkhove said last week. "The world is facing a significant shortage of PPE for our frontline workers -- including masks and gloves and gowns and face shields -- and protecting our health care workers must be the top priority for use of this PPE."

Related Article: People around the country are sewing masks. And some hospitals, facing dire shortage, welcome them

Advice on the use of masks in the community, during home care and in health care settings in the context of the novel coronavirus (2019-nCoV) outbreak

Interim guidance

29 January 2020

World Health Organization

Introduction

This document provides rapid advice on the use of medical masks in communities, at home and at health care facilities in areas that have reported outbreaks caused by the 2019 novel coronavirus (2019-nCoV). It is intended for public health and infection prevention and control (IPC) professionals, health care managers, health care workers and community health workers. It will be revised as more data become available.

With the current information available, it is suggested that the route of human-to-human transmission of 2019-nCoV is either via respiratory droplets or contact. Any person who is in close contact (within 1 meter) with someone who has respiratory symptoms (e.g., sneezing, coughing, etc.) is at risk of being exposed to potentially infective respiratory droplets.

Medical masks are surgical or procedure masks that are flat or pleated (some are like cups); they are affixed to the head with straps[a].

General Advice

Wearing a medical mask is one of the prevention measures to limit spread of certain respiratory diseases, including 2019-nCoV, in affected areas. However, the use of a mask alone is insufficient to provide the adequate level of protection and other equally relevant measures should be adopted. If masks are to be used, this measure must be combined with hand hygiene and other IPC measures to prevent the human-to-human transmission of 2019-nCov. WHO has developed guidance for home care[b] and health care settings[c] on infection prevention and control (IPC) strategies for use when infection with 2019-nCoV is suspected.

Wearing medical masks when not indicated may cause unnecessary cost, procurement burden and create a false sense of security that can lead to neglecting other essential measures such as hand hygiene practices. Furthermore, using a mask incorrectly may hamper its effectiveness to reduce the risk of transmission.

Community setting

Individuals without respiratory symptoms should:

- avoid agglomerations and frequency of closed crowded spaces;
- maintain distance of at least 1 meter from any individual with 2019-nCoV respiratory symptoms (e.g., coughing, sneezing);
- perform hand hygiene frequently, using alcohol-based hand rub if hands are not visibly soiled or soap and water when hands are visibly soiled;
- if coughing or sneezing cover nose and mouth with flexed elbow or paper tissue, dispose of tissue immediately after use and perform hand hygiene;
- refrain from touching mouth and nose;
- a medical mask is not required, as no evidence is available on its usefulness to protect non-sick persons. However, masks might be worn in some countries according to local cultural habits. If masks are used, best practices should be followed on how to wear, remove, and dispose of them and on hand hygiene action after removal (see below advice regarding appropriate mask management).

Individuals with respiratory symptoms should:

- wear a medical mask and seek medical care if experiencing fever, cough and difficulty breathing, as soon as possible or in accordance with to local protocols;
- follow the below advice regarding appropriate mask management.

Home Care

In view of the currently available data on the disease and its transmission, WHO recommends that suspected cases of 2019-nCoV infection be cared for using isolation precautions and monitored in a hospital setting. This would ensure both safety and quality of health care (in case patients' symptoms worsen) and public health security.

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[a] Infection prevention and control of epidemic- and pandemic-prone acute respiratory infections in health care. World Health Organization. (2014). Available at https://apps.who.int/iris/handle/10665/174652

[b] Home care for patients with suspected novel coronavirus (nCoV) infection presenting with mild symptoms and management of contacts. Available at https://www.who.int/publications-detail/home-care-for-patients-with-suspected-novel-coronavirus-(ncov)-infection-presenting-with-mild-symptoms-and-management-of-contacts

[c] Infection prevention and control during health care when novel coronavirus (nCoV) infection is suspected. Available at https://www.who.int/publications-detail/infection-prevention-and-control-during-health-care-when-novel-coronavirus-(ncov)-infection-is-suspected-20200125

However, for several possible reasons, including situations when inpatient care is unavailable or unsafe (i.e. limited capacity and resources unable to meet demand for health care services), or in a case of informed refusal of hospitalization, home settings for health care provision may need to be considered. Specific IPC guidance for home care should be followed[b].

Individuals with suspected 2019-nCoV infection with mild respiratory symptoms should:
- perform hand hygiene frequently, using alcohol-based hand rub if hands are not visibly soiled or soap and water when hands are visibly soiled;
- keep distance from well individuals as much as possible (at least 1 meter);
- to contain respiratory secretions, a medical mask should be provided to the individual and worn as much as possible, if it can be tolerated. For individuals who cannot tolerate a medical mask, he/she should rigorously apply respiratory hygiene, i.e. cover mouth and nose when coughing or sneezing with disposable paper tissue. Dispose of the material after use. Clean hands immediately after contact with respiratory secretions;
- improve airflow in living space by opening windows and door as much as possible.

Relatives or caregivers to individuals with suspected 2019-nCoV infection with mild respiratory symptoms should:
- perform hand hygiene frequently, using alcohol-based hand rub if hands are not visibly soiled or soap and water when hands are visibly soiled;
- keep distance from affected individual as much as possible (at least 1 meter);
- wear a medical mask when in the same room with the affected individual;
- dispose of the material immediately after use. Clean hands immediately after contact with respiratory secretions;
- improve airflow in living space by opening windows as much as possible.

Health Care Facilities

Individuals with respiratory symptoms should:
- wear a medical mask while waiting in triage or waiting areas or during transportation within the facility;
- wear a medical mask when staying in cohorting areas dedicated to suspected or confirmed cases;
- do not wear a medical mask when isolated in single rooms but cover mouth and nose when coughing or sneezing with disposable paper tissues. Dispose them appropriately and perform hand hygiene immediately afterwards.

Health care workers should:
- wear a medical mask when entering a room where patients suspected or confirmed of being infected with 2019-nCoV are admitted and in any situation of care provided to a suspected or confirmed case[c];
- use a particulate respirator at least as protective as a US National Institute for Occupational Safety and Health (NIOSH)-certified N95, European Union (EU) standard FFP2, or equivalent, when performing aerosol-generating procedures such as tracheal intubation, non-invasive ventilation, tracheotomy, cardiopulmonary resuscitation, manual ventilation before intubation, and bronchoscopy.

Masks management

If medical masks are worn, appropriate use and disposal is essential to ensure they are effective and to avoid any increase in risk of transmission associated with the incorrect use and disposal of masks.

The following information on correct use of medical masks derives from the practices in health-care settings[d]:
- place mask carefully to cover mouth and nose and tie securely to minimise any gaps between the face and the mask;
- while in use, avoid touching the mask;
- remove the mask by using appropriate technique (i.e. do not touch the front but remove the lace from behind);
- after removal or whenever you inadvertently touch a used mask, clean hands by using an alcohol-based hand rub or soap and water if visibly soiled
- replace masks with a new clean, dry mask as soon as they become damp/humid;
- do not re-use single-use masks;
- discard single-use masks after each use and dispose of them immediately upon removal.

Cloth (e.g. cotton or gauze) masks are not recommended under any circumstance.

WHO reference number: WHO/nCov/IPC_Masks/2020.1

[d] Infection prevention and control of epidemic- and pandemic-prone acute respiratory infections in health care. World Health Organization. (2014). Organization. https://apps.who.int/iris/handle/10665/112656

npr.org

Why There Are So Many Different Guidelines For Face Masks For The Public

Huo Jingnan Twitter

13-17 minutes

A do-it-yourself mask culture is springing up in the Czech Republic. This woman was photographed on the Charles Bridge in Prague on March 28. **Michal Cizek/AFP via Getty Images** hide caption

toggle caption

Michal Cizek/AFP via Getty Images

A do-it-yourself mask culture is springing up in the Czech Republic. This woman was photographed on the Charles Bridge in Prague on March 28.

Michal Cizek/AFP via Getty Images

On Feb. 29, the U.S. surgeon general Dr. Jerome Adams tweeted that masks do not offer any benefit to the average citizen.

> Seriously people- STOP BUYING MASKS!
>
> They are NOT effective in preventing general public from catching #Coronavirus, but if healthcare providers can't get them to care for sick patients, it puts them and our communities at risk! https://t.co/UxZRwxxKL9
>
> — U.S. Surgeon General (@Surgeon_General) February 29, 2020

About a month later, on Friday, April 3, the Centers for Disease Control and Prevention recommended that Americans wear "cloth face coverings fashioned from household items or made at home from common materials ... as an additional, voluntary public health measure."

This isn't the only example of a change or updating of mask-wearing policies during the coronavirus crisis. It's happened in countries around the world — from Singapore to Austria to Kenya (which just announced one of the world's strictest policies — police are arresting anyone caught without a mask in their vehicle, on a bus or in a public place.)

Meanwhile, some health agencies have taken a stand that calls for mask-wearing in public from the early stages of the outbreak — Hong Kong on Jan. 24, mainland China on Jan. 31.

In Wuhan, China, and other parts of East Asia, wearing masks in public has been commonplace since the SARS outbreak in the early 2000s. This photo was taken on January 23, about a week before China called on citizens to wear masks as a way to stem the spread of the novel coronavirus. **Stringer for NPR** hide caption

toggle caption

Stringer for NPR

To understand why mask guidelines have been so varied, NPR reached out to specialists in academia and in government. What we learned is that face mask guidelines are about science — but go beyond. The reasons for a policy may have to do with practical considerations like the national supply of masks but may also reflect cultural values and history.

Shifting Guidelines

In order to understand the range of guidelines, the first issue to consider is the data on the potential benefits of masks. As with so many points surrounding the novel coronavirus, there's not a clear-cut finding.

But there is emerging research and data that suggests transmission of COVID-19 by asymptomatic and pre-symptomatic individuals. Such research has been coming out at least since February; the latest report is from Singapore on April 1. These studies emphasize that people can spread the virus before realizing that they are sick — and that wearing a mask in public could help keep the infected person from spreading infectious droplets.

Among the reasons for reluctance on the part of some health agencies and places to urge mask wearing is the concern about the shortage of masks for medical workers. That's why the World Health Organization has stayed consistent in its recommendation, Margaret Harris of its coronavirus response team told NPR. And that position is: yes to masks for health-care workers and people with symptoms, no for the general public.

WHO and other agencies have also raised concerns about the potential problems that could arise due to the wearing of a mask — for example, a false sense of security that would undermine other preventive measures or self-contamination from touching a contaminated mask.

Epidemiologist Sergio Brusin who works on the European Center for Disease Control's coronavirus response, offered NPR a similar rationale in an interview. However, ECDC only mentioned that face masks aren't effective in protecting the wearer on its public-facing website. A number of other health agencies — like WHO and the CDC — offered little explanation on their website.

The result of these sometimes incomplete messages: "I think that if you talk to even the highly informed members of the general public and ask[ed] them a week, or two or three weeks ago, if the face masks work, they would say 'no' because they would have read CDC guidance, WHO guidance," says Lawrence Gostin, professor of global health law at Georgetown University and director of the World Health Organization Center on National & Global Health Law.

"But that wouldn't have been correct. Based upon the science [about potential benefits of masks for the public] we knew at the time."

Governments should not have downplayed the importance of face masks [as a protective measure for the public], says Leiyu Shi, who researches comparative health systems and health policy at Johns Hopkins University, "because it will make them [seem] very foolish when they change their stance. Again and again," Shi says.

In response to NPR's inquiry about its April 3 guideline change, the CDC said its change was driven by "increasing and widespread transmission of the new coronavirus across the country," citing studies published in February and March showing pre-symptomatic and a symptomatic spread. A CDC spokesperson also noted reports from Asian countries showing that a cloth face covering can reduce the chance of spreading respiratory droplets when people need to be in places with others.

Asked by NPR about the Surgeon General's earlier tweet about the ineffectiveness of masks, the office of the Surgeon General issued a statement Thursday noting that back in February Dr. Adams was following the CDC, WHO and other health organizations, which all recommended against wearing masks as a way to protect the person wearing them. The statement said that the understanding on spread from infected individuals who have not shown symptoms has since changed.

The Impact Of SARS On Mask Guidance

For Jeremy Lim, Adjunct Associate professor of public health from the National University of Singapore School of Public Health, East Asia's threshold for taking action on face masks and more potentially preventive measures was sparked by SARS, or Severe Acute Respiratory Syndrome, another coronavirus that swept through the region in 2003.

"Policymakers will always have to live with uncertainty and incomplete information,' Lim says. "For East Asian countries, the attitude was 'better to be safe than to be sorry.' "

Asked about the new CDC position in the U.S., public health academics like Gostin and Shi believe the guideline changes in the U.S. could have come sooner, given the emerging evidence of potential benefits.

This guidance was updated on 5 June. Click here to access the new version.

Advice on the use of masks in the context of COVID-19

Interim guidance

6 April 2020

World Health Organization

Background

This document provides advice on the use of masks in communities, during home care, and in health care settings in areas that have reported cases of COVID-19. It is intended for individuals in the community, public health and infection prevention and control (IPC) professionals, health care managers, health care workers (HCWs), and community health workers. It will be revised as more data become available.

Current information suggests that the two main routes of transmission of the COVID-19 virus are respiratory droplets and contact. espiratory droplets are generated when an infected person coughs or sneezes. Any person who is in close contact (within 1 m) with someone who has respiratory symptoms (coughing, sneezing) is at risk of being exposed to potentially infective respiratory droplets. Droplets may also land on surfaces where the virus could remain viable; thus, the immediate environment of an infected individual can serve as a source of transmission (contact transmission).[1]

WHO has recently summarized reports of transmission of the COVID-19 virus and provided a brief overview of current evidence on transmission from symptomatic, pre-symptomatic, and asymptomatic [a] people infected with COVID-19 (full details are provided in WHO COVID-19 Situation report 73).[2]

Current evidence suggests that most disease is transmitted by symptomatic laboratory confirmed cases. The incubation period for COVID-19, which is the time between exposure to the virus and symptom onset, is on average 5-6 days, but can be as long as 14 days. During this period, also known as the pre-symptomatic period, some infected persons can be contagious and therefore transmit the virus to others.[3-] In a small number of reports, pre-symptomatic transmission has been documented through contact tracing efforts and enhanced investigation of clusters of confirmed cases.[3-] This is supported by data suggesting that some people can test positive for COVID-19 from 1-3 days before they develop symptoms.[9,10]

Thus, it is possible that people infected with COVID-19 could transmit the virus before symptoms develop. It is important to recognize that pre-symptomatic transmission still requires the virus to be spread via infectious droplets or through touching contaminated surfaces. WHO regularly monitors all emerging evidence about this critical topic and will provide updates as more information becomes available.

In this document medical masks are defined as surgical or procedure masks that are flat or pleated (some are shaped like cups); they are affixed to the head with straps. They are tested according to a set of standardized test methods (ASTM F2100, EN 146 3, or equivalent) that aim to balance high filtration, adequate breathability and optionally, fluid penetration resistance. This document does not focus on respirators; for guidance on use of respirators see IPC guidance during health care when COVID-19 infection is suspected.[11]

Wearing a medical mask is one of the prevention measures that can limit the spread of certain respiratory viral diseases, including COVID-19. o e e e eo a a alone n en o o eana e aele elo oe on an o e ea e o l al o e a o e Whether or not masks are used, maximum compliance with hand hygiene and other IPC measures is critical to prevent human-to-human transmission of COVID-19. WHO has developed guidance on IPC strategies for home care[12] and health care settings[11] for use when COVID-19 is suspected.

Community settings

Studies of influenza, influenza-like illness, and human coronaviruses provide evidence that the use of a medical mask can prevent the spread of infectious droplets from an infected person to someone else and potential contamination of the environment by these droplets.[13] There is limited evidence that wearing a medical mask by healthy individuals in the households or among contacts of a sick patient, or among attendees of mass gatherings may be beneficial as a preventive measure.[14-23] However, there is currently no evidence that wearing a mask (whether medical or other types) by healthy persons in the wider community setting, including universal community masking, can prevent them from infection with respiratory viruses, including COVID-19.

e al a o l e e e e o eal a e o e The use of medical masks in the community may create a false sense of security, with neglect of other essential measures, such as hand hygiene practices and physical distancing, and may lead to touching the face under the masks and under the eyes, result in unnecessary costs, and take

[a] An asymptomatic laboratory-confirmed case is a person infected with COVID-19 who does not develop symptoms. Asymptomatic transmission refers to transmission of the virus from a person, who does not develop symptoms. The true extent of asymptomatic infections will be determined from serologic studies.

masks away from those in health care who need them most, especially when masks are in short supply.

e on o o l :

- wear a medical mask, self-isolate, and seek medical advice as soon as they start to feel unwell. Symptoms can include fever, fatigue, cough, sore throat, and difficulty breathing. It is important to note that early symptoms for some people infected with COVID-19 may be very mild;
- follow instructions on how to put on, take off, and dispose of medical masks;
- follow all additional preventive measures, in particular, hand hygiene and maintaining physical distance from other persons.

ll e on o l :

- avoid groups of people and enclosed, crowded spaces;
- maintain physical distance of at least 1 m from other persons, in particular from those with respiratory symptoms (e.g., coughing, sneezing);
- perform hand hygiene frequently, using an alcohol-based hand rub if hands are not visibly dirty or soap and water when hands are visibly dirty;
- cover their nose and mouth with a bent elbow or paper tissue when coughing or sneezing, dispose of the tissue immediately after use, and perform hand hygiene;
- refrain from touching their mouth, nose, and eyes.

In some countries masks are worn in accordance with local customs or in accordance with advice by national authorities in the context of COVID-19. In these situations, best practices should be followed about how to wear, remove, and dispose of them, and for hand hygiene after removal.

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As described above, the wide use of masks by healthy people in the community setting is not supported by current evidence and carries uncertainties and critical risks. WHO offers the following advice to decision makers so they apply a risk-based approach.

Decisions makers should consider the following:

1. o e of mask use: the rationale and reason for mask use should be clear whether it is to be used for source control (used by infected persons) or prevention of COVID-19 (used by healthy persons)
2. isk of e o e to the COVID-19 virus in the local context:
   - The population: current epidemiology about how widely the virus is circulating (e.g., clusters of cases versus community transmission), as well as local surveillance and testing capacity (e.g., contact tracing and follow up, ability to carry out testing).
   - The individual: working in close contact with public (e.g., community health worker, cashier)
3. lne a l of the person/population to develop severe disease or be at higher risk of death, e.g. people with comorbidities, such as cardiovascular disease or diabetes mellitus, and older people
4. e n in which the population lives in terms of population density, the ability to carry out physical distancing (e.g. on a crowded bus), and risk of rapid spread (e.g. closed settings, slums, camps/camp-like settings).

   ea l : availability and costs of the mask, and tolerability by individuals
6. e of mask: medical mask versus nonmedical mask (see below)

In addition to these factors, potential advantages of the use of mask by healthy people in the community setting include reducing potential exposure risk from infected person during the pre-symptomatic period and stigmatization of individuals wearing mask for source control.

However, the following potential risks should be carefully taken into account in any decision-making process:

- self-contamination that can occur by touching and reusing contaminated mask
- depending on type of mask used, potential breathing difficulties
- false sense of security, leading to potentially less adherence to other preventive measures such as physical distancing and hand hygiene
- diversion of mask supplies and consequent shortage of mask for health care workers
- diversion of resources from effective public health measures, such as hand hygiene

Whatever approach is taken, it is important to develop a strong communication strategy to explain to the population the circumstances, criteria, and reasons for decisions. The population should receive clear instructions on what masks to wear, when and how (see mask management section), and on the importance of continuing to strictly follow all other IPC measures (e.g., hand hygiene, physical distancing, and others).

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The use of masks made of other materials (e.g., cotton fabric), also known as nonmedical masks, in the community setting has not been well evaluated. There is no current evidence to make a recommendation for or against their use in this setting.

WHO is collaborating with research and development partners to better understand the effectiveness and efficiency of nonmedical masks. WHO is also strongly encouraging countries that issue recommendations for the use of masks in healthy people in the community to conduct research on this critical topic. WHO will update its guidance when new evidence becomes available.

In the interim, decision makers may be moving ahead with advising the use of nonmedical masks. Where this is the case, the following features related to nonmedical masks should be taken into consideration:

- Numbers of layers of fabric/tissue
- Breathability of material used
- Water repellence/hydrophobic qualities
- Shape of mask
- Fit of mask

Home care

For COVID-19 patients with mild illness, hospitalization may not be required. All patients cared for outside hospital (i.e. at home or non-traditional settings) should be instructed to follow local/regional public health protocols for home isolation and return to designated COVID-19 hospital if they develop any worsening of illness.[7]

Home care may also be considered when inpatient care is unavailable or unsafe (e.g. capacity is limited, and resources are unable to meet the demand for health care services). Specific IPC guidance for home care should be followed.[3]

e on e e o l o o l :

- Self-isolate if isolation in a medical facility is not indicated or not possible
- Perform hand hygiene frequently, using an alcohol-based hand rub if hands are not visibly dirty or soap and water when hands are visibly dirty;
- eep a distance of at least 1 m from other people;
- Wear a medical mask as much as possible; the mask should be changed at least once daily. Persons who cannot tolerate a medical mask should rigorously apply respiratory hygiene (i.e. cover mouth and nose with a disposable paper tissue when coughing or sneezing and dispose of it immediately after use or use a bent elbow procedure and then perform hand hygiene.)
- Avoid contaminating surfaces with saliva, phlegm, or respiratory secretions.
- Improve airflow and ventilation in their living space by opening windows and doors as much as possible.

a e e o o e a n l n a e e on e e o o l o o l :

- Perform hand hygiene frequently, using an alcohol-based hand rub if hands are not visibly dirty or soap and water when hands are visibly dirty;
- eep a distance of at least 1 meter from the affected person when possible;
- Wear a medical mask when in the same room as the affected person;
- Dispose of any material contaminated with respiratory secretions (disposable tissues) immediately after use and then perform hand hygiene.
- Improve airflow and ventilation in the living space by opening windows as much as possible.

Health care settings

WHO provides guidance for the use of PPE, including masks, by health care workers in the guidance document: ational use of PPE in the context of COVID-19.[24] Here we provide advice for people visiting a health care setting:

o a eo le n a eal a e e n o l :

- Wear a medical mask while waiting in triage or other areas and during transportation within the facility;
- Not wear a medical mask when isolated in a single room, but cover their mouth and nose when coughing or sneezing with disposable paper tissues. Tissues must be disposed of appropriately, and hand hygiene should be performed immediately afterwards.

eal a e o e o l

- Wear a medical mask when entering a room where patients with suspected or confirmed COVID-19 are admitted.
- Use a particulate respirator at least as protective as a US National Institute for Occupational Safety and Health-certified N95, European Union standard FFP2, or equivalent, when performing or working in settings where aerosol-generating procedures, such as tracheal intubation, non-invasive ventilation, tracheotomy, cardiopulmonary resuscitation, manual ventilation before intubation, and bronchoscopy are performed.
- Full infection prevention and control guidance for health care workers is provided here.

One study that evaluated the use of cloth masks in a health care facility found that health care workers using cotton cloth masks were at increased risk of infection compared with those who wore medical masks.[25] Therefore, cotton cloth masks are not considered appropriate for health care workers. As for other PPE items, if production of cloth masks for use in health care settings is proposed locally in situations of shortage or stock out, a local authority should assess the proposed PPE according to specific minimum standards and technical specifications.

Mask management

For any type of mask, appropriate use and disposal are essential to ensure that they are effective and to avoid any increase in transmission.

The following information on the correct use of masks is derived from practices in health care settings.

- Place the mask carefully, ensuring it covers the mouth and nose, and tie it securely to minimize any gaps between the face and the mask.
- Avoid touching the mask while wearing it.
- emove the mask using the appropriate technique: do not touch the front of the mask but untie it from behind.
- After removal or whenever a used mask is inadvertently touched, clean hands using an alcohol-based hand rub or soap and water if hands are visibly dirty.
- eplace masks as soon as they become damp with a new clean, dry mask.
- Do not re-use single-use masks.
- Discard single-use masks after each use and dispose of them immediately upon removal.

WHO continues to monitor the situation closely for any changes that may affect this interim guidance. Should any factors change, WHO will issue a further update. Otherwise, this interim guidance document will expire 2 years after the date of publication.

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businessinsider.com

WHO says there is no need for healthy people to wear face masks, days after the CDC told all Americans to cover their faces

Julia Naftulin

8-9 minutes

- On April 6, the World Health Organization released new guidance saying that healthy people don't need to wear face masks to prevent coronavirus spread.
- Masks should be for the sick, their caretakers, and healthcare workers, the WHO guidance said.
- Scientists and public-health organizations can't agree on the best face-mask protocol, and the WHO guidelines go against the CDC's face-mask recommendations.
- *Editor's note: As of June 5, the WHO recommends the use of fabric face masks and/or face shields for the general public as a tool to reduce the spread of the novel coronavirus.*
- Visit Business Insider's homepage for more stories.

The use of face masks on healthy people during the coronavirus pandemic has been a major point of contention and confusion among scientists and the public.

On Friday, the US Centers for Disease Control and Prevention recommended that all Americans wear face masks when they are in public.

But new guidance from the World Health Organization released on Monday says healthy people don't need to wear face masks and that doing so won't provide added protection from the coronavirus.

There's some evidence that caretakers of infected people can protect their health by wearing masks, the WHO guidance said, but "there is currently no evidence that wearing a mask (whether medical or other types) by healthy persons in the wider community setting, including universal community masking, can prevent them from infection with respiratory viruses, including COVID-19."

WHO also said community masking could lead to a "false sense of security" and cause people to ignore other evidence-based measures like handwashing and self-isolation.

WHO says masks should be saved for healthcare workers, caretakers, and sick people — everyone else should just stay home

Crystal Cox/Business Insider

WHO said masks should be reserved for people who have COVID-19 or are in regular close contact with people who have the disease, like caretakers and hospital workers.

People with COVID-19 symptoms like a cough or shortness of breath should wear masks even if they haven't tested positive, and they should self-isolate, seek medical advice from home, and practice good hygiene, including handwashing and changing their masks, WHO said.

The organization also said that healthcare workers should use medical-grade masks, not makeshift cloth masks, when they can after one study showed that medical workers who used cloth masks were at increased risk of infection compared with those who used medical-grade masks.

"If production of cloth masks for use in health care settings is proposed locally in situations of shortage or stock out, a local authority should assess the proposed PPE according to specific minimum standards and technical specifications," the WHO report said.

Masks could slow transmission, but there's room for infection-causing human error

Some health experts believe community masking efforts can't hurt.

"The argument ... about everybody wearing a mask is not that it will prevent everyone from getting infected — it's that it will slow down transmission in the community a bit," Ben Cowling, a professor of epidemiology and a mask researcher at the University of Hong Kong's School of Public Health, previously told Business Insider. "That's already useful. Just to have even a small effect is useful."

At the same time, Cowling recognized that face masks aren't a perfect public-health tool because they allow room for user error, a point made in the WHO guidance.

WHO officials said healthy people who wear masks might touch their own faces more often than necessary, which could increase their risk for COVID-19.

Cowling said user error was a potential reason studies have yet to show community masking is effective at preventing disease spread.

"Randomized trials don't support a big effect of face masks, but there is the mechanistic plausibility for face masks to work, right? So why not consider it?" Cowling said. "If you don't wear the mask properly, and if there's a lot of chances for you to get infected, then the mask may not do a lot of good."

But with much of the world already dealing with severe outbreaks, Cowling said masking efforts for the healthy are unlikely to stop the spread at this point in time.

"I think it's too late to do a lot for the current epidemic because it's already spread such a lot, and then the cases that you're getting now are people infected two or three weeks ago. And the lockdowns that are in place will hopefully really slow down infections," Cowling said. "Adding masks now I don't think would make a lot of difference to that trajectory."

You can protect yourself without a mask

The coronavirus is typically spread through tiny droplets that are ejected when an infected person coughs, sneezes, or talks, and the droplets land on another person or surface.

Scientists are still studying to understand to what extent coronavirus-containing aerosols linger in the air, which would make face-mask wearing more important, Business Insider previously reported.

So far, evidence suggests that the virus does not linger in the air outside hospital settings, where certain procedures, such as intubating a patient, can aerosolize virus particles.

For people who isolate at home and practice social distancing when outdoors, aerosols are likely not an issue. Running outdoors alone without wearing a mask, for example, is safe if you feel healthy, Business Insider previously reported.

As such, WHO said, practicing self-isolation, good hygiene, and social distancing are the best ways for healthy people to stay safe. The organization said it would also update its face-mask guidance based on new information as it comes out.

More: Health coronavirus Face masks hygiene

Advice on the use of masks in the context of COVID-19

Interim guidance

5 June 2020

This document is an update of the guidance published on 6 April 2020 and includes updated scientific evidence relevant to the use of masks for preventing transmission of Coronavirus disease 2019 (COVID-19) as well as practical considerations. The main differences from the previous version include the following:

- Updated information on transmission from symptomatic, pre-symptomatic and asymptomatic people infected with COVID-19, as well as an update of the evidence of all sections of this document;
- New guidance on the targeted continuous use of medical masks by health workers working in clinical areas in health facilities in geographical areas with community transmission[1] of COVID-19;
- Updated guidance and practical advice for decision-makers on the use of medical and non-medical masks by the general public using a risk-based approach;
- New guidance on non-medical mask features and characteristics, including choice of fabric, number and combination of layers, shape, coating and maintenance.

Guidance and recommendations included in this document are based on previous WHO guidelines (in particular the WHO Guidelines on infection prevention and control of epidemic- and pandemic-prone acute respiratory infections in health care) (1) and the evaluation of current evidence by the WHO ad hoc COVID-19 IPC Guidance Development Group (COVID-19 IPC GDG) that meets at least once a week. The process of interim guidance development during emergencies consists of a transparent and robust process of evaluation of the available evidence on benefits and harms, synthetized through expedited systematic reviews and expert consensus-building facilitated by methodologists. This process also considers, as much as possible, potential resource implications, values and preferences, feasibility, equity, ethics and research gaps.

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This document provides guidance to decision makers, public health and IPC professionals, health care managers, and health workers on the use of medical and non-medical masks in health care (including long-term care and residential) settings, for the general public, and during home care. It will be revised as more data become available.

Background

The use of masks is part of a comprehensive package of the prevention and control measures that can limit the spread of certain respiratory viral diseases, including COVID-19. Masks can be used either for protection of healthy persons (worn to protect oneself when in contact with an infected individual) or for source control (worn by an infected individual to prevent onward transmission).

However, the use of a mask alone is insufficient to provide an adequate level of protection or source control, and other personal and community level measures should also be adopted to suppress transmission of respiratory viruses. Whether or not masks are used, compliance with hand hygiene, physical distancing and other infection prevention and control (IPC) measures are critical to prevent human-to-human transmission of COVID-19.

This document provides information and guidance on the use of masks in health care settings, for the general public, and during home care. The World Health Organization (WHO) has developed specific guidance on IPC strategies for health care settings (2), long-term care facilities (TCF) (3), and home care.(4)

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nowledge about transmission of the COVID-19 virus is accumulating every day. COVID-19 is primarily a respiratory disease and the spectrum of infection with this virus can range from people with very mild, non-respiratory symptoms to severe acute respiratory illness, sepsis with organ dysfunction and death. Some people infected have reported no symptoms at all.

According to the current evidence, COVID-19 virus is primarily transmitted between people via respiratory droplets and contact routes. Droplet transmission occurs when a person is in close contact (within 1 metre) with an infected person and exposure to potentially infective respiratory droplets occurs, for example, through coughing, sneezing or very close personal contact resulting in the inoculation of entry portals such as the mouth, nose or con unctivae

[1] Defined by WHO as experiencing larger outbreaks of local transmission defined through an assessment of factors including, but not limited to: large numbers of cases not linkable to transmission chains; large numbers of cases from sentinel surveillance; and/or multiple unrelated clusters in several areas of the country/territory/area (https://www.who.int/publications-detail/global-surveillance-for-covid-19-caused-by-human-infection-with-covid-19-virus-interim-guidance)

community transmission, consider additional precautions, including the wearing of a medical mask, when community health workers provide essential routine services (Table 2).

When a patient is suspected or confirmed to have COVID-19 infection, community health workers should use contact and droplet precautions. Contact and droplet precautions include the use of a medical mask, gown, gloves and eye protection.(53)

Guidance on the use of masks for the general public

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Studies of influenza, influenza-like illness, and human coronaviruses (not including COVID-19) provide evidence that the use of a medical mask can prevent the spread of infectious droplets from a symptomatic infected person (source control) to someone else and potential contamination of the environment by these droplets.(54, 55) There is limited evidence that wearing a medical mask by healthy individuals in households, in particular those who share a house with a sick person, or among attendees of mass gatherings may be beneficial as a measure preventing transmission.(41, 56-61) A recent meta-analysis of these observational studies, with the intrinsic biases of observational data, showed that either disposable surgical masks or reusable 12 16-layer cotton masks were associated with protection of healthy individuals within households and among contacts of cases.(42)

This could be considered to be indirect evidence for the use of masks (medical or other) by healthy individuals in the wider community; however, these studies suggest that such individuals would need to be in close proximity to an infected person in a household or at a mass gathering where physical distancing cannot be achieved, to become infected with the virus.

esults from cluster randomized controlled trials on the use of masks among young adults living in university residences in the United States of America indicate that face masks may reduce the rate of influenza-like illness, but showed no impact on risk of laboratory-confirmed influenza.(62, 63) At present, there is no direct evidence (from studies on COVID-19 and in healthy people in the community) on the effectiveness of universal masking of healthy people in the community to prevent infection with respiratory viruses, including COVID-19.

WHO regularly monitors all emerging evidence about this important topic and will provide updates as more information becomes available.

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- wear a medical mask, self-isolate, and seek medical advice as soon as they start to feel unwell with potential symptoms of COVID-19, even if symptoms are mild. Symptoms can include: fever, cough, fatigue, loss of appetite, shortness of breath and muscle pain. Other non-specific symptoms such as sore throat, nasal congestion, headache, diarrhoea, nausea and vomiting, have also been reported. oss of smell and taste preceding the onset of respiratory symptoms have also been reported.(64, 65) Older people and immunosuppressed patients may present with atypical symptoms such as fatigue, reduced alertness, reduced mobility, diarrhoea, loss of appetite, delirium, and absence of fever.(26, 66, 67) It is important to note that early symptoms for some people infected with COVID-19 may be very mild and unspecific;
- follow instructions on how to put on, take off, and dispose of medical masks and perform hand hygiene;(6)
- follow all additional measures, in particular respiratory hygiene, frequent hand hygiene and maintaining physical distance of at least 1 metre (3.3 feet) from other persons.(42)

In the context of the COVID-19 pandemic, it is recommended that all persons, regardless of whether they are using masks or not, should:

- avoid groups of people and crowded spaces (follow local advice);
- maintain physical distance of at least 1 metre (3.3 feet) from other persons, especially from those with respiratory symptoms (e.g. coughing, sneezing);
- perform hand hygiene frequently, using an alcohol-based handrub if hands are not visibly dirty or soap and water;
- use respiratory hygiene i.e. cover their nose and mouth with a bent elbow or paper tissue when coughing or sneezing, dispose of the tissue immediately after use, and perform hand hygiene;
- refrain from touching their mouth, nose, and eyes.

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Many countries have recommended the use of fabric masks/face coverings for the general public. At the present time, the widespread use of masks by healthy people in the community setting is not yet supported by high quality or direct scientific evidence and there are potential benefits and harms to consider (see below).

However, taking into account the available studies evaluating pre- and asymptomatic transmission, a growing compendium of observational evidence on the use of masks by the general public in several countries, individual values and preferences, as well as the difficulty of physical distancing in many contexts, WHO has updated its guidance to advise that to prevent COVID-19 transmission effectively in areas of community transmission, governments should encourage the general public to wear masks in specific situations and settings as part of a comprehensive approach to suppress SA S-CoV-2 transmission (Table 2).

WHO advises decision makers to apply a risk-based approach focusing on the following criteria when considering or encouraging the use of masks for the general public:

1. o e of mask use: if the intention is preventing the infected wearer transmitting the virus to others (that is, source control) and/or to offer protection to the healthy wearer against infection (that is, prevention).

2. isk of e o e to the COVID-19 virus
   - due to epidemiology and intensity of transmission in the population: if there is community transmission and there is limited or no capacity to implement other containment measures such as contact tracing, ability to carry out testing and isolate and care for suspected and confirmed cases.
   - depending on occupation: e.g., individuals working in close contact with the public (e.g., social workers, personal support workers, cashiers).
3. lne a l of the mask wearer/population: for example, medical masks could be used by older people, immunocompromised patients and people with comorbidities, such as cardiovascular disease or diabetes mellitus, chronic lung disease, cancer and cerebrovascular disease.(69)
4. e n in which the population lives: settings with high population density (e.g. refugee camps, camp-like settings, those living in cramped conditions) and settings where individuals are unable to keep a physical distance of at least 1 metre (3.3 feet) (e.g. public transportation).
5. ea l : availability and costs of masks, access to clean water to wash non-medical masks, and ability of mask wearers to tolerate adverse effects of wearing a mask.
6. e of mask: medical mask versus non-medical mask

Based on these criteria, Table 2 provides practical examples of situations where the general public should be encouraged to wear a mask and it indicates specific target populations and the type of mask to be used according to its purpose. The decision of governments and local urisdictions whether to recommend or make mandatory the use of masks should be based on the above criteria, and on the local context, culture, availability of masks, resources required, and preferences of the population.

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Situations/settings	Population	Purpose of mask use	Type of mask to consider wearing if recommended locally
Areas with known or suspected widespread transmission and limited or no capacity to implement other containment measures such as physical distancing, contact tracing, appropriate testing, isolation and care for suspected and confirmed cases.	General population in public settings, such as grocery stores, at work, social gatherings, mass gatherings, closed settings, including schools, churches, mosques, etc.	Potential benefit for source control	Non-medical mask
Settings with high population density where physical distancing cannot be achieved; surveillance and testing capacity, and isolation and quarantine facilities are limited	People living in cramped conditions, and specific settings such as refugee camps, camp-like settings, slums	Potential benefit for source control	Non-medical mask
Settings where a physical distancing cannot be achieved (close contact)	General public on transportation (e.g., on a bus, plane, trains) Specific working conditions which places the employee in close contact or potential close contact with others e.g., social workers, cashiers, servers	Potential benefit for source control	Non-medical mask
Settings where physical distancing cannot be achieved and increased risk of infection and/or negative outcomes	Vulnerable populations: • People aged ≥60 years • People with underlying comorbidities, such as cardiovascular disease or diabetes mellitus, chronic lung disease, cancer, cerebrovascular disease, immunosuppression	Protection	Medical mask
Any setting in the community*	Persons with any symptoms suggestive of COVID-19	Source control	Medical mask

This applies to any transmission scenario

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The likely advantages of the use of masks by healthy people in the general public include:

- reduced potential exposure risk from infected persons before they develop symptoms;
- reduced potential stigmatization of individuals wearing masks to prevent infecting others (source control) or of people caring for COVID-19 patients in non-clinical settings;(70)
- making people feel they can play a role in contributing to stopping spread of the virus;

- reminding people to be compliant with other measures (e.g., hand hygiene, not touching nose and mouth). However, this can also have the reverse effect (see below);
- potential social and economic benefits. Amidst the global shortage of surgical masks and PPE, encouraging the public to create their own fabric masks may promote individual enterprise and community integration. Moreover, the production of non-medical masks may offer a source of income for those able to manufacture masks within their communities. Fabric masks can also be a form of cultural expression, encouraging public acceptance of protection measures in general. The safe re-use of fabric masks will also reduce costs and waste and contribute to sustainability.

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The likely disadvantages of the use of mask by healthy people in the general public include:

- potential increased risk of self-contamination due to the manipulation of a face mask and subsequently touching eyes with contaminated hands;(4 , 49)
- potential self-contamination that can occur if non-medical masks are not changed when wet or soiled. This can create favourable conditions for microorganism to amplify;
- potential headache and/or breathing difficulties, depending on type of mask used;
- potential development of facial skin lesions, irritant dermatitis or worsening acne, when used frequently for long hours;(50)
- difficulty with communicating clearly;
- potential discomfort;(41, 51)
- a false sense of security, leading to potentially lower adherence to other critical preventive measures such as physical distancing and hand hygiene;
- poor compliance with mask wearing, in particular by young children;
- waste management issues; improper mask disposal leading to increased litter in public places, risk of contamination to street cleaners and environment hazard;
- difficulty communicating for deaf persons who rely on lip reading;
- disadvantages for or difficulty wearing them, especially for children, developmentally challenged persons, those with mental illness, elderly persons with cognitive impairment, those with asthma or chronic respiratory or breathing problems, those who have had facial trauma or recent oral maxillofacial surgery, and those living in hot and humid environments.

If masks are recommended for the general public, the decision-maker should:

- clearly communicate the purpose of wearing a mask, where, when, how and what type of mask should be worn. Explain what wearing a mask may achieve and what it will not achieve, and communicate clearly that this is one part of a package of measures along with hand hygiene, physical distancing and other measures that are all necessary and all reinforce each other;
- inform/train people on when and how to use masks safely (see mask management and maintenance sections), i.e. put on, wear, remove, clean and dispose;
- consider the feasibility of use, supply/access issues, social and psychological acceptance (of both wearing and not wearing different types of masks in different contexts);
- continue gathering scientific data and evidence on the effectiveness of mask use (including different types and makes as well as other face covers such as scarves) in non-health care settings;
- evaluate the impact (positive, neutral or negative) of using masks in the general population (including behavioral and social sciences).

WHO encourages countries and community adopting policies on masks use in the general public to conduct good quality research to assess the effectiveness of this intervention to prevent and control transmission.

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Medical masks should be certified according to international or national standards to ensure they offer predictable product performance when used by health workers, according to the risk and type of procedure performed in a health care setting. Designed for single use, a medical mask's initial filtration (at least 95 droplet filtration), breathability and, if required, fluid resistance are attributed to the type (e.g. spunbond or meltblown) and layers of manufactured non-woven materials (e.g. polypropylene, polyethylene or cellulose). Medical masks are rectangular in shape and comprise three or four layers. Each layer consists of fine to very fine fibres. These masks are tested for their ability to block droplets (3 micrometres in size; EN 146 3 and ASTM F2100 standards) and particles (0.1 micrometre in size; ASTM F2100 standard only). The masks must block droplets and particles while at the same time they must also be breathable by allowing air to pass. Medical masks are regulated medical devices and categorized as PPE.

The use of medical masks in the community may divert this critical resource from the health workers and others who need them the most. In settings where medical masks are in short supply, e al a o l e e e e o eal o e an a n al en n a e

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Non-medical (also referred to as fabric in this document) masks are made from a variety of woven and non-woven fabrics, such as polypropylene. Non-medical masks may be made of different combinations of fabrics, layering sequences and available in diverse shapes. Few of these combinations have been systematically evaluated and there is no single design, choice of material, layering or shape among the non-medical masks that are available. The unlimited combination of fabrics and materials results in variable filtration and breathability.

A non-medical mask is neither a medical device nor personal protective equipment. However, a non-medical mask standard has been developed by the French Standardization Association (AFNO Group) to define minimum performance in terms of filtration (minimum 70 solid particle filtration or droplet filtration) and breathability (maximum pressure difference of 0.6 mbar/cm^2 or maximum inhalation resistance of 2.4 mbar and maximum exhalation resistance of 3 mbar).(71)

The lower filtration and breathability standardized requirements, and overall expected performance, indicate that the use of non-medical masks, made of woven fabrics such as cloth, and/or non-woven fabrics, should only be considered for source control (used by infected persons) in community settings and not for prevention. They can be used ad-hoc for specific activities (e.g., while on public transport when physical distancing cannot be maintained), and their use should always be accompanied by frequent hand hygiene and physical distancing.

Decision makers advising on type of non-medical mask should take into consideration the following features of non-medical masks: filtration efficiency (FE), or filtration, breathability, number and combination of material used, shape, coating and maintenance.

a) Type of materials: filtration efficiency (FE), breathability of single layers of materials, filter quality factor

The selection of material is an important first step as the filtration (barrier) and breathability varies depending on the fabric. Filtration efficiency is dependent on the tightness of the weave, fibre or thread diameter, and, in the case of non-woven materials, the manufacturing process (spunbond, meltblown, electrostatic charging).(49, 72) The filtration of cloth fabrics and masks has been shown to vary between 0.7 and 60 .(73, 74) The higher the filtration efficiency the more of a barrier provided by the fabric.

Breathability is the ability to breathe through the material of the mask. Breathability is the difference in pressure across the mask and is reported in millibars (mbar) or Pascals (Pa) or, for an area of mask, over a square centimeter ($mbar/cm^2$ or Pa/cm^2). Acceptable breathability of a medical mask should be below 49 Pa/cm^2. For non-medical masks, an acceptable pressure difference, over the whole mask, should be below 100 Pa.(73)

Depending on fabric used, filtration efficiency and breathability can complement or work against one another. ecent data indicate that two non-woven spunbond layers, the same material used for the external layers of disposable medical masks, offer adequate filtration and breathability. Commercial cotton fabric masks are in general very breathable but offer lower filtration.(75) The filter quality factor known as is a commonly used filtration quality factor; it is a function of filtration efficiency (filtration) and breathability, with higher values indicating better overall efficiency.(76) Table 3 shows FE, breathability and the filter quality factor, , of several fabrics and non-medial masks.(73, 77) According to expert consensus three (3) is the minimum factor recommended. This ranking serves as an initial guide only.

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Material	Source	Structure	Initial Filtration Efficiency (%)	Initial Pressure drop (Pa)	Filter quality factor, Q ** (kPa^{-1})
Polypropylene	Interfacing material, purchased as-is	Spunbond (Nonwoven)	6	1.6	16.9
Cotton 1	Clothing (T-shirt)	Woven	5	4.5	5.4
Cotton 2	Clothing (T-shirt)	Knit	21	14.5	7.4
Cotton 3	Clothing (Sweater)	Knit	26	17	7.6
Polyester	Clothing (Toddler wrap)	Knit	17	12.3	6.8
Cellulose	Tissue paper	Bonded	20	19	5.1
Cellulose	Paper towel	Bonded	10	11	4.3
Silk	Napkin	Woven	4	7.3	2.8
Cotton, gauze	N/A	Woven	0.7	6.5	0.47
Cotton, handkerchief	N/A	Woven	1.1	9.8	0.48
Nylon	Clothing (Exercise pants)	Woven	23	244	0.4

This table refers only to materials reported in experimental peer-reviewed studies. The filtration efficiency, pressure drop and factor are dependent on flow rate. According to expert consensus, three (3) is the minimum factor recommended.

It is preferable not to select elastic material for making masks; during wear, the mask material may be stretched over the face, resulting in increased pore size and lower filtration efficiency throughout use. Also, elastic materials may degrade over time and are sensitive to washing at high temperatures.

b) Number of layers

A minimum of three layers is required for non-medical masks, depending on the fabric used. The innermost layer of the mask is in contact with the wearer's face. The outermost layer is exposed to the environment.(7)

Fabric cloths (e.g., nylon blends and 100 polyester) when folded into two layers, provides 2-5 times increased filtration efficiency compared to a single layer of the same cloth,-and filtration efficiency increases 2-7 times if it is folded into 4 layers.(75) Masks made of cotton handkerchiefs alone should consist of at least 4 layers, but have achieved only 13 filtration efficiency.(73) Very porous materials, such as gauze, even with multiple layers will not provide sufficient filtration; only 3 filtration efficiency. (73)

It is important to note that with more tightly woven materials, as the number of layers increases, the breathability may be reduced. A quick check for breathability may be performed by attempting to breathe, through the mouth, and through the multiple layers.

c) Combination of material used

The ideal combination of material for non-medical masks should include three layers as follows: 1) an innermost layer of a hydrophilic material (e.g. cotton or cotton blends); 2), an outermost layer made of hydrophobic material (e.g., polypropylene, polyester, or their blends) which may limit external contamination from penetration through to the wearer's nose and mouth; 3) a middle hydrophobic layer of synthetic non-woven material such as polyproplylene or a cotton layer which may enhance filtration or retain droplets.

d) Mask shape

Mask shapes include flat-fold or duckbill and are designed to fit closely over the nose, cheeks and chin of the wearer. When the edges of the mask are not close to the face and shift, for example, when speaking, internal/external air penetrates through the edges of the mask rather than being filtered through the fabric. eaks where unfiltered air moves in and out of the mask may be attributed to the size and shape of the mask.(79)

It is important to ensure that the mask can be held in place comfortably with little ad ustment using elastic bands or ties.

e) Coating of fabric

Coating the fabric with compounds like wax may increase the barrier and render the mask fluid resistant; however, such coatings may inadvertently completely block the pores and make the mask difficult to breathe through. In addition to decreased breathability unfiltered air may more likely escape the sides of the mask upon exhalation. Coating is therefore not recommended.

f) Mask maintenance

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All masks should be changed if wet or visibly soiled; a wet mask should not be worn for an extended period of time. emove the mask without touching the front of the mask, do not touch the eyes or mouth after mask removal. Either discard the mask or place it in a sealable bag where it is kept until it can be washed and cleaned. Perform hand hygiene immediately afterwards.

Non-medical masks should be washed frequently and handled carefully, so as not to contaminate other items.

If the layers of fabrics look noticeably worn out, discard the mask.

Clothing fabrics used to make masks should be checked for the highest permitted washing temperature. If instructions for washing are indicated on the clothing label, verify if washing in warm or hot water is tolerated. Select washable fabrics that can be washed. Wash in warm hot water, 60 C, with soap or laundry detergent Non-woven polypropylene (PP) spunbond may be washed at high temperatures, up to 125 C.(72) Natural fibres may resist high temperature washes and ironing. Wash the mask delicately (without too much friction, stretching or wringing) if nonwoven materials (e.g. spunbond) are used. The combination of non-woven PP spunbond and cotton can tolerate high temperatures; masks made of these combinations may be steamed or boiled.

Where hot water is not available, wash mask with soap/detergent at room temperature water, followed by either i) boiling mask for one minute O ii) soak mask in 0.1 chlorine for one minute then thoroughly rinse mask with room temperature water, to avoid any toxic residual of chlorine.

WHO is collaborating with research and development partners and the scientific community engaged in textile engineering and fabric design to facilitate a better understanding of the effectiveness and efficiency of non-medical masks. WHO urges countries that have issued recommendations on the use of both medical and non-medical masks by healthy people in community settings to conduct research on this important topic. Such research needs to look at whether SA S-CoV-2 particles can be expelled through non-medical masks of poor quality worn by a person with symptoms of COVID-19 while that person is coughing, sneezing or speaking. esearch is also needed on non-medical mask use by children and other medically challenging persons and settings as mentioned above.

Table 4 provides a summary of guidance and practical considerations on the composition, construction and management of non-medical masks.

Advice on the use of masks for children in the community in the context of COVID-19

Annex to the Advice on the use of masks in the context of COVID-19

21 August 2020

Purpose of the document

This document provides guidance to decision makers, public and child health professionals to inform policy on the use of masks for children in the context of the COVID-19 pandemic. It does not address the use of masks for adults working with children or parents/guardians or the use of masks for children in health-care settings. This interim guidance will be revised and updated as new evidence emerges.

Background

The World Health Organization (WHO) and the United Nations Children's Fund (UNICEF) advise the use of masks according to a risk-based approach, as part of a comprehensive package of public health interventions that can prevent and control the transmission of certain viral respiratory diseases, including COVID-19. Compliance with other measures including physical distancing, hand hygiene, respiratory etiquette and adequate ventilation in indoor settings is essential for reducing the spread of SA S-CoV-2, the virus that causes COVID-19.

This guidance provides specific considerations for the use of non-medical masks, also known as fabric masks, by children as a means for source control in the context of the current COVID-19 pandemic. The document is an annex to the WHO's Advice on the use of masks in the context of COVID-19[1] in which further details on fabric masks can be found. This annex also advises the use of medical masks for children under certain conditions. For the purposes of this guidance, children are defined as anyone below the age of 1 years[2].

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The World Health Organization (WHO) Infection Prevention and Control (IPC) Guidance Development Group (GDG) and experts from UNICEF and the International Paediatric Association (IPA) ointly reviewed the available evidence to develop guidance on the use of masks for children in the context of the current pandemic. Five international expert meetings were held between une and August 2020. In the absence of strong scientific evidence, consensus among these groups forms the main basis for this guidance. Furthermore, the draft guidance was reviewed by a multidisciplinary group of additional external experts prior to finalization.

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ransmission of C VI -19 in children

Currently, the extent to which children contribute to transmission of SA S-CoV-2 is not completely understood. According to the WHO global surveillance database of laboratory-confirmed cases developed from case report forms provided to WHO by Member States[3] and other studies, 1-7 of COVID-19 cases are reported to be among children, with relatively few deaths compared to other age groups[4-] . The European Centre for Disease Prevention and Control (ECDC) has recently reported the age distribution of COVID-19 among children in the European Union (EU), European Economic Area (EEA) and the United ingdom (U); they reported that as of 26 uly 2020, 4 of all cases in the EU/EEA and the U were among children[6].

To date, the available evidence suggests that most reported cases among children have resulted from transmission within households, although this observation may have been influenced by school closures and other stay at home measures implemented by some countries[7,9]. Although culture-competent virus has been isolated from symptomatic children with viral load levels found to be similar to that in adults[10], evidence from available studies of contacts of COVID-19 cases and cluster investigations suggests that children are unlikely to be the main drivers of COVID-19 transmission[7,9 11-14]. To date, documented transmission among children and staff within educational settings is limited[15-20]. Evidence is also limited regarding the prevalence of SA S-CoV-2 infection among children, as measured by seroepidemiology studies. However, available evidence suggests that seroprevalence appears to be lower for younger children compared to older children and adults[17,21-25].

Studies of viral load and the duration of viral shedding of infectious virus in children compared to adults, are also limited. One published study suggests that viral load in infected patients may differ by age, and that symptomatic children have a longer duration of viral shedding than asymptomatic children[25]. Some studies have reported that children below five years are reported to have lower amounts of viral NA in respiratory secretions and faeces compared to school children, adolescents and adults[26,27]. However, one study from the United States of America found that children below five years with mild to moderate COVID-19 have higher amounts of viral NA in their upper respiratory samples compared with older children and adults[2] , while a pre-print (non-peer-reviewed) study from Germany reported no differences in the amount of viral NA among adults and children[29].

In summary, the degree to which age alone, regardless of symptoms, affects viral load and transmission is not well understood.

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Evidence on the benefits and harms of children wearing masks to mitigate transmission of COVID-19 and other coronaviruses is limited. However, some studies have evaluated the effectiveness of mask use in children for influenza and other respiratory viruses[30-34]. A study of mask wearing during seasonal influenza outbreaks in apan noted that the use of masks was more effective in higher school grades (9-12 year old children in grades 4-6) than lower grades (6-9 year old children, in grades 1-3)[34]. One study, conducted under laboratory conditions and using non-betacoronaviruses, suggested that children between five and 11 years old were significantly less protected by mask wearing compared to adults, possibly related to inferior fit of the mask[35]. Other studies found evidence of some protective effect for influenza for both source control[30] and protection in children[34], although overall compliance with consistent mask wearing, especially among children under the age of 15, was poor.

Some studies, including studies conducted in the context of influenza and air pollution, found the use and acceptability of mask wearing to be highly variable among children, ranging from very low to acceptable levels and decreasing over time while wearing masks[30,31,33,36-3] . One study was carried out among primary school children during COVID-19 and reported 51.6 compliance.[31]

Several studies found that factors such as warmth, irritation, breathing difficulties, discomfort, distraction, low social acceptability and poor mask fit were reported by children when using masks[30,33,36,37]. So far, the effectiveness and impact of masks for children during play and physical activity have not been studied; however, a study in adults found that N95 respirator and surgical masks reduced cardiopulmonary capacity during heavy exertion[39].

ain conclusions

According to the limited available evidence, young children may have lower susceptibility to infection compared to adults[11,14], however available data suggests that this may vary by age among children[17, 21-25]. Data from seroepidemiology studies and transmission studies suggest that older children (e.g. teenagers) may play a more active role in transmission than younger children.[11,14,17, 21-25]

The benefits of wearing masks in children for COVID-19 control should be weighed against potential harm associated with wearing masks, including feasibility and discomfort, as well as social and communication concerns. Factors to consider also include age groups, sociocultural and contextual considerations and availability of adult supervision and other resources to prevent transmission.

There is a need for data from high quality prospective studies in different settings on the role of children and adolescents in transmission of SA S-CoV-2[40], on ways to improve acceptance and compliance of mask use and on the effectiveness of masks use in children. These studies must be prioritized and include prospective studies of transmission within educational settings and households stratified by age groups (ideally 2, 2-4, 5-11 and 12 years) and with different prevalence and transmission patterns. Particular emphasis must be placed on studies in schools in low- and middle-income settings.

Advice to decision makers on the use of masks for children in the community

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Given the limited evidence on the use of masks in children for COVID-19 or other respiratory diseases, including limited evidence about transmission of SA S-CoV-2 in children at specific ages, the formulation of policies by national authorities should be guided by the following overarching public health and social principles:

- Do no harm: the best interest, health and well-being of the child should be prioritized.
- The guidance should not negatively impact development and learning outcomes.
- The guidance should consider the feasibility of implementing recommendations in different social, cultural and geographic contexts, including settings with limited resources, humanitarian settings and among children with disabilities or specific health conditions.

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WHO and UNICEF advise decision makers to apply the following criteria for use of masks in children when developing national policies, in countries or areas where there is known or suspected community transmission[a] of SA S-CoV-2 and in settings where physical distancing cannot be achieved.

1. Based on the expert opinion gathered through online meetings and consultative processes, children aged up to five years should not wear masks for source control. This advice is motivated by a do no harm approach and considers:
    - childhood developmental milestones[b] [41]
    - compliance challenges and
    - autonomy required to use a mask properly.

The experts (following the methods described above) recognized that the evidence supporting the choice of the age cut-off is limited (see above, section related to transmission of COVID-19 in children), and they reached this decision mainly by consensus. The rationale included consideration of the fact that by the age of five years, children usually achieve significant developmental milestones, including the manual dexterity and fine motor coordination movements needed to appropriately use a mask with minimal assistance.

In some countries, guidance and policies recommend a different and lower age cut-off for mask use[42-45]. It is recognized that children may reach developmental milestones at different ages and children five years of age and under may have the dexterity needed to manage a mask. Based on the do no harm approach, if the lower age cut-off of two or three years of age is to be used for recommending mask use for children, appropriate and consistent supervision, including direct line of sight supervision by a competent adult and compliance need to be ensured, especially if mask wearing is expected for an extended period of time. This is both to ensure correct use of the mask and to prevent any potential harm associated with mask wearing to the child.

Children with severe cognitive or respiratory impairments who have difficulties tolerating a mask should, under no circumstances, be required to wear masks.

Other IPC, public health and social measures should be prioritized to minimize the risk of SA S-CoV-2 transmission for children five years of age and under; specifically maintaining physical distance of at least 1 meter where feasible, educating children to perform frequent hand hygiene and limiting the size of school classes. It is also noted that there may be other specific considerations, such as the presence of vulnerable persons or other local medical and public health advice that should be considered when determining if children five years of age and under need to wear a mask.

2. For children between six and 11 years of age, a risk-based approach should be applied to the decision to use of a mask. This approach should take into consideration:
    - intensity of transmission in the area where the child is and updated data/available evidence on the risk of infection and transmission in this age group;
    - social and cultural environment such as beliefs, customs, behaviour or social norms that influence the community and population's social interactions, especially with and among children;
    - the child's capacity to comply with the appropriate use of masks and availability of appropriate adult supervision;
    - potential impact of mask wearing on learning and psychosocial development; and
    - additional specific considerations and adaptions for specific settings such as households with elderly relatives, schools, during sport activities or for children with disabilities or with underlying diseases.

3. Advice on mask use in children and adolescents 12 years or older should follow the WHO guidance for mask use in adults[1] and/or the national mask guidelines for adults.

    Even where national guidelines apply, additional specific considerations (see below) and adaptions for special settings such as schools, during sport, or for children with disabilities or with underlying diseases will need to be specified.

4. The use of a medical mask for immunocompromised children or for paediatric patients with cystic fibrosis or certain other diseases (e.g. cancer) is usually recommended but should be assessed in consultation with the child's medical provider[46,47].

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[a] Defined by WHO as experiencing larger outbreaks of local transmission defined through an assessment of factors including, but not limited to: large numbers of cases not linkable to transmission chains; large numbers of cases from sentinel surveillance; and/or multiple unrelated clusters in several areas of the country/territory/area (https://www.who.int/publications-detail/global-surveillance-for-covid-19-caused-by-human-infection-with-covid-19-virus-interim-guidance)

[b] An example of considering childhood developmental milestones as defined by CDC are available here:

https://www.cdc.gov/ncbddd/actearly/pdf/checklists/Checklists-with-Tips_ eader_50 .pdfhttps://www.cdc.gov/ncbddd/actearly/pdf/checklists/Checklists-with-Tips_ eader_50 .pdf

For children of any age with developmental disorders, disabilities or other specific health conditions that might interfere with mask wearing, the use of masks should not be mandatory and should be assessed on a case by case basis by the child's educator and/or medical provider.

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ocal epidemiology and contextual issues, such as intensity of transmission, ability to physically distance or implement appropriate ventilation measures in indoor settings, age mixing and contact with other vulnerable individuals should be considered when adopting advice for wearing masks among different age groups, in addition to potential harms and adverse effects of mask wearing.

Age-appropriate communication aimed at improving understanding of the purpose of mask wearing, safe and appropriate mask wearing and maintenance of masks, should be provided by parents/guardians, teachers, educators, and trusted community members through role-modelling. Materials, messages and mechanisms for communication on masks for children should remain flexible and adaptive and be systematically reviewed and updated based on changes in evidence and community needs and questions[4 ,49]. Children should also be listened to regarding their perceptions and any concerns about wearing a mask. Adapted communication should be available for different social, cultural and linguistic settings, with feedback mechanisms in place for responding to children's questions and expectations.

Specific education and communication messages should be developed to ensure that the use of masks does not result in a false sense of security or disregard for other public health measures by children. It is important to emphasize that the use of masks is one tool and that children should also adhere to physical distancing, hand hygiene and respiratory etiquette. Parents, family members, teachers and educators have a critical role in ensuring that these messages are consistently conveyed to children.

Strategies for assisting children, especially in younger age groups, to manage the wearing of masks safely and effectively should be included in the implementation of this advice. This may include processes for safe storage of used masks for reuse by the same child after eating or exercising, storing soiled masks (e.g. in dedicated bags or containers) before they can be laundered and storage and supply of additional clean masks if a child's mask becomes soiled, wet, or is lost.

Masks should be made accessible free of charge to children living in households or geographic areas with social vulnerabilities and limited resources to ensure equitable access for all children. Consideration should also be made for provision of masks for the ourney to and from school.

The design of face masks for children should take into consideration the overall quality of the fabric, suitable breathability and comfort[1] and child-friendliness (appropriate size, colours, design, etc.) to help improve their acceptance of and use by children. Specific attention needs to be given to the care of masks and the need for masks to be changed when they get wet or soiled. Specific measures will need to be in place for children under 12 years who are in a situation where they are asked to wear masks.

The age cut-off for wearing a mask should be adapted to social or school settings to avoid stigmatizing and alienating children in mixed-aged groups where individuals may be on opposite sides of a recommended age cut-off. For example, in situations where older children for whom masks are advised are in the same class as younger children who fall below the age cut-off for wearing masks, the older learners might be exempt from wearing masks.

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Children with developmental disorders or disabilities may face additional barriers, limitations and risks and therefore should be given alternative options to mask wearing, such as face shields (see below). Policies on masks should be adapted for children with disabilities based on social, cultural and environmental considerations.

Some children with disabilities require close physical contact with therapists, educators or social workers. In this context, it is critical that all care providers adopt key IPC measures, including wearing masks, and that settings are adapted to strengthen IPC.

The wearing of masks by children with hearing loss or auditory problems may present learning barriers and further challenges, exacerbated by the need to adhere to the recommended physical distancing[50]. These children may miss learning opportunities because of the degraded speech signal stemming from mask wearing, the elimination of lipreading and speaker expressions and physical distancing. Adapted masks to allow lipreading (e.g. clear masks) or use of face shields (see below) may be explored as an alternative to fabric masks[51].

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To facilitate the operationalization of this guidance in school settings (as per national standards) it is advised that the age categories be adapted to the national/local education level structure.

The use of masks by children and adolescents in schools should only be considered as one part of a comprehensive strategy to limit the spread of COVID-19. The following guidance documents can be used to inform policy making and programming either for a comprehensive school safety strategy when re-opening or operations in the context of COVID-19:

- WHO considerations for school-related public health measures in the context of COVID-19
- WB/WFP/UNESCO/UNICEF framework for school reopening
- WHO/UNICEF/IF C Interim Guidance for COVID-19 Prevention and Control in Schools

As part of the comprehensive school safety strategy for reopening, the views of teachers and educators on the perception of risks and the time burden required to ensure adherence to COVID-19 policies in schools and classrooms including the use of masks by children should be considered. Situations where wearing a mask can significantly interfere with the learning process and have a negative impact on critical school activities like physical education, meal programs, play time and sports as well as learning require special consideration.

If wearing of fabric masks is recommended in schools, specific instructions and supplies should be provided for the safe storage, handling and availability of fabric masks (see above). A sufficient supply of appropriate masks should be ensured for all school children. Basic water, sanitation and hygiene requirements should be met in the school building so that comprehensive IPC measures can be implemented, linked to specific age-appropriate educational activities.

If medical or disposable masks are used in specific situations, a system for waste management including disposal of used masks will need to be established to reduce the risk of contaminated masks being disposed of in classrooms and playgrounds.

No children should be denied access to education because of mask wearing or the lack of a mask because of low resources or unavailability.

Alternative to fabric masks for children

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Face shields are designed to be used[52] to provide protection from splashes of biological fluid (particularly respiratory secretions), chemical agents and debris[53,54] into the eyes. In the context of protection from SA S-CoV-2 transmission through respiratory droplets, they are used by health workers as personal protective equipment (PPE) for eye protection in combination with a medical mask or a respirator[55,56]. In the context of COVID-19 in community settings, some children may not be able to wear a mask for a variety of reasons (e.g. health issues, fear of mask), and thus, face shields may be considered as an alternative to masks as respiratory droplet protection or as source control, based on availability, improved feasibility and better tolerability[57,5] . Some countries, such as Australia[59] recommend face shields as an alternative to a mask. Other countries, such as Singapore[60] advise that both a mask and a shield can be worn together, but acknowledge that children with special needs may need to be exempt from wearing either.

WHO and UNICEF have reviewed the current available evidence on the use of face shields for respiratory droplet protection and/or source control in the context of the COVID-19 pandemic. While a face shield may confer partial protection[52] of the facial area against respiratory droplets with the added benefit of ease of use, the effectiveness of face shields for source control has not yet been adequately studied. Droplets may be exhaled or inhaled from the open gaps between the visor and the face[52], which is a disadvantage inherent to its design[53]. Other design disadvantages include glaring, fogging, optical imperfection, and being bulkier than goggles and safety glasses[61]. There are many emerging face shield designs that attempt to overcome these limitations, but current laboratory testing standards only assess face shields for their ability to provide eye protection from chemical splashes[61,62]. Further research and laboratory challenge standards are urgently needed to investigate the effectiveness of face shields for respiratory droplet protection and/or source control[56]. At present, face shields are considered to provide a level of eye protection only and should not be considered as an equivalent to masks with respect to respiratory droplet protection and/or source control.

WHO and UNICEF will continue to monitor emerging information on the use of face shields for the prevention of respiratory virus transmission. WHO and UNICEF advise that when physical distance cannot be maintained, and in special situations where it is not practical to wear a mask (for example, among children with hearing loss or other disabilities or health conditions that limit compliance with wearing fabric or medical masks and consequently their utility), face shields may be used while taking the following considerations into account:

- The face shield is an incomplete physical barrier and does not provide the filtration layers of a mask.
- The face shield should cover the entire face, be wrapped around the sides of the face and extend to below the chin[5] .
- eusable face shields must be properly cleaned (with soap or a detergent and water), disinfected (with 70-90 alcohol) and stored after each use[44]. Face shields that will withstand the use of disinfectants without damaging their optical properties should be selected.
- Maintaining physical distance of at least 1 m (3.3 feet) should be maintained where feasible, with ongoing promotion of frequent hand hygiene and respiratory etiquette[56].
- Caution should be taken to avoid in ury when children don, wear, and doff face shields.

Monitoring and evaluation of the impact of the use of masks in children

If authorities decide to recommend mask-wearing for children, key information should be collected on a regular basis to accompany and monitor the intervention. Monitoring and evaluation should be established at the onset and should include indicators that measure the impact on the child's health, including mental health; reduction in transmission of SA S-CoV-2; motivators and barriers to mask wearing; and secondary impacts on a child's development learning, attendance in school, ability to express him/herself or access school; and impact on children with developmental delays, health conditions, disabilities or other vulnerabilities.

Data should be used to inform strategies on communication; training and support to teachers, educators, and parents; engagement activities for children; and distribution of materials that empower children to use masks appropriately.

Analysis should include sex, age, physical, social and economic stratification to ensure that the policy implementation contributes to reducing health and social inequities.

WHO and UNICEF will continue to closely monitor emerging evidence about this topic and the situation for any changes that may affect this interim guidance. Should any factors change, WHO and UNICEF will issue a further update. Otherwise, this interim guidance document will expire six months after the date of publication.

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1. The WHO Health Emergencies Programme (WHE) Ad-hoc COVID-19 Guidance Development Group:
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WHO and UNICEF continue to monitor the situation closely for any changes that may affect this interim guidance. Should any factors change, an update will be issued. Otherwise, this interim guidance document will expire 2 years after the date of publication.

WHO reference number: WHO/2019-nCoV/IPC_Masks/Children/2020.1

Mask use in the context of COVID-19

Interim guidance

1 December 2020

World Health Organization

This document, which is an update of the guidance published on 5 une 2020, includes new scientific evidence relevant to the use of masks for reducing the spread of SA S-CoV-2, the virus that causes COVID-19, and practical considerations. It contains updated evidence and guidance on the following:

- mask management;
- SA S-CoV-2 transmission;
- masking in health facilities in areas with community, cluster and sporadic transmission;
- mask use by the public in areas with community and cluster transmission;
- alternatives to non-medical masks for the public;
- exhalation valves on respirators and non-medical masks;
- mask use during vigorous intensity physical activity;
- essential parameters to be considered when manufacturing non-medical masks (Annex).

Key points

- The World Health Organization (WHO) advises the use of masks as part of a comprehensive package of prevention and control measures to limit the spread of SA S-CoV-2, the virus that causes COVID-19. A mask alone, even when it is used correctly, is insufficient to provide adequate protection or source control. Other infection prevention and control (IPC) measures include hand hygiene, physical distancing of at least 1 metre, avoidance of touching one's face, respiratory etiquette, adequate ventilation in indoor settings, testing, contact tracing, quarantine and isolation. Together these measures are critical to prevent human-to-human transmission of SA S-CoV-2.
- Depending on the type, masks can be used either for protection of healthy persons or to prevent onward transmission (source control).
- WHO continues to advise that anyone suspected or confirmed of having COVID-19 or awaiting viral laboratory test results should wear a medical mask when in the presence of others (this does not apply to those awaiting a test prior to travel).
- For any mask type, appropriate use, storage and cleaning or disposal are essential to ensure that they are as effective as possible and to avoid an increased transmission risk.

Mask use in health care settings

- WHO continues to recommend that health workers (1) providing care to suspected or confirmed COVID-19 patients wear the following types of mask/respirator in addition to other personal protective equipment that are part of standard, droplet and contact precautions:
  - medical mask in the absence of aerosol generating procedures (AGPs)
  - respirator, N95 or FFP2 or FFP3 standards, or equivalent in care settings for COVID-19 patients where AGPs are performed; these may be used by health workers when providing care to COVID-19 patients in other settings if they are widely available and if costs is not an issue.
- In areas of known or suspected community or cluster SA S-CoV-2 transmission WHO advises the following:
  - universal masking for all persons (staff, patients, visitors, service providers and others) within the health facility (including primary, secondary and tertiary care levels; outpatient care; and long-term care facilities)
  - wearing of masks by inpatients when physical distancing of at least 1 metre cannot be maintained or when patients are outside of their care areas.
- In areas of known or suspected sporadic SA S-CoV-2 transmission, health workers working in clinical areas where patients are present should continuously wear a medical mask. This is known as targeted continuous medical masking for health workers in clinical areas;
- Exhalation valves on respirators are discouraged as they bypass the filtration function for exhaled air by the wearer.

Mask use in community settings

- Decision makers should apply a risk-based approach when considering the use of masks for the general public.
- In areas of known or suspected community or cluster SA S-CoV-2 transmission:
  - WHO advises that the general public should wear a non-medical mask in indoor (e.g. shops, shared workplaces, schools - see Table 2 for details) or outdoor settings where physical distancing of at least 1 metre cannot be maintained.
  - If indoors, unless ventilation has been be assessed to be adequate[1], WHO advises that the general public should wear a non-medical mask, regardless of whether physical distancing of at least 1 metre can be maintained.

[1] For adequate ventilation refer to regional or national institutions or heating, refrigerating and air-conditioning societies enacting ventilation requirements. If not available or applicable, a recommended ventilation rate of 10 l/s/person should be met (except healthcare facilities which have specific requirements). For more information consult Coronavirus (COVID-19) response

- Individuals/people with higher risk of severe complications from COVID-19 (individuals _ 60 years old and those with underlying conditions such as cardiovascular disease or diabetes mellitus, chronic lung disease, cancer, cerebrovascular disease or immunosuppression) should wear medical masks when physical distancing of at least 1 metre cannot be maintained.

- In any transmission scenarios:
  - Caregivers or those sharing living space with people with suspected or confirmed COVID-19, regardless of symptoms, should wear a medical mask when in the same room.

Mask use in children (2)

- Children aged up to five years should not wear masks for source control.
- For children between six and 11 years of age, a risk-based approach should be applied to the decision to use a mask; factors to be considered in the risk-based approach include intensity of SA S-CoV-2 transmission, child's capacity to comply with the appropriate use of masks and availability of appropriate adult supervision, local social and cultural environment, and specific settings such as households with elderly relatives, or schools.
- Mask use in children and adolescents 12 years or older should follow the same principles as for adults.
- Special considerations are required for immunocompromised children or for paediatric patients with cystic fibrosis or certain other diseases (e.g., cancer), as well as for children of any age with developmental disorders, disabilities or other specific health conditions that might interfere with mask wearing.

Manufacturing of non-medical (fabric) masks (Annex)

- Homemade fabric masks of three-layer structure (based on the fabric used) are advised, with each layer providing a function: 1) an innermost layer of a hydrophilic material 2) an outermost layer made of hydrophobic material 3) a middle hydrophobic layer which has been shown to enhance filtration or retain droplets.
- Factory-made fabric masks should meet the minimum thresholds related to three essential parameters: filtration, breathability and fit.
- Exhalation valves are discouraged because they bypass the filtration function of the fabric mask rendering it unserviceable for source control.

Methodology for developing the guidance

Guidance and recommendations included in this document are based on published WHO guidelines (in particular the WHO Guidelines on infection prevention and control of epidemic- and pandemic-prone acute respiratory infections in health care) (2) and ongoing evaluations of all available scientific evidence by the WHO ad hoc COVID-19 Infection Prevention and Control Guidance Development Group (COVID-19 IPC GDG) (see acknowledgement section for list of GDG members). During emergencies WHO publishes interim guidance, the development of which follows a transparent and robust process of evaluation of the available evidence on benefits and harms. This evidence is evaluated through expedited systematic reviews and expert consensus-building through weekly GDG consultations, facilitated by a methodologist and, when necessary, followed up by surveys. This process also considers, as much as possible, potential resource implications, values and preferences, feasibility, equity, and ethics. Draft guidance documents are reviewed by an external review panel of experts prior to publication.

Purpose of the guidance

This document provides guidance for decision makers, public health and IPC professionals, health care managers and health workers in health care settings (including long-term care and residential), for the public and for manufactures of non-medical masks (Annex). It will be revised as new evidence emerges.

WHO has also developed comprehensive guidance on IPC strategies for health care settings (3), long-term care facilities (TCF) (4), and home care (5).

Background

The use of masks is part of a comprehensive package of prevention and control measures that can limit the spread of certain respiratory viral diseases, including COVID-19. Masks can be used for protection of healthy persons (worn to protect oneself when in contact with an infected individual) or for source control (worn by an infected individual to prevent onward transmission) or both.

However, the use of a mask alone, even when correctly used (see below), is insufficient to provide an adequate level of protection for an uninfected individual or prevent onward transmission from an infected individual (source control). Hand hygiene, physical distancing of at least 1 metre, respiratory etiquette, adequate ventilation in indoor settings, testing, contact tracing, quarantine, isolation and other infection prevention and control (IPC) measures are critical to prevent human-to-human transmission of SA S-CoV-2, whether or not masks are used (6).

Mask management

For any type of mask, appropriate use, storage and cleaning, or disposal are essential to ensure that they are as effective as possible and to avoid any increased risk of transmission. Adherence to correct mask management practices varies, reinforcing the need for appropriate messaging (7).

WHO provides the following guidance on the correct use of masks:

- Perform hand hygiene before putting on the mask.
- Inspect the mask for tears or holes, and do not use a damaged mask.
- Place the mask carefully, ensuring it covers the mouth and nose, ad ust to the nose bridge and tie it securely to minimize any gaps between the face and the mask. If using ear loops, ensure these do not cross over as this widens the gap between the face and the mask.

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resources from ASH AE and others''
https://www.ashrae.org/technical-resources/resources

Guidance on mask use in community settings

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At present there is only limited and inconsistent scientific evidence to support the effectiveness of masking of healthy people in the community to prevent infection with respiratory viruses, including SA S-CoV-2 (75). A large randomized community-based trial in which 4 62 healthy participants were divided into a group wearing medical/surgical masks and a control group found no difference in infection with SA S-CoV-2 (76). A recent systematic review found nine trials (of which eight were cluster-randomized controlled trials in which clusters of people, versus individuals, were randomized) comparing medical/surgical masks versus no masks to prevent the spread of viral respiratory illness. Two trials were with healthcare workers and seven in the community. The review concluded that wearing a mask may make little or no difference to the prevention of influenza-like illness (I I) (0.99, 95 CI 0. 2 to 1.1) or laboratory confirmed illness (CI) (0.91, 95 CI 0.66-1.26) (44); the certainty of the evidence was low for I I, moderate for CI.

By contrast, a small retrospective cohort study from Bei ing found that mask use by entire families before the first family member developed COVID-19 symptoms was 79 effective in reducing transmission (O 0.21, 0.06-0.79) (77). A case-control study from Thailand found that wearing a medical or non-medical mask all the time during contact with a COVID-19 patient was associated with a 77 lower risk of infection (aO 0.23; 95 CI 0.09 0.60) (7). Several small observational studies with epidemiological data have reported an association between mask use by an infected person and prevention of onward transmission of SA S-CoV-2 infection in public settings. (, 79- 1).

A number of studies, some peer reviewed (2- 6) but most published as pre-prints (7-104), reported a decline in the COVID-19 cases associated with face mask usage by the public, using country- or region-level data. One study reported an association between community mask wearing policy adoption and increased movement (less time at home, increased visits to commercial locations) (105). These studies differed in setting, data sources and statistical methods and have important limitations to consider (106), notably the lack of information about actual exposure risk among individuals, adherence to mask wearing and the enforcement of other preventive measures (107, 10).

Studies of influenza, influenza-like illness and human coronaviruses (not including COVID-19) provide evidence that the use of a medical mask can prevent the spread of infectious droplets from a symptomatic infected person to someone else and potential contamination of the environment by these droplets (75). There is limited evidence that wearing a medical mask may be beneficial for preventing transmission between healthy individuals sharing households with a sick person or among attendees of mass gatherings (44, 109-114).

A meta-analysis of observational studies on infections due to betacoronaviruses, with the intrinsic biases of observational data, showed that the use of either disposable medical masks or reusable 12 16-layer cotton masks was associated with protection of healthy individuals within households and among contacts of cases (46). This could be considered to be indirect evidence for the use of masks (medical or other) by healthy individuals in the wider community; however, these studies suggest that such individuals would need to be in close proximity to an infected person in a household or at a mass gathering where physical distancing cannot be achieved to become infected with the virus. esults from cluster randomized controlled trials on the use of masks among young adults living in university residences in the United States of America indicate that face masks may reduce the rate of influenza-like illness but showed no impact on risk of laboratory-confirmed influenza (115, 116).

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The WHO COVID-19 IPC GDG considered all available evidence on the use of masks by the general public including effectiveness, level of certainty and other potential benefits and harms, with respect to transmission scenarios, indoor versus outdoor settings, physical distancing and ventilation. Despite the limited evidence of protective efficacy of mask wearing in community settings, in addition to all other recommended preventive measures, the GDG advised mask wearing in the following settings:

1. In areas with known or suspected community or cluster transmission of SA S-CoV-2, WHO advises mask use by the public in the following situations (see Table 2):

   Indoor settings:
   - in public indoor settings where ventilation is known to be poor regardless of physical distancing: limited or no opening of windows and doors for natural ventilation; ventilation system is not properly functioning or maintained; or cannot be assessed;
   - in public indoor settings that have adequate[3] ventilation if physical distancing of at least 1 metre cannot be maintained;
   - in household indoor settings: when there is a visitor who is not a household member and ventilation is known to be poor, with limited opening of windows and doors for natural ventilation, or the ventilation system cannot be assessed or is not properly functioning, regardless of whether physical distancing of at least 1 metre can be maintained;
   - in household indoor settings that have adequate ventilation if physical distancing of at least 1 metre cannot be maintained.

[3] For adequate ventilation refer to regional or national institutions or heating, refrigerating and air-conditioning societies enacting ventilation requirements. If not available or applicable, a recommended ventilation rate of 10 l/s/person should be met (except healthcare facilities which have specific requirements). For more information consult Coronavirus (COVID-19) response resources from ASH AE and others'' https://www.ashrae.org/technical-resources/resources

In outdoor settings:

- where physical distancing of at least 1 metre cannot be maintained;
- individuals/people with higher risk of severe complications from COVID-19 (individuals ≥ 60 years old and those with underlying conditions such as cardiovascular disease or diabetes mellitus, chronic lung disease, cancer, cerebrovascular disease or immunosuppression) should wear medical masks in any setting where physical distance cannot be maintained.

2. In areas with known or suspected sporadic transmission or no documented transmission, as in all transmission scenarios, WHO continues to advise that decision makers should apply a risk-based approach focusing on the following criteria when considering the use of masks for the public:

- o e o a e. Is the intention source control (preventing an infected person from transmitting the virus to others) or protection (preventing a healthy wearer from the infection)
- o e o e o o . Based on the epidemiology and intensity of transmission in the population, is there transmission and limited or no capacity to implement other containment measures such as contact tracing, ability to carry out testing and isolate and care for suspected and confirmed cases Is there risk to individuals working in close contact with the public (e.g., social workers, personal support workers, teachers, cashiers)
- lne a l o e a ea e o la on. Is the mask wearer at risk of severe complications from COVID-19 Medical masks should be used by older people (_ 60 years old), immunocompromised patients and people with comorbidities, such as cardiovascular disease or diabetes mellitus, chronic lung disease, cancer and cerebrovascular disease (117).
- e n n e o la on l e . Is there high population density (such as in refugee camps, camp-like settings, and among people living in cramped conditions) and settings where individuals are unable to keep a physical distance of at least 1 metre (for example, on public transportation)
- ea l . Are masks available at an affordable cost Do people have access to clean water to wash fabric masks, and can the targeted population tolerate possible adverse effects of wearing a mask
- e o a . Does the use of medical masks in the community divert this critical resource from the health workers and others who need them the most In settings where medical masks are in short supply, o o l e o e o eal o e an a n al

The decision of governments and local urisdictions whether to recommend or make mandatory the use of masks should be based on the above assessment as well as the local context, culture, availability of masks and resources required.

3. In any transmission scenario:

- Persons with any symptoms suggestive of COVID-19 should wear a medical mask and (5) additionally:
  - self-isolate and seek medical advice as soon as they start to feel unwell with potential symptoms of COVID-19, even if symptoms are mild);
  - follow instructions on how to put on, take off, and dispose of medical masks and perform hand hygiene (11);
  - follow all additional measures, in particular respiratory hygiene, frequent hand hygiene and maintaining physical distance of at least 1 metre from other persons (46). If a medical mask is not available for individuals with suspected or confirmed COVID-19, a fabric mask meeting the specifications in the Annex of this document should be worn by patients as a source control measure, pending access to a medical mask. The use of a non-medical mask can minimize the pro ection of respiratory droplets from the user (119, 120).
  - Asymptomatic persons who test positive for SA S-CoV-2, should wear a medical mask when with others for a period of 10 days after testing positive.

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The potential advantages of mask use by healthy people in the general public include:

- reduced spread of respiratory droplets containing infectious viral particles, including from infected persons before they develop symptoms (121);
- reduced potential for stigmatization and greater of acceptance of mask wearing, whether to prevent infecting others or by people caring for COVID-19 patients in non-clinical settings (122);
- making people feel they can play a role in contributing to stopping spread of the virus;
- encouraging concurrent transmission prevention behaviours such as hand hygiene and not touching the eyes, nose and mouth (123-125);
- preventing transmission of other respiratory illnesses like tuberculosis and influenza and reducing the burden of those diseases during the pandemic (126).

The potential disadvantages of mask use by healthy people in the general public include:

- headache and/or breathing difficulties, depending on type of mask used (55);
- development of facial skin lesions, irritant dermatitis or worsening acne, when used frequently for long hours (5 , 59, 127);
- difficulty with communicating clearly, especially for persons who are deaf or have poor hearing or use lip reading (12 , 129);
- discomfort (44, 55, 59)
- a false sense of security leading to potentially lower adherence to other critical preventive measures such as physical distancing and hand hygiene (105);
- poor compliance with mask wearing, in particular by young children (111, 130-132);
- waste management issues; improper mask disposal leading to increased litter in public places and environmental hazards (133);
- disadvantages for or difficulty wearing masks, especially for children, developmentally challenged persons, those with mental illness, persons with cognitive impairment, those with asthma or chronic respiratory or breathing problems, those who have had facial trauma or recent oral maxillofacial surgery and those living in hot and humid environments (55, 130).

Annex: pdated guidance on non-medical (fabric) masks

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A non-medical mask, also called fabric mask, community mask or face covering, is neither a medical device nor personal protective equipment. Non-medical masks are aimed at the general population, primarily for protecting others from exhaled virus-containing droplets emitted by the mask wearer. They are not regulated by local health authorities or occupational health associations, nor is it required for manufacturers to comply with guidelines established by standards organizations. Non-medical masks may be homemade or manufactured. The essential performance parameters include good breathability, filtration of droplets originating from the wearer, and a snug fit covering the nose and mouth. Exhalation valves on masks are discouraged as they bypass the filtration function of the mask.

Non-medical masks are made from a variety of woven and non-woven fabrics, such as woven cotton, cotton/synthetic blends, polyesters and breathable spunbond polypropylene, for example. They may be made of different combinations of fabrics, layering sequences and available in diverse shapes. Currently, more is known about common household fabrics and combinations to make non-medical masks with target filtration efficiency and breathability (119, 146-150). Few of these fabrics and combinations have been systematically evaluated and there is no single design, choice of material, layering or shape among available non-medical masks that are considered optimal. While studies have focussed on single fabrics and combinations, few have looked at the shape and universal fit to the wearer. The unlimited combination of available fabrics and materials results in variable filtration and breathability.

In the context of the global shortage of medical masks and PPE, encouraging the public to create their own fabric masks may promote individual enterprise and community integration. Moreover, the production of non-medical masks may offer a source of income for those able to manufacture masks within their communities. Fabric masks can also be a form of cultural expression, encouraging public acceptance of protection measures in general. The safe re-use of fabric masks will also reduce costs and waste and contribute to sustainability (151-156).

This Annex is destined intended for two types of readers: homemade mask makers and factory-made masks manufacturers. Decision makers and managers (national/sub-national level) advising on a type of non-medical mask are also the focus of this guidance and should take into consideration the following features of non-medical masks: breathability, filtration efficiency (FE), or filtration, number and combination of fabric layers material used, shape, coating and maintenance.

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A number of reviews have been identified on the effectiveness of non-medical masks (151-156). One systematic review (155) identified 12 studies and evaluated study quality. Ten were laboratory studies (157-166), and two reports were from a single randomized trial (72, 167). The ma ority of studies were conducted before COVID-19 emerged or used laboratory generated particles to assess filtration efficacy. Overall, the reviews concluded that cloth face masks have limited efficacy in combating viral infection transmission.

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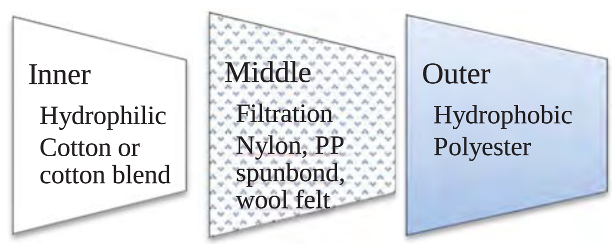
Homemade non-medical masks made of household fabrics (e.g., cotton, cotton blends and polyesters) should ideally have a three-layer structure, with each layer providing a function (see Figure 1) (16). It should include:

1. an innermost layer (that will be in contact with the face) of a hydrophilic material (e.g., cotton or cotton blends of terry cloth towel, quilting cotton and flannel) that is non-irritating against the skin and can contain droplets (14)
2. a middle hydrophobic layer of synthetic breathable non-woven material (spunbond polypropylene, polyester and polyaramid), which may enhance filtration, prevent permeation of droplets or retain droplets (14 , 150)
3. an outermost layer made of hydrophobic material (e.g. spunbond polypropylene, polyester or their blends), which may limit external contamination from penetrating through the layers to the wearer's nose and mouth and maintains and prevents water accumulation from blocking the pores of the fabric (14).

Although a minimum of three layers is recommended for non-medical masks for the most common fabric used, single, double or other layer combinations of advanced materials may be used if they meet performance requirements. It is important to note that with more tightly woven materials, breathability may be reduced as the number of layers increases. A quick check may be performed by attempting to breathe, through the mouth, through the multiple layers.



igure 1 Non-medical mask construction using breathable fabrics such as cotton, cotton blends, polyesters, nylon and polypropylene spunbond that are breathable may impart adequate filtration performance when layered. Single- or double-layer combinations of advanced materials may be used if they meet performance requirements (72).

Assumptions regarding homemade masks are that individual makers only have access to common household fabrics and do not have access to test equipment to confirm target performance (filtration and breathability). Figure 1 illustrates a multi-layer mask construction with examples of fabric options. Very porous materials, such as gauze, even with multiple layers, may provide very low filtration efficiency (147). Higher thread count fabrics offer improved filtration performance (169). Coffee filters, vacuum bags and materials not meant for clothing should be avoided as they may contain in urious content when breathed in. Microporous films such as Gore-Tex are not recommended (170).

Centers for Disease Control and Prevention

Plaintiff's Exhibit 59

Order: Wearing of face masks while on conveyances and at transportation hubs

The Centers for Disease Control and Prevention (CDC) issued an Order [PDF – 11 pages] on January 29, 2021 requiring the wearing of masks by travelers to prevent spread of the virus that causes COVID-19. Conveyance operators must also require all persons onboard to wear masks when boarding, disembarking, and for the duration of travel. Operators of transportation hubs must require all persons to wear a mask when entering or on the premises of a transportation hub.

This Order must be followed by all passengers on public conveyances (e.g., airplanes, ships, ferries, trains, subways, buses, taxis, ride-shares) traveling into, within, or out of the United States as well as conveyance operators (e.g., crew, drivers, conductors, and other workers involved in the operation of conveyances) and operators of transportation hubs (e.g., airports, bus or ferry terminals, train or subway stations, seaports, ports of entry) or any other area that provides transportation in the United States.

People must wear masks that cover both the mouth and nose when awaiting, boarding, traveling on, or disembarking public conveyances. People must also wear masks when entering or on the premises of a transportation hub in the United States.

This Order [PDF – 11 pages] is effective as of February 2, 2021 and was published in the Federal Register on February 3, 2021.

For frequently asked questions, visit the FAQs.

The following are attributes of masks needed to fulfill the requirements of the Order. CDC will update this guidance as needed.

- A properly worn mask completely covers the nose and mouth.
- Cloth masks should be made with two or more layers of a breathable fabric that is tightly woven (i.e., fabrics that do not let light pass through when held up to a light source).
- Mask should be secured to the head with ties, ear loops, or elastic bands that go behind the head. If gaiters are worn, they should have two layers of fabric or be folded to make two layers.
- Mask should fit snugly but comfortably against the side of the face.
- Mask should be a solid piece of material without slits, exhalation valves, or punctures.

The following attributes are additionally acceptable as long as masks meet the requirements above.

- Masks can be either manufactured or homemade.
- Masks can be reusable or disposable.
- Masks can have inner filter pockets.
- Clear masks or cloth masks with a clear plastic panel may be used to facilitate communication with people who are hearing impaired or others who need to see a speaker's mouth to understand speech.
- Medical masks and N-95 respirators fulfill the requirements of the Order.

The following do not fulfill the requirements of the Order.

- Masks worn in a way that does not cover both the mouth and nose
- Face shields or goggles (face shields or goggles may be worn to supplement a mask that meets above required attributes)
- Scarves, ski masks, balaclavas, or bandannas
- Shirt or sweater collars (e.g., turtleneck collars) pulled up over the mouth and nose.
- Masks made from loosely woven fabric or that are knitted, i.e., fabrics that let light pass through
- Masks made from materials that are hard to breathe through (such as vinyl, plastic or leather)
- Masks containing slits, exhalation valves, or punctures
- Masks that do not fit properly (large gaps, too loose or too tight)

Additional guidance on the use of masks to slow the spread of COVID-19 is available on CDC's website.

Disability Exemptions of the Order

Who is covered by the exemption for "a person with a disability who cannot wear a mask, or cannot safely wear a mask, because of the disability as defined by the Americans with Disabilities Act (ADA, 42 U.S.C. 12101 *et seq.*)"?

Most people, including those with disabilities, can tolerate and safely wear a mask and are required to wear one as per CDC's Order. However, certain people with disabilities who, because of their disability, cannot wear a mask, or cannot safely wear a mask, are exempted from CDC's mask-wearing requirement.

The exemption is not meant to cover people with disabilities for whom wearing a mask might only be difficult or whose disability does not prevent them from wearing a mask or wearing a mask safely.

The following narrow subset of persons with disabilities are exempt from CDC's requirement to wear a mask:

- A person with a disability who, for reasons related to the disability, would be physically unable to remove a mask without assistance if breathing becomes obstructed. Examples might include a person with impaired motor skills, quadriplegia, or limb restrictions
- A person with an intellectual, developmental, cognitive, or psychiatric disability that affects the person's ability to understand the need to remove a mask if breathing becomes obstructed

The following persons with disabilities might be exempt from CDC's requirement to wear a mask based on factors specific to the person:

- A person with a disability who cannot wear a mask because it would cause the person to be unable to breathe or have respiratory distress if a mask were worn over the mouth and nose. A person with a condition that causes intermittent respiratory distress, such as asthma, likely does not qualify for this exemption because people with asthma, or other similar conditions, can generally wear a mask safely.
- A person with a disability requiring the use of an assistive device, such as for mobility or communication, that prevents the person from wearing a mask and wearing or using the assistive device at the same time. If use of the device is intermittent and the person can remove the mask independently to use the device, then a mask must be worn during periods when the person is not using the device.
- A person with a severe sensory disability or a severe mental health disability who would pose an imminent threat of harm to themselves or others if required to wear a mask. Persons who experience discomfort or anxiety while wearing a mask without imminent threat of harm would not qualify for this exemption.

How can operators facilitate safer transportation where a passenger is a person with a disability who is exempt from the requirement to wear a mask?

Operators of conveyances or transportation hubs should consider providing options for additional protective measures that improve the ability of the people who are subject to the exemption to maintain social distance (separation from others by at least 6 feet/2 meters [about 2 arm lengths]). Examples include—

- If travel is pre-scheduled, schedule travel for people who are exempt at less crowded times or on less crowded conveyances.
- Seat or otherwise situate the person in a less crowded section of the conveyance or transportation hub.
- Inform people with disabilities who cannot wear a mask safely that these additional measures might be taken to facilitate safer transportation.

All people should consider the necessity of using public transportation, especially those with disabilities or underlying conditions that may place them at increased risk for severe illness from COVID-19. Disability alone may not be related to higher risk for getting COVID-19 or having severe illness. Most people with disabilities are not inherently at higher risk for becoming infected with or having severe illness from COVID-19. However, some people with disabilities might be at a higher risk of infection or severe illness, at least in part because of their underlying medical conditions.

People with disabilities should talk with their healthcare providers if they have questions about their health or how their health conditions are being managed.

While this guidance uses the ADA's definition of disability, it does not address other ADA provisions that may be pertinent to issues involving the use of masks.

Page last reviewed: March 23, 2021

Plaintiff's Exhibit 60

www.fitness.gov when it has been finalized.

The meeting that is scheduled to be held on May 5, 2015, is open to the public. Every effort will be made to provide reasonable accommodations for persons with disabilities and/or special needs who wish to attend the meeting. Persons with disabilities and/or special needs should call (240) 276–9567 no later than close of business on April 21, 2015, to request accommodations. Members of the public who wish to attend the meeting are asked to pre-register by sending an email to *rsvp.fitness@hhs.gov* or by calling (240) 276–9567. Registration for public attendance must be completed before close of business on April 28, 2015.

Dated: March 20, 2015.

Shellie Y. Pfohl,

Executive Director, Office of the President's Council on Fitness, Sports, and Nutrition, U.S. Department of Health and Human Services.

[FR Doc. 2015–06999 Filed 3–26–15; 8:45 am]

BILLING CODE 4150–35–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Criteria for Requesting Federal Travel Restrictions for Public Health Purposes, Including for Viral Hemorrhagic Fevers

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC) in the Department of Health and Human Services (HHS) is publishing this Notice to inform the public of the criteria CDC considers for requesting federal travel restrictions for public health purposes, including for use of the Do Not Board (DNB) list and Public Health Border Lookout records. Individuals with communicable diseases that pose a public health threat to travelers can be placed on this list to restrict them from boarding commercial aircraft arriving into, departing from, or traveling within the United States. This notice further describes the factors that HHS/CDC will consider in evaluating whether to request that an individual who may have been exposed to a hemorrhagic fever virus be placed on the DNB list, which is administered by the Department of Homeland Security (DHS). It also contains information for individuals who have been placed on this list to respond to this decision in writing, if they believe the decision was made in error. This notice is effective immediately.

DATES: This notice is effective on March 27, 2015.

FOR FURTHER INFORMATION CONTACT: For information regarding this Notice: Ashley A. Marrone, J.D., Division of Global Migration and Quarantine, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–E03, Atlanta, GA 30329. For information regarding CDC operations related to this Notice: Travel Restrictions and Intervention Activity, ATTN.: Francisco Alvarado-Ramy, M.D., Division of Global Migration and Quarantine, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–C–01, Atlanta, GA 30329. Either may also be reached by telephone 404–498–1600 or email *travelrestrictions@cdc.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Individuals with communicable diseases who travel on commercial aircraft can pose a risk for infection to the traveling public. In June 2007, HHS/CDC and DHS developed a public health DNB list, enabling domestic and international public health officials to request that individuals with communicable diseases who meet specific criteria, including having a communicable disease that poses a public health threat to the traveling public, be restricted from boarding commercial aircraft arriving into, departing from, or traveling within the United States.[1] The public health DNB list, administered by DHS and based on HHS/CDC's requests, is intended to supplement state and/or local public health measures to prevent individuals who are infectious, or reasonably believed to have been exposed to a communicable disease and may become infectious, from boarding commercial aircraft. Use of the list is limited to those communicable diseases that would pose a public health threat to travelers should the infected individual be permitted to board a flight. Once an individual is placed on the DNB list, airlines are instructed not to issue a boarding pass to the individual for any commercial domestic flight or for any commercial international flight arriving in or departing from the United States.

An individual is typically removed from the DNB upon receipt by HHS/CDC of the treating physician's or public health authority's statement (or other medical documentation) that the individual is no longer considered infectious, or lapse of the period that the individual is at risk of becoming infectious without development of symptoms.

Individuals included on the DNB list are assigned a Public Health Border Lookout (''Lookout'') record that assists in ensuring that an individual placed on the DNB is detected if he or she attempts to enter or depart the United States through a port of entry. When this happens, officials from U.S. Customs and Border Protection (CBP), a component agency of DHS, notify HHS/CDC so that a thorough public health inquiry and evaluation can be conducted and appropriate public health action taken, as needed.

Requests for an individual to be placed on the public health DNB list with an associated Lookout record happen through a number of means, including: State or local public health officials contact the CDC Quarantine Station of jurisdiction, health-care providers make requests by contacting their state or local public health departments, and foreign and U.S. government agencies contact the CDC's Emergency Operations Center (EOC) in Atlanta. HHS/CDC may also request that DHS place an individual on the public health DNB and Lookout lists if HHS/CDC becomes independently aware of an individual who meets the placement criteria.[2]

HHS/CDC has refined the criteria that it initially considered, as published in the Morbidity and Mortality Weekly Report (MMWR) in 2008, and this notice describes the criteria CDC currently considers when making requests to DHS to include an individual on the DNB list and associated Lookout record. If an individual satisfies the first criteria and any of the three other criteria, then he/she may qualify to be placed on the list. Currently, HHS/CDC considers whether:

(1) The individual is known or reasonably believed to be infectious or reasonably believed to have been exposed to a communicable disease and may become infectious with a communicable disease that would be a public health threat should the individual be permitted to board a commercial aircraft or travel in a manner that would expose the public; and

[1] CDC. *Federal air travel restrictions for public health purposes—United States, June 2007–May 2008.* MMWR 2008; 57:1009–12. Available at *http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5737a1.htm.*

[2] CDC. Federal air travel restrictions for public health purposes—United States, June 2007–May 2008. MMWR 2008; 57:1009–12. Available at *http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5737a1.htm.*

(2) the individual is not aware of his or her diagnosis, has been advised regarding the diagnosis and is non-compliant with public health requests or has shown potential for non-compliance, or is unable to be located; or

(3) the individual is at risk of traveling on a commercial flight or of traveling internationally by any means; or

(4) the individual's placement on the DNB is necessary to effectively respond to outbreaks of communicable disease or other conditions of public health concern. For example, an individual's placement on the DNB may be considered when necessary to aid in the application of controlled movement [3] or in the execution of a federal, state, or local quarantine, isolation, or conditional release order.

II. Authority

The DNB list and Lookout record are based on requests made by HHS/CDC regarding public health decisions and actions, and are administered by DHS. Under the Public Health Service Act, the Secretary of HHS is authorized to make and enforce regulations and take other actions necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the United States or between states.[4] Under its delegated authority, the HHS/CDC Division of Global Migration and Quarantine fulfills this responsibility through a variety of activities that may include operating quarantine stations at ports of entry, conducting routine public health screening, and administering quarantine regulations that govern the international and interstate movement of persons, animals, and cargo.[5]

Authority of DHS

Federal law authorizes CBP, U.S. Immigration and Customs Enforcement (ICE), and U.S. Coast Guard (USCG) officers to assist HHS by enforcing quarantine rules and regulations.[6] In addition, other DHS Components such as the Transportation Security Administration (TSA), relying on their existing authorities, may provide supportive roles to federal screening efforts designed to prevent the introduction and spread of communicable disease.

TSA has the authority to accept the services of, or otherwise cooperate with, other federal agencies including implementing the DNB list.[7] Further, TSA may "develop policies, strategies, and plans for dealing with the threats . . . including coordinating countermeasures with appropriate departments, agencies, and instrumentalities of the United States." [8] Consistent with this authority, TSA may assist another Federal agency in carrying out its authority in order to address a threat to transportation. These threats may involve passenger safety.[9] In administering the DNB list, TSA relies on CDC to make public health findings as the basis for its request. As the medical authority for DHS,[10] the Office of Health Affairs reviews and approves the medical appropriateness of HHS/CDC's request prior to DHS implementing HHS/CDC's request by placing the person on the DNB list.

III. Operations

Because of the urgency involved in restricting individuals with serious communicable diseases from boarding commercial aircraft, individuals might not be notified prior to their inclusion on the DNB list and associated Lookout record. When an individual is placed on the DNB list with an associated Lookout record, HHS/CDC advises in writing that the individual is temporarily restricted from traveling by commercial air carrier and provides the reasons why HHS/CDC has reached this decision. HHS/CDC interprets "temporarily restricted" to mean that the individual will remain on the lists until no longer considered to be infectious or at risk of becoming infectious. HHS/CDC's notification to the individual also explains that, while the individual is on these lists, travel by commercial aircraft is forbidden and any attempt to enter the United States through any port of entry will be stopped by CBP officials and that the individual will be referred for public health evaluation. If an individual cannot be located, HHS/CDC works with state and local public health officials to contact the individual through family or other contacts. HHS/CDC and DHS take great care to ensure personal medical information is safeguarded.

As part of its notification process HHS/CDC also asks the appropriate state or local health department to notify the individual directly, state the reasons for the placement on the DNB list and associated Lookout record, and provide the medical or public health requirements that must be satisfied to be removed from the lists. The primary consideration for requesting removal from the DNB list and associated Lookout record is CDC's determination that the individual is no longer considered to be infectious or at risk of becoming infectious; however, other factors may be taken into consideration including the individual's return to treatment, if applicable, and following public health recommendations. Once HHS/CDC receives documentation that these medical and other stated requirements have been met, it sends a request to DHS to lift the travel restrictions (both the DNB list and the Lookout record).[11] Once an individual is removed from the DNB list and the associated Lookout record is removed, a second notification letter is sent by HHS/CDC to the individual informing him or her that the public health travel restrictions have been removed and providing further recommendations on an as-needed basis (*e.g.,* advising that the individual continue treatment, if applicable).

HHS/CDC's letter informing individuals that they have been placed on the DNB list and associated Lookout records invites individuals who believe that HHS/CDC's public health decision was made in error to submit a written response to the Director of HHS/CDC's Division of Global Migration and Quarantine and provide any supporting facts or other evidence supporting their belief. These operations and procedures will not change as a result of this Notice.

IV. Requesting Travel Restrictions for Viral Hemorrhagic Fevers

To date, the DNB list and associated Lookout records have been used primarily with respect to individuals with suspected or confirmed pulmonary tuberculosis (TB), including multidrug-resistant tuberculosis (MDR–TB), and a very small number with measles. However, travel restrictions are also applicable to other suspected or confirmed communicable diseases that could pose a public health threat during travel, including viral hemorrhagic fevers such as Ebola virus disease

[3] See *http://www.cdc.gov/vhf/ebola/exposure/monitoring-and-movement-of-persons-with-exposure.html.*

[4] 42 U.S.C. 264–265. The Secretary has promulgated implementing regulations at 42 CFR parts 70 and 71, administered by the CDC.

[5] See generally U.S. Department of Health and Human Services Centers for Disease Control and Prevention, Public Health Screening at U.S. Ports of Entry: A Guide for Federal Inspectors (July 2007) (describing port of entry health screening procedures); 42 CFR part 70 (interstate quarantine regulations); 42 CFR part 71 (foreign quarantine regulations).

[6] See 42 U.S.C. 97, 268(b).

[7] 49 U.S.C. 106(l), (m), 114(m).

[8] 49 U.S.C. 114(f)(3), (4).

[9] See, *e.g.,* 49 U.S.C. 114(h)(3).

[10] 6 U.S.C. 321e(c)(1).

[11] In addition to contacting CDC, individuals seeking removal from the Public Health DNB may also seek assistance through the redress process established by DHS in 49 CFR 1560.205.

(Ebola). Ebola is a type of viral hemorrhagic fever that is often fatal in humans and nonhuman primates. Ebola can spread through human-to-human transmission, with infection resulting from direct contact (through broken skin or mucous membranes) with the blood, secretions, droplets, or other body fluids of infected people, and indirectly from contact with surfaces or items (such as needles) contaminated with such fluids.

With respect to viral hemorrhagic fevers, placement on the DNB list and associated Lookout record is requested for people known or suspected to have a viral hemorrhagic fever. Placement may also be requested for people without symptoms who have been exposed to a viral hemorrhagic fever, particularly if these individuals intend to travel against public health recommendations. Even though people without symptoms are not infectious, these restrictions are requested because of the possibility that symptoms could develop during travel, particularly long international flights. Exposure is determined through a CDC risk factor assessment using information available from a variety of public health, medical and other official sources. Examples of types of potential exposure to viral hemorrhagic fevers contained within the CDC risk factor assessment include the following. It should be noted that not all of these exposures may result in travel restrictions.

- Having been in a country with widespread Ebola virus transmission within the past 21 days and, although having had no known exposures, is showing symptoms
- Percutaneous (*e.g.,* needle stick) or mucous membrane exposure to blood or body fluids of a person with Ebola while the person was showing symptoms
- Exposure to the blood or body fluids (including but not limited to feces, saliva, sweat, urine, vomit, and semen) of a person with Ebola while the person was showing symptoms without appropriate personal protective equipment (PPE) (see *http://www.cdc.gov/vhf/ebola/hcp/procedures-for-ppe.html*)
- Laboratory processing of blood or body fluids of a person with Ebola while the person was showing symptoms without appropriate PPE or standard biosafety protections
- Direct contact with a dead body without appropriate PPE in a country with widespread Ebola virus transmission (see *http://www.cdc.gov/vhf/ebola/outbreaks/2014-west-africa/distribution-map.html*)
- Having lived in the immediate household and provided direct care to a person with Ebola while the person was showing symptoms
- In countries with widespread Ebola virus transmission: Direct contact while using appropriate PPE with a person with Ebola while the person was showing symptoms, or with the person's body fluids, or any direct patient care in other healthcare settings
- Close contact in households, healthcare facilities, or community settings with a person with Ebola while the person was showing symptoms
  - Close contact is defined as not wearing appropriate PPE within approximately 3 feet (1 meter) of a person with Ebola while the person was showing symptoms
- Having brief direct contact (*e.g.,* shaking hands), while not wearing appropriate PPE, with a person with Ebola while the person was in the early stage of disease
- In countries without widespread Ebola virus transmission: Direct contact while using appropriate PPE with a person with Ebola while the person was showing symptoms
- Traveled on an aircraft with a person with Ebola while the person was showing symptoms

Exposure risk factors, such as those just described, will be considered by HHS/CDC in their totality when determining whether an individual meets the first criteria for placement on the DNB List, as described in Section I of this notice. HHS/CDC would also consider other facts and information it may have to make a decision with respect to the other criteria, as described in Section I of this notice. It should be noted that all facts are considered when applying the criteria. Again, with the exception of the first criteria, not all of the other criteria need to be present for HHS/CDC to make a request to DHS to have an individual placed on DNB and Lookout.

HHS/CDC would also consider these risk factors when assessing an individual who has been in a country where outbreaks of viral hemorrhagic fevers were occurring and refuses to comply with a public health assessment, and otherwise meets the travel restriction criteria. Refusing to comply with a public health risk assessment in this situation could include refusing to provide relevant information that would allow public health officials to assess the exposure risk.

V. Provisions of This Notice

HHS/CDC will make requests of DHS based on the criteria in this notice effective immediately. Individuals who have had their travel temporarily restricted as a result of placement on the DNB list and associated Lookout records may submit a written response to the Director, Division of Global Migration and Quarantine, if they believe that HHS/CDC has erred in its public health request to DHS. The response should be addressed to: Director, Division of Global Migration and Quarantine, ATTN: Travel Restriction and Intervention Activity, Centers for Disease Control and Prevention, 1600 Clifton Road, MS E–03, Atlanta, GA 30329. Responses may also be faxed to CDC at (404) 718–2158 or emailed to *travelrestrictions@cdc.gov.*

As part of the response, individuals should include the reference number listed in the notification letter they received and any facts or other evidence indicating why they believe that HHS/CDC's public health request was made in error.

The policy and program operations described above will become effective on March 27, 2015.

Dated: March 24, 2015.

Sylvia M. Burwell,

Secretary.

[FR Doc. 2015–07118 Filed 3–26–15; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0908]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Clinical Trial Sponsors: Establishment and Operation of Clinical Trial Data Monitoring Committees

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on the collection of information concerning the establishment and operation of clinical trial data monitoring committees.

Plaintiff's Exhibit 61

cdc.gov

Travel Restrictions | CDC

3 minutes

Credit: David Snyder

Disease is just a flight away. To protect America's health, CDC partners with the Department of Homeland Security to prevent the spread of serious contagious diseases during travel. CDC uses a **Do Not Board list** to prevent travelers from boarding commercial airplanes if they are known or suspected to have a contagious disease that poses a threat to the public's health. Sick travelers are also placed on a **Lookout** list so they will be detected if they attempt to enter the United States by land or sea. **These tools can be used for anyone who poses a threat to the public's health.**

Local and state public health officials can request CDC's assistance if a person who poses a public health threat intends to travel. CDC helps ensure these people do not travel while contagious.

Placing people on the lists

The criteria for adding people to the **Do Not Board** and **Lookout** lists are

1. Known or believed to be infectious with, or at risk for, a serious contagious disease that poses a public health threat to others during travel; **and** any of the following three:

1. **not** aware of diagnosis or **not** following public health recommendations, **or**

2. Likely to travel on a commercial flight involving the United States or travel internationally by any means; **or**

3. Need to issue travel restriction to respond to a public health outbreak or to help enforce a public

health order.

Criteria number one plus one of the three subsets must be met for a person to be placed on the **Do Not Board** and **Lookout** lists.

Credit: David Heaberlin

Once a person is placed on these lists, airlines will not issue a boarding pass to the person for any commercial flight within, arriving to, or departing from the United States.

To date, the Do Not Board and Lookout lists have been used for people with suspected or confirmed infectious tuberculosis (TB), including multidrug-resistant tuberculosis (MDR-TB), and measles. However, travel restrictions can also be used for other suspected or confirmed contagious diseases that could pose a public health threat during travel, including viral hemorrhagic fevers such as Ebola.

Preventing people with contagious diseases from traveling also helps to make sure they get or continue medical treatment, such as for infectious tuberculosis.

Taking people off the lists

Once public health authorities confirm a person is no longer contagious, the person is removed from the lists (typically within 24 hours). Also, CDC reviews the records of all persons on the lists every two weeks to determine whether they are eligible for removal.

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FROM CHECK-IN TO ARRIVAL AT YOUR DESTINATION, WE ARE COMMITTED TO YOUR HEALTH AND SAFETY

The next time you fly with us, you'll notice that we've made several changes. We've been working around the clock to improve our customer experience and to safeguard your well-being. Whether you are planning a trip back home to give mom a hug or dreaming of planting your feet in the sand, rest assured that the extra measures we are taking are designed to provide a safe and pleasant travel experience from the time you check-in until you arrive at your destination.

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ENHANCED CLEANING ON & OFF THE PLANE

Our **Ticket Counters, Gate Areas, and Aircraft** are getting extra attention. We've increased cleaning intervals with EPA approved anti-virus cleaning solutions. Here's a more specific look at what we're doing onboard:

- **Before Every Flight** the aircraft is cleaned with a focus on passenger seating, cabin walls, overhead bins, galleys and lavatories.
- **Aircraft with Extended Time Between Flights** are cleaned to include a wipe down of all customer and crew touchpoints - lavatories, seats, armrests, tray tables, walls, overhead panels and bins, window shades and galleys - with a disinfectant EPA rated to be effective against viruses, including SARS-CoV-2, the virus that causes COVID-19.
- **Every night** while our planes are positioned overnight, our Aircraft Appearance Team spends 4 to 6 hours thoroughly cleaning the aircraft's interior from top to bottom using industry-recommended disinfectant.
- **Monthly** enhanced deep cleaning of the entire aircraft

TEMPERATURE SCREENING

To help ensure the well-being of everyone onboard, a non-invasive temperature screening taken on the forehead using a touchless thermometer will be taken at the gate for all passengers and crew.

Anyone with a temperature of 100.4 degrees Fahrenheit or higher will not be able to board the plane. If time allows, we will give customers the opportunity to rest before receiving a second check. If the second temperature screening is 100.4 degrees or higher, our team will help the customer to rebook travel on a later date when they are feeling better.

QUICK & EASY HEALTH ACKNOWLEDGEMENT

When you check-in for your flight on our website or mobile app, you will be asked to accept the following health acknowledgment:

- You will have your temperature screened by a touch-less thermometer prior to boarding. Anyone with a temperature of 100.4 degrees or higher will not be allowed to fly.
- You will **wear a face covering over your nose and mouth throughout your journey,** including ticket counters, gate areas, and onboard our aircraft.
- In the last 14 days, neither you, nor anyone in your household or that you have come in close contact with, has tested positive for, exhibited symptoms of, or been advised to quarantine for COVID-19.
- You will wash your hands/sanitize before boarding the flight.

Plaintiff's Exhibit 63

HARVARD T.H. CHAN SCHOOL OF PUBLIC HEALTH

NATIONAL PREPAREDNESS LEADERSHIP INITIATIVE

HARVARD Kennedy School Center for Public LEADERSHIP

The National Preparedness Leadership Initiative is a joint program of the Harvard T.H. Chan School of Public Health and the Harvard Kennedy School of Government, Center for Public Leadership

Aviation Public Health Initiative

Assessment of Risks of SARS-CoV-2 Transmission During Air Travel and Non-Pharmaceutical Interventions to Reduce Risk

Phase One Report: Gate-to-Gate Travel Onboard Aircraft

Prepared by

Faculty and Scientists at the Harvard T.H. Chan School of Public Health

ACKNOWLEDGEMENTS

This project arose in response to a complex set of problems during an unprecedented crisis. Three months into the COVID-19 pandemic, the aviation industry faced a significant decline in passenger traffic and revenue. There was interest in finding an independent, science-based resource to answer difficult public health safety questions, critical to both protect the workforce and the public, and essential to restarting this important segment of the national economy.

Out of that interest to reopen the sector safely, discussions began between Airlines for America (A4A) and faculty at the National Preparedness Leadership Initiative (NPLI), a joint program of the Harvard T.H, Chan School of Public Health and the Harvard Kennedy School of Government.

Those conversations led to development of the Aviation Public Health Initiative (APHI). As lead sponsoring organization, A4A engaged their member organizations, along with a group of manufacturers and airport operators. These companies generously provided financial support, shared data and information, facilitated conversations with airline COVID-19 working groups, and opened opportunities to speak with the airline crewmembers. That breadth of conversation and data access was critical to collecting the body of knowledge required to reach the findings and recommendations in this report. That interest led to discussions and briefs with numerous government officials associated with the aviation industry. Through it all, this group of industry and government leaders respected the independence of the APHI scientists and their research. The APHI team deeply appreciates the numerous contributions, the support, and the commitment of these sponsors and leaders to the scientific objectives of this inquiry.

The APHI project team includes faculty and associates of the Harvard T.H. Chan School of Public Health. The leadership includes Director Leonard J. Marcus, PhD; Deputy Director Vice Admiral Peter V. Neffenger, USCG (ret); Science Director John D. Spengler, PhD.; and Deputy Science Director John F. McCarthy, ScD, C.I.H. The project team includes Senior Project Manager Leila Roumani, DMD, MPH; Communications Specialist Richard Ades; Infectious Disease Consultant, Edward A. Nardell, MD; and Lead Science and Technical Writer Wendy M. Purcell, PhD, FRSA. The science and technology research team includes Ramon Alberto Sanchez, PhD; Ted Myatt, ScD; Jose Guillermo Cedeno Laurent, PhD; Jerry F. Ludwig, PhD; Steve Hanna, PhD; Judith Irene Rodriquez, MS; and Steve Bloom, MS. Susan Flaherty, Regina Jungbluth, Michelle Tracanna, and Joan Arnold provided essential administrative support.

The findings and recommendations of this report are the independent conclusions of the Harvard T.H. Chan School of Public Health Aviation Public Health Initiative. The APHI team hopes its contents will underscore the importance of following science, to save lives, to reinvigorate economic well-being, and to lead the country and the world to overcome the COVID-19 crisis.

Leonard J. Marcus, PhD
Director, Aviation Public Health Initiative
Harvard T.H. Chan School of Public Health

susceptibility of the person exposed, the biological dose of virus particles delivered to a target organ and the duration over which the exposure occurs. The infectious dose for SARS-CoV-2 is yet unknown. Particles (detectable, viable, and infectious) are estimated from source measurements, but include many particles that do not cause infection due to viability, infectivity, host defenses, etc. In such situations, the concept of quanta is used (see Section 3.2.6) to describe whatever that unknown number might be, and probability is applied to estimate the likelihood of inhaling an infectious dose, i.e., quanta of infection. Quanta are therefore agnostic about the actual number of particles, but quantifies the number of doses generated by the source under specific circumstances and considering the probability of inhaling an infectious dose. As such, quanta allows quantification of risk reductions for mitigation strategies and calculations of comparative risk for different social activities, and it applies to analysis of disease transmission in the unique circumstances of an aircraft cabin.

2. **The Layered Approach to Risk Reduction:** The NPI **(**Non-Pharmaceutical Interventions) proposed for risk mitigation of SARS-CoV-2 transmission includes the consistent operation of ventilation systems, disinfection of surfaces, consistent wearing of face masks, and procedures during boarding and deplaning to maximize social distancing among passengers and crewmembers. The efficacy of these combined strategies is given in Table 1.1. Details underpinning the approach are found in the thematic sections of the Report that present the detailed scientific rationale and evidence in support of the strategy. This layered NPI approach serves to reduce significantly the risks of disease transmission in the aircraft environment.

3. **Ventilation Systems on Aircraft:** These sophisticated systems deliver high amounts of clean air to the cabin that rapidly disperses exhaled air, with displacement in the downward direction, reducing the risk of passenger-to-passenger spread of respiratory pathogens. Aircraft ventilation offers enhanced protection for diluting and removing airborne contagions in comparison to other indoor spaces with conventional mechanical ventilation and is substantially better than residential situations. This level of ventilation effectively counters the proximity travelers will be subject to during flights. The level of ventilation provided onboard aircraft would substantially reduce the opportunity for person-to-person transmission of infectious particles, when coupled with consistent compliance with mask-wearing policies.

4. **Crew and Passenger Behavior:** Deterrence of behaviors that increase the likelihood of transmission of SARS-CoV-2 from one person to the next is the most critical factor in enhancing public health safety onboard aircraft. Health attestations and screening for crew and passengers who show symptoms of COVID-19 reduce the likelihood that an infectious individual will board a plane until rapid, reliable, and inexpensive testing becomes available. Face masks significantly reduce transmission and airlines now require passengers to wear

strategies. Particular emphasis is placed on the effectiveness of aircraft ventilation systems, which are able to filter 99.97% of SARS-CoV-2 particles out of air found on aircraft.

Air travel demands the design of effective strategies to mitigate transmission given people are typically in close proximity to one another. These conditions may be exacerbated onboard. Prior to arrival at the airport, at check-in and/or before boarding, passengers may be subject to health screening and testing (see Section 6.0), with those of concern isolated or refused boarding. Passengers can be required to wear an appropriate face covering, typically a mask (see Section 7.0). Upon boarding and deplaning, an orderly process can be implemented to support physical distancing and reduced density (see Section 8.0). In reality, 100% compliance with these measures will be difficult to achieve in all settings. The success of these NPI depends upon educating travelers to the benefits they offer travelers and workers associated with their travel. Compliance and enforcement are essential. Furthermore, transmission is reduced by enhanced cleaning protocols and disinfection of surfaces (see Section 9.0) along with physical engineering controls and ventilation (see Section 10.0). New technologies and innovative techniques are being developed and implemented to meet the continuing challenges posed by the COVID-19 pandemic.

The risk of transmission on an aircraft can be reduced to very low levels with full compliance of the recommended NPI. Few peer-reviewed reports have been published on in-flight transmission of communicable illnesses, including COVID-19. As of September 30, 2020, there were 13 peer-reviewed case studies available for analysis that focused on COVID-19 transmission and exposure mitigation on aircraft. Of these studies, eight were commercial flights and five were evacuation or repatriation flights. Section 2.0 provides a critical account of each case study, including type of flight, number of passengers, number of potential cases, and transmission mitigation procedures reportedly in use.

After detailed analysis of these reports, it is the view of APHI that there have been a very low number of infections that could be attributed to exposure on aircraft during travel. Also, had transmission mitigation procedures, i.e., maintaining appropriate physical distancing prior to travel and use of face masks throughout the trip, been used consistently on these flights a further reduced probability of transmission of COVID-19 during the flights would be anticipated. When masks were used by crewmembers (Yang et al., 2020), no transmission to crew was found. A significant finding from the evaluation of the evacuation flight procedures was that there was no COVID-19 infection among any of the air medical crews, despite the exposure to numerous positive cases. The lack of transmission to air medical crews indicates the effectiveness of the layering approach to reduce the risk of COVID-19 transmission.

warning to passengers who refuse to follow airline public health safety rules, such as properly wearing masks. After reaching the limit of successive warnings, most major airlines make it clear to the public that offenders will be placed on a no-fly list. It is noteworthy that while each airline developed its own protocols, there is overall uniformity in how the airlines address risk reduction for passengers and crew.

The airlines have issued hundreds of no-fly determinations during the COVID-19 crisis. After the limit of successive warnings have been issued, passengers may receive a yellow slip on board or a notification after the flight to signify this designation. In order to avoid in-air conflict, crewmembers may also gently request onboard compliance. If it is not given, notification of service denial occurs only after the flight is completed. The vast majority of passengers and crew conform to mandated protocols. In the most egregious situations, pilots have interrupted a flight and landed in order to discharge a defiant passenger. Though notification procedures vary, the airlines are uniformly unwavering in their stance about compliance. It is a powerful motivator to achieve passenger behavioral compliance, and it is essential for achieving consistent public health-protecting behaviors during flight.

In addition to the face mask policies, most airlines require a **health attestation** prior to boarding. The enforcement policies extend to compliance with physical distancing in the gate area prior to boarding, and include aircraft boarding and deplaning procedures. The airlines vary on their load factors, with some though not all keeping the middle seat on larger aircraft or the aisle seat on smaller aircraft unoccupied. All airlines have policies that address concerns about crowding on aircrafts, in some cases allowing passengers to rebook flights when they learn that their booked flight is at more than 70% capacity.

Safety as a Signal for Potential Fliers

The combination of mandate and strict enforcement will likely be required for the course of the COVID-19 public health crisis. Should fast and definitive pre-boarding viral testing become available, this may change such requirements. Passengers routinely comply with requirements for security screening, seat belt use, and other safety protocols. However, in the U.S. behaviors relating to wearing face masks and/or physical distancing during the pandemic have assumed a level of symbolic significance, translating nonconformity into a statement on politics or injustices, contrary to the science-based recommendations.

For prospective passengers, confidence in their safety from COVID-19 is a key factor in their decision to fly (Lamb et al., 2020). This involves the universal adoption of face masks and enforcement of face mask policies, along with other risk-reducing procedures (Graham et al., 2020). These interventions support public health safety, and trust in their enforcement has become equivalent to trust in the airworthiness of the plane and security from a terrorist threat. As with any activity, such as driving, playing sports, or lifestyle choices, there are risks.

with mild to moderate disease (Wolfel et al., 2020; He et al., 2020; Zhou et al., 2020), and can be much longer in patients with severe COVID-19 disease (Pan et al., 2020). One case study reported that infectivity of asymptomatic people may be weak (Gao et al., 2020), while another reported that infectiousness may last for as long as 21 days in asymptomatic individuals (Hu et al., 2020). Approximately 40-45% of SARS-COV-2 infections are considered asymptomatic (Oran et al., 2020), although it has been reported that mild or asymptomatic cases could be as high as 80% (WHO, 2020c). This is an important consideration for the aviation industry, as asymptomatic and pre-symptomatic passengers and/or crew could board aircraft and pose a risk. For this reason, strict enforcement of face mask policies are critical, since such cases cannot be identified.

2.4 CRITICAL REVIEW OF POSSIBLE TRANSMISSION ON AIRCRAFT

Although the CDC has stated that *"the risk of getting a contagious disease on an airplane is low"*, they have developed specific protocols to contact and investigate travelers who may have been exposed to a passenger harboring a contagious disease on a flight (CDC, 2019). The CDC document states that the major contacts of concern are within two rows of the *"Index patient (case)"* and specifies that *"Identifying contacts is based on the disease, how it spreads, and where a passenger was seated in relation to the index patient."* It recommends contact tracing for those individuals seated two rows in front and two rows behind the index case for highly contagious infectious diseases, such as measles and tuberculosis that have recognized airborne or droplet transmission vectors.

Airline travel presents many unique environments and opportunities to come into close contact with possible infectious people and materials. The chance for infectious contact can occur in many locations during a trip, such as in the general population at the origin or destination city, during transit to the airport, in the terminal, at an amenity destination or at the gate, besides being on an aircraft. Specifically, when onboard an aircraft, which is the focus of this Report, there are several physical factors such as very high air exchange rates, limited mobility in cabins and cabin crews that are trained in management processes to identify and segregate ill passengers, that are particular to air travel and likely help to mitigate potential exposure. During 2020, the aviation industry and the government in the United States have engaged in discussions to introduce contact-tracing systems when a case is identified on board a flight. At the time of writing, these proposed policies and practices have not been implemented.

2.4.1 Summary of Case Studies

Few reports have been published on **in-flight transmission of communicable illnesses**, including COVID-19. Indeed, a transmission event is a trigger for development of an academic paper; as such, non-transmissions are likely under-represented in the literature. As of September 28, 2020, there were 13 peer-reviewed case studies, describing 12 flights (two authors

Based on the available scientific evidence, it is the view of APHI that there have been a very low number of infections that could be attributed to exposure on aircraft during travel. Also, had transmission mitigation procedures, i.e., maintaining appropriate physical distancing prior to travel and use of face masks throughout the trip, been used consistently on these flights, a further reduced probability of transmission of COVID-19 during the flights would be anticipated.

The use of masks is an important consideration when drawing conclusions from these studies. The case study with the highest estimated COVID-19 transmission rate (7%) reported that masks were not mandatory during the flight (Khanh et al., 2020). The cases that had the next highest COVID-19 transmission rate (up to 2%) either did not provide masks, or provided masks to passengers on the plane instead of prior to boarding; this posed a risk of transmission among passengers during the check-in and boarding process (Hoehl et al., 2020). Other studies that described the use of masks reported a transmission rate of less than 1%. When masks were employed on commercial flights by infectious cases (Ng et al., 2020; Nir-Paz et al., 2020; Schwartz et al., 2020) close contacts on the aircraft remained uninfected. (Note: The son of one patient in the Ng et al. 2020 study tested positive on quarantine day 3, possibly indicating transfer on the aircraft or possibly exposure prior to boarding.) **When masks were used by crewmembers (Yang et al., 2020), no transmission to crew was found.**

The next most common reported transmission mitigation strategy was the use of **temperature checks and/or medical screening of passengers prior to boarding the flight**. The practice of temperature checking as a pre-boarding screening method has come into question, simply because presymptomatic positive cases may not be exhibiting a fever even though they are infectious. It can be effective at identifying symptomatic individuals so that they might be isolated and prevented from exposing passengers in the terminal or on the flight, though its limitations must be acknowledged. Without quick and reliable pre-boarding viral testing, it will be difficult to distinguish a COVID-19 symptomatic passenger from a passenger experiencing another respiratory illness. Temperature screenings and symptom self-declarations have limitations and can still result in the boarding of symptomatic passengers; therefore, these approaches should not be relied upon as the only implemented transmission mitigation strategy.

The only studies that reported implementing **social distancing outside the flight**, for example at check-in and during onboarding, were evacuation flights. Similarly, case studies on evacuation or repatriation flights were the only ones that reported the use of barriers on the plane to segregate patients; enhanced ventilation on the plane was also noted with cabin ventilation remaining on at all times, including while on the ground and at the gate (Cornelius et al., 2020), and specific decontamination procedures during the flight were also reported. One study described using nearly all the transmission mitigation strategies listed in Table 2.1. This study summarized multiple flights that resulted in the repatriation of over 2,000 individuals flown on

39 flights, all of whom were either COVID-19 positive, persons under investigation (PUI), or individuals who were asymptomatic. These evacuation flights all employed a layered approach to risk mitigation, implementing multiple levels of transmission mitigation strategies. **A significant finding from the evaluation of these evacuation flight procedures was that there was no COVID-19 infection among any of the air medical crews, despite the exposure to numerous positive cases. The lack of transmission to air medical crews supports the effectiveness of the layering approach to reduce the risk of COVID-19 transmission.**

2.4.2 Summary of Past Transmission of Diseases Attributed To Air Travel

Given the volume of commercial flights daily, carrying millions of passengers and crew worldwide, the number of documented incidents of infectious disease transmission occurring on board an aircraft remains infrequent. Outbreaks of respiratory diseases associated with air travel have however been reported, such as severe acute respiratory syndrome (SARS), measles, tuberculosis, and influenza (Olsen et al., 2003; Lei, 2018; Amler et al., 1982; CDC, 1983; CDC, 2004; Mangili & Gendreau, 2005; de Barros et al., 2006). Generally, these diseases are transmitted via aerosols (e.g., measles, tuberculosis) or via multiple routes (e.g., influenza). Each disease differs in the susceptibility of non-infected persons and the degree of infectiousness of the virus concerned. These cases however did not involve use of protective measures, such as wearing a face mask, now being employed. Furthermore, most of these appear to have occurred on aircraft that were likely in-service before 1990 when HEPA filters became standard equipment on most commercial aircraft. Regardless, useful information relevant to the COVID-19 pandemic can be gleaned from such accounts.

While there are occurrences of transmissibility that could inform the current crisis, **SARS** is the most closely related disease to COVID-19. In a SARS-related investigation, passengers and crew on three flights that included an infected person were interviewed. On one flight with a pre-symptomatic SARS case, no infection was documented among the passengers (Olsen et al., 2003). Another flight carried four SARS symptomatic people, with reported potential transmission to one passenger (Olsen et al., 2003). A flight with one symptomatic passenger confirmed SARS infections in 16 persons, two others were diagnosed as probable SARS, and four were reported to have SARS but could not be interviewed (Olsen et al., 2003). Illness in passengers was related to physical proximity to the index (i.e., infected) patient, with illness reported in eight of the 23 persons seated in the three rows in front of the index patient; this compared with 10 of the 88 persons seated elsewhere. Based on the locations of the secondary cases, the report suggested that airborne transmission had occurred (Olsen et al., 2003).

Lei et al. (2018) conducted a meta-analysis of 10 studies with possible **influenza** outbreaks on aircraft. The analysis showed that the risk of acquiring influenza was greater for passengers within two rows of the infected person; the risk was greater the longer the duration of the flight and the total infectivity of the index cases (Lei et al., 2018).

Measles is transmitted via aerosols and is highly infectious (CDC, 2018). However, measles transmission onboard aircrafts is believed to be uncommon (Amornkul et al., 2004; Mangili & Gendreau, 2005), with few case studies describing measles transmission during commercial air travel (Amler et al., 1982; CDC, 1983; CDC, 2004; Mangili & Gendreau, 2005; de Barros et al., 2006). In one of the most recent cases, an infectious individual traveled on six flights (one international flight arriving in Brazil and five local flights within Brazil) over a short period of time while infected, and the investigation identified just six confirmed cases (de Barros et al., 2006).

Several studies about the in-flight transmission of **tuberculosis** have been reported, with most undertaken in the mid-1990s (MacFarland, 1993; Driver, 1994; CDC, 1995; Kenyon, 1996; WHO, 1998; Wang, 2000). Of these six investigations, two revealed a probable link to onboard transmission. In one case (Kenyon et al., 1996), four of 15 fellow passengers seated within two rows of the index passenger had a positive tuberculin skin test conversion. Overall, transmission of tuberculosis onboard aircraft is a rare event, most likely to happen to those in close proximity to the infectious passenger (within two rows) and/or exposed over a long time (greater than eight hours).

Based on the investigations of outbreaks of other respiratory diseases on aircraft, it appears that transmission on aircraft is relatively infrequent. Where transmission does occur, those close to the infectious passenger are at a higher risk than those seated at some distance. Depending on the transmissibility of the particular disease agent, determining how transmission occurs on aircraft (e.g., aerosol, direct contact, fomite) can be difficult. For example, did the transmission occur prior to boarding, during the use of a public lavatory or on the flight? In none of the published cases of respiratory disease transmission on aircraft did the authors indicate that the reference case(s) or the passengers were wearing protective face masks, as they must do on U.S. airlines today.

In many of the case reports, the difficulty of contact tracing due to lack of contact information was noted. Therefore, it would be beneficial to improve contact information to be able to respond more efficiently to a disease outbreak (Sevilla, 2018).

2.4.3 Potential Transmission of SARS-Cov-2 on a Flight from Singapore to Hangzhou, China: An Epidemiological Investigation (Chen et al., 2020)

An outbreak of COVID-19 among 324 passengers accompanied by 11 crew on a 5-hour flight from Changi Airport, Singapore to Hangzhou, China on January 24, 2020, was investigated (Chen et al., 2020). Though the flight originated in Singapore, it was strictly managed upon arrival in Hangzhou because approximately 100 passengers had departed from Wuhan to Singapore on a flight on January 19, 2020.

On the flight, face coverings were not required. No Personal Protective Equipment (PPE) was provided to the passengers and no barriers were erected on the plane. The flight operated at 89% seating capacity; the middle seat was not left unoccupied. The Boeing 787-9 aircraft was equipped with standard air handling systems.

Upon arrival in Hangzhou, passengers' temperatures were taken before deplaning. All passengers were required to follow medical isolation and observation protocols for at least 14 days. During this time, passengers were asked to take their temperature twice daily and report any upper respiratory symptoms. Crewmembers (n=11), all Singaporean, returned to Singapore on January 26, 2020, and were not part of this investigation.

All infected passengers from the January 24, 2020, flight to Hangzhou were also on the January 19, 2020, flight to Singapore. Three cases reported symptoms before the January 24, 2020, flight: two on January 23, 2020, and one on the day of the flight. On January 26, 2020, all passengers were tested for SARS-CoV-2 by RT-PCR; eight passengers tested positive, six of whom reported symptoms and two of whom were asymptomatic. On January 31, 2020, one passenger reported symptoms and on February 2, 2020, an additional two passengers reported symptoms. All passengers were tested again for SARS-CoV-2 by RT-PCR and no additional cases were identified by February 6, 2020. On February 8, 2020, all passengers not originating from Wuhan were released and the rest were released on February 15, 2020.

All the cases belonged to tour groups while in Singapore, denoted as Tour Groups A, B, C and D. There were 15 members of Tour Group A and 12 of them were confirmed SARS-CoV-2 positive. Therefore, investigators in this study attributed all infections among Tour Group A to activities amongst the tour group members prior to the flight. Three other cases, one from Tour Group B and two from Tour Group C (all asymptomatic) were identified by RT-PCR on January 26, 2020. As such, investigators ruled out transmission during the flight given the incubation time of COVID-19 being inconsistent with that timeline. Investigators concluded there was only evidence that one case, identified on February 2, 2020 and part of Tour Group D, was attributable to transmission during the flight. They reasoned that this case was consistent with the incubation time expected for COVID-19, was the only member of the tour group to become infected and was the only one not to have been on the January 19, 2020, flight from Wuhan to Singapore. This case reported that he removed his mask to eat and drink during the flight and that when he spoke, he had not worn the mask "tightly" and had his nose exposed. This actually implies that the true attack rate was 0.3%.

2.4.4 Asymptomatic Transmission of SARS-CoV-2 on Evacuation Flight (Bae et al., 2020)

A cohort study of passengers on an evacuation flight from Milan, Italy to South Korea on March 31, 2020, was evaluated (Bae et al., 2020). Prior to the flight, medical staff performed physical examinations, medical interviews, and temperature checks on 310 planned passengers; 11 were subsequently excluded from the flight. The investigation followed 299 passengers who boarded the 11-hour flight. During pre-boarding, passengers were kept 2 meters (6.56-feet) apart and were provided with N95 respirators. During the flight, most passengers wore the N95s the entire time, except for mealtimes and restroom use, though they were not required to do so. No other PPE was provided. Physical barriers were not in place during the flight and middle seats

All nine airlines prohibited masks with holes, vents, valves, openings, or made from mesh materials. In addition, face shields cannot be worn without wearing a mask underneath. One airline updated their policy to prohibit powered air purifying respirators (PAPRs) or breathing apparatus that enclose the face or the head. For passengers without a mask or with a non-compliant mask, all nine airlines provide one. Airlines have surgical-style or disposable masks available for crewmembers and passengers. A few airlines have branded masks or face shields available for crew or are considering offering face shields to their flight crew.

> *"…we've restricted face mask types to either the surgical mask or to the cotton mask that would be worn, not N95 mask, and not a gaitor or a neck gaitor or a bandana… not a valve mask either."* (Airline #3)

All nine airlines deny boarding to passengers without a mask and have a process to handle non-compliance during a flight. Flight attendants and pilots remind people to wear their masks, and issue warnings to non-compliant passengers. The warning process varies among the airlines, albeit most provide three warnings, verbal and written; a final warning is issued before filing a report or instituting a flight ban. Such no-fly bans remain in place for a defined period, which can be a year, for the duration of the passenger's passport, or until the airline's mask policy subsides; the latter is the most common ban among the airlines examined. Only one airline indicated that non-compliance could lead to a permanent no-fly ban on the airline. Overall, the airlines reported having good compliance, but on average, an airline may handle up to 15 reports per day where passengers had not complied but have fewer than 65 people listed on a no-fly ban.

> *"What we have done though is ensure that we are enforcing the mask policy. So essentially we have a three strikes or you are out, so we tell you about it before you get on board the aircraft, once you do get on, we reiterate it from both the captain and attendants, and if you take it off during flight, you can only do that if you're eating or drinking…"* (Airline #3)

> *"For in flight, we've actually adopted a three strike policy. … at the third time they actually provide them this face mask policy enforcement card… if there is no further compliance from the passenger then the flight attendant brings up an in-flight incident report and reviews the situation … we have been basically suspending travel …for a period of a year."* (Airline #6)

The only time a passenger onboard is permitted to remove their mask briefly is while eating and/or drinking. Most airlines have limited the beverage and snack service on board, and/or have suspended it altogether on shorter flights, and/or suspended offering food for purchase. Some airlines only offer or sell bottled water or have available a pre-sealed snack bag for customers, which can be self-served or provided upon request. One airline has straws available upon request.

"… we're trying to get our customers to stay seated when they're deplaning … getting them to deplane a little bit more slowly, … it's something we're going to have to work on how do we get that behavior to change (Airline #1)

"… additional information for our customers, whether it be on a seat back TV screens, for example, so upon landing it will it queue up a brief commercial or a brief kind of reminder for the deplaning processes, 'Please remain seated until the front row in front of you deplanes'." (Airline #7)

The lower load factors airlines are experiencing have helped to maintain physical distancing in the cabin, as well as while boarding and deplaning. Three of the airlines continue to block the middle seat to provide more spacing between travelers. For capacity control on seating, one airline caps non-revenue flying and stand-by boarding while another offers to rebook passengers where a flight has a 70% loading factor. Several airlines do not block the middle seat and noted that there is no evidence currently on how blocking seats might help to reduce COVID-19 infections. In order to attract customers and reinstate trust, all nine airlines have loosened the flight change policies, most have eliminated fees altogether, and a couple have eliminated change fees permanently.

2.5.4 Aircraft Cleaning and Disinfection

The airlines' disinfection processes have changed significantly in order to reduce any contaminated surfaces or fomites inside the cabin. All airlines have added additional cleaning, prioritizing between flights highly touched areas, and adding additional disinfection overnight or when there is enough time between flights or "turns." Between turns, most disinfection activities require wiping down the high touch areas, lavatories, and galleys. Deeper cleaning is done mostly overnight and often includes use of electrostatic spraying (see Section 9.2.1).

Seven of the airlines have implemented electrostatic spraying of disinfectants, which should reach most areas inside the cabin. Some airlines perform electrostatic spraying at least once per day, or between flights, when having at least two to six hours or more. The other two airlines are not undertaking electrostatic spraying and have instead implemented use of fogging disinfectants overnight or once a week. In addition to antiviral spraying, three airlines have incorporated antimicrobial spraying, ranging from a weekly application to once a month. In order to carry out these extensive cleaning protocols, almost all airlines have included additional cleaning training.

"… before onboard the aircraft, we do go through an extensive cleaning process … we've done really two significant enhancements. One, … we've increased just the number of touch points on the aircraft. … The other … has been the electrostatic spraying, which I think there's been a lot about that in the media...." (Airline #3)

"we're looking at thermal, heating aircraft to a certain temperature... waiting for their studies to come out because there's a lot of things that need to happen to heat up to a certain temperature and sustain that." (Airline #6)

2.5.5 Healthy Air in the Cabin: Ventilation During Different Stages

An aircraft cabin has inherently a high airflow volume and high-quality air filtration during cruising, which are managed through the environmental control system (ECS) that also controls the temperature and cabin pressurization. All nine airlines mentioned having high air exchange rates of approximately every 2 to 3 minutes (20 to 30 ACH) while cruising, a rate that is similar to, or even higher than the recommended air exchange rates for an operating room in a hospital.

"…we've accomplished a fair amount of work on understanding onboard air quality, being so important to our customers…." (Airline #3)

The ECS air supply when flying is bleed air, or air that is compressed and sent to the air conditioning units, known as A/C packs. The ECS has been designed to recirculate some of the air inside the cabin. Air recirculation happens mostly when cruising, where about 40% to 50% of the cabin air is recirculated and filtered through a high-efficiency particulate air filter, also known as a HEPA filter. All the airlines interviewed have aircraft that are equipped with HEPA filters, and one of the airlines has increased the replacement frequency of their HEPA filters.

"For the most part, onboard air is composed of approximately 50% fresh air from the engine-driven pneumatic system and 50% recycled air, the recycled air goes through every circulation system through HEPA filters. We began by increasing the frequency by which we maintained and replace the HEPA filters." (Airline #3)

Once an aircraft is on the ground, the source of air supply can come from various sources, it is then mixed and distributed to the cabin. One source is through the airplane auxiliary power unit (APU) with the engine in operation, which consumes fuel and can generate noise and emissions at the airport. The air supply may also come from airport ground sources (jet-bridge or cart), known as pre-conditioned air (PCA) that supplies the cabin with fresh air, usually outside air, but at a more reduced flow. Whether the airline owns or controls the ground-based systems varies by airport. In many cases, the air that is being supplied by jet-bridge or cart, is managed by the airport. One of the airlines has been conducting air quality studies in their fleet and at different flight stages, to understand when the risk of SARS-CoV-2 might be higher inside the cabin.

"We then began sampling onboard air at the various stages of flight from the boarding process to …, push back, taxi out, climb, cruise, descent, landing, ride, and deplaning… as a proxy for clean air we only measured particles, fine particles 0.3 to 25 microns in

Figure 2.3 Example of a Jet-bridge Mounted PCA Unit and Yellow Hose Supplying Air to the Aircraft Parked at the Gate (Source: Munich Airport, retrieved from https://www.munich-airport.com/a-fresh-breeze-thanks-to-pca-1229006#)

One of the airlines noted that the ground pre-conditioned air is not recirculated, so it is 100% fresh air from outside the aircraft that comes into the cabin. Another airline mentioned that when running the APU, the air has a recirculated percentage, as it is outside air that is initially compressed at high temperatures. It is then passed thorough the A/C packs in the ECS to be cooled down, is unfiltered as it enters the cabin, then a certain percentage of cabin air is recirculated and passed through the HEPA filtration, while the rest is vented.

4.0 VENTILATION REQUIREMENTS ASSOCIATED WITH AIRCRAFT

The airline cabin is a unique setting given its rigorous requirements for maintaining critical control of its environment and the compact seating arrangements in passenger aircraft. Ventilation, essential in all enclosed spaces for basic respiratory needs, also supports thermal comfort and dilutes and removes gaseous and particulate contaminants from breathing zones. The aircraft Environmental Control System (ECS) is designed to meet these needs and must be able to operate in extremes of temperature, ambient air quality, and air pressure.

Travelers and crewmembers have long expressed potential concerns regarding the air quality inside commercial aircraft cabins (NRC, 1986; NRC, 2002). However, much of that concern is likely due to not having a clear understanding of the way aircraft ventilation systems operate. The cabin environment must be safe and comfortable for occupants, given extreme external environmental conditions. Pressurizing the cabin to meet the metabolic requirements of passengers and crew, means that ventilation must be sufficient to dilute contaminants and odors as well as dissipate the heat emanating from people, entertainment systems, galleys and avionics. Specific industry guidance, Federal Aviation Regulations and international regulations are in place to help ensure acceptable conditions of cabin safety, air quality and thermal comfort are always maintained inside the aircraft. This includes the need to provide adequate control of potential airborne transmission of infectious diseases, including SARS-CoV-2 virus within the aircraft environment.

The current pandemic demands a critical evaluation of the interaction of the ventilation system components and their performance through the different phases of air travel, from boarding the aircraft to deplaning upon arrival. Since individual airlines are not required to audit actual ventilation performance it is strongly recommended that airlines adopt voluntary programs to ensure OEM recommendations are being met during all phases of travel.

The aircraft ECS is different from ventilation systems used in most other settings, such as typical buildings and road vehicles, in that it is absolutely essential in enabling the aircraft to operate in the extremes of outside air temperature, ambient air quality, and air pressure encountered while flying. Given the rigorous operating specifications, the ECS can be optimized to reduce the potential risk of exposure to airborne viruses; this analysis is discussed in Section 10.0. The description given here largely apply to narrow body and wide body commercial transport aircraft of recent design; older regional jets or turboprops will not incorporate all these ventilation systems.

The aircraft components include the onboard ECS powered by engines or the auxiliary power unit (APU). When the plane is at the gate, a ground air supply system may be used to provide conditioned air to the cabin. While aircraft systems are generally similar across airplane models and manufacturers there are a variety of ground preconditioned air units (PCAs). Both the onboard and ground systems have variable settings of airflow rates and thermal conditions. Operating parameters for the ECS, APU, and PCAs are determined by air carriers, with PCA settings (flow/pressure) in practice set for the type of aircraft.

The following sections discuss the various elements of ventilation on the "Gate-to-Gate" journey and evaluates how they may affect potential risk of infection.

4.1 AIRCRAFT VENTILATION SYSTEM AND VENTILATION RATES

Ventilation standards for the aircraft cabin vary by country, following the regulations and guidelines of the corresponding international and national aviation authorities. In the USA, the minimum ventilation rates in an aircraft cabin is mandated by FAA regulations, while the ANSI/ASHRAE Standard 161-2018 (ANSI/ASHRAE, 2018) guidance defines the requirements for air quality in the aircraft and specifies methods for measurement and testing. The FAA established FARs to guide the operation of commercial airliners. FAR 14 CFR 25.831 states that *"the cabin ventilation system must provide at least 0.55 lb. (0.25 kg) of fresh air for each passenger per minute".* This is equivalent to 4.7 L/s/p at 8000-feet and a cabin temperature of 22°C (72°F). The NRC report (NRC, 1986) states, *"This ventilation rate is also specified by the joint design regulation FAR/JAR Part 25 for crewmembers to perform their duties without undue discomfort or fatigue and to provide reasonable passenger comfort."* The ASHRAE standard specifies ventilation requirements for maintenance of air quality within commercial aircraft.

As detailed in Table 4.1, ventilation requirements can vary based on whether an aircraft is in flight or on the ground. As such, it does not discriminate between specific activities that may be occurring at various times i.e., boarding, deplaning, and when seated. With these regulations and standards, the cabin is supplied with outside air and highly filtered "clean air" providing air exchange rates significantly in excess to those found in well-ventilated offices and retail spaces (see Table 4.2). **The high air exchange rates utilized in aircraft ventilation systems mean that any contaminant introduced into the cabin should be flushed out much faster than would occur in other types of spaces, i.e., in the order of two to five minutes.**

The HEPA filters remove, at a minimum, 99.97% of the particulate matter from the return air. This high level of filtration ensures that the air supplied to the cabin is virtually free of particulate matter, including bacteria and viruses.

4.2 AIR DISTRIBUTION AND CIRCULATION – ENGINES ON AND ECS OPERATING

The air supplied to the cabin to dilute occupant generated gaseous and particulate emissions is a mixture of outside air, and HEPA-filtered recirculated air set to remove particles and aerosols of all sizes with efficiencies greater than 99.97%.

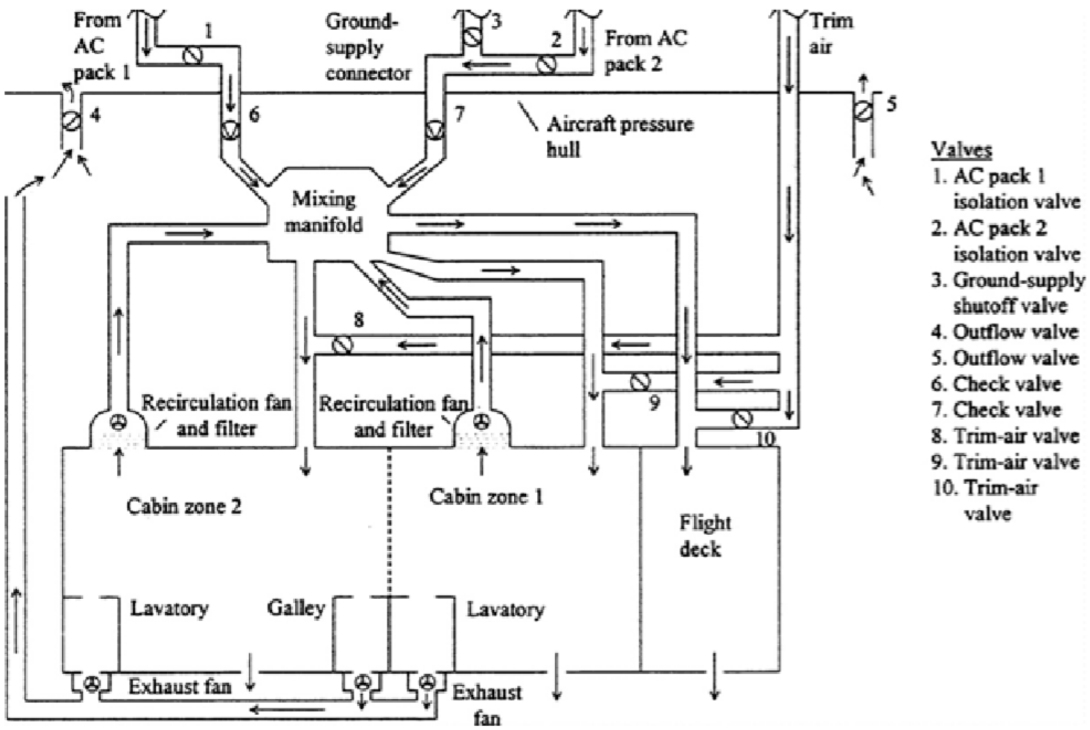


Figure 4.1 Typical Cabin Air Distribution System (NRC, 2002)

As shown in Figure 4.1, a common architecture exists for delivering outside air and filtered recirculated air, extracted air from the galley, lavatories, and cabin. Typically, air is supplied and exhausted relatively equally through air inlets distributed along the cabin to avoid overheating or overcooling at any specific location. Personal Airflow Outlets (PAOs) or "gaspers", common for short-haul rather than long-haul aircraft, and while not the main source of air allow limited and fine tuning of air to an occupant's breathing zone. Although the air mixes locally in the cabin, the air supply and air exhaust flow rates are generally well matched along the length of the cabin to minimize net flows along the length of the aircraft. Distribution of the air to the cabin can occur through diffusers located in the center of the ceiling in the aisles, above the windows, or along the overhead baggage compartments. Wide-body aircraft will use multiple ceiling diffusers across the typically correspond to a MERV 6 rating that have no reliable efficacy for removing 1 um particles. The filtration of smaller particles increases as the MERV value increases.

Aircraft meeting current ventilation standards with 50% recirculation HEPA-filtered air will supply passengers with a clean air delivery rate of 19 cfm/person, which is essentially free of any virus particles. This far exceeds the ventilation rate in a typical naturally ventilated home of 1,000 ft^2 occupied by four persons without mechanical ventilation (8 cfm/person), where the only source of clean dilution air is the outdoor air. In the grocery store and office with no filtration, the only way to dilute virus concentrations in the space is to introduce outdoor air via mechanical systems. As the filtration efficiency increases the percentage of the smaller particles, including viruses, are removed by the systems' recirculated air increases. Another way to look at this is, as the filtration efficiency of recirculated air is increased, the clean air delivery rate will be increased proportionally. The amount of clean air per person is equivalent to the amount of outdoor air per person and the filtration efficiency times the flow of recirculated air per person. In equation form:

$$\text{Clean Air (cfm/person)} = \text{OA cfm/person} + \text{Filter Eff} * \text{Recirculated cfm/person}$$

For example, in an office, increasing the filtration from MERV 6A to MERV 11A will increase filtration efficiency from 0 to 62% for 1 μm particles. With a total supply airflow rate of 1 cfm/ft^2 in 1,000 ft^2 of space, with the ASHRAE design recommendations of 17 cfm of outdoor air per person, and an occupancy of five persons per 1,000 ft^2 of office space, 85 cfm of outdoor air is delivered, with the remaining 915 cfm of air recirculating through the system. Increasing the filtration efficiency of the recirculation air to 62% results in an additional 567 cfm of clean air for five persons (or 113 cfm/person) for a total of 130 cfm/person.

Table 4.3 shows the comparison of clean air delivery expressed in terms of rate of clean air delivery per person, air exchange rates for the volume of the occupied space (air changes per hour), as well as the average age of air for control of potentially infectious particles. It is presented for code compliant conditions and evaluates the effect of using enhanced particulate filtration in the different environments. Note that as filtration efficiency is increased in various environments, as is being currently recommended to reduce the impact of the pandemic, the Clean Air ACH increases and the Average Age of Air decreases.

These values permit comparison of ventilation rates of different environments in which people commonly find themselves. These environments are further compared by increasing the air exchange rates accomplished by improving the filtration efficiency. When the pollutant generation rate is relatively uniformly distributed among occupants over time, such as individually generated bio effluents (CO_2, body odors, etc.), they will be best controlled by increasing the outdoor air delivery rate per person. If the source were related to relatively rare, periodic/occasional emissions, such as one or two individual passengers shedding viruses during a cough or sneeze, then the air exchange rate of total air and the age of air would be more relevant since these terms will better reflect the length of time other passengers could be potentially exposed to infectious aerosols.

The aircraft environment, when meeting current ventilation standards, with 50% recirculation of HEPA-filtered air, supplies a much higher delivery rate of clean air than any other commonly encountered environment. In fact, the aircraft air exchange rate significantly exceeds all normally encountered environments. When infectious particles are released in a typical, code compliant ventilated building and the aerosol has much more volume in which to disperse than that found on an aircraft, mitigating much of the exposure potential.

This analysis shows that aircraft will have a significantly lower age of air, resulting in a very short residence time for particles, and possibility of exposure to infectious particles than any other commonly encountered environment, which will help offset the counteracting effect of being in a smaller volume and in closer proximity to other passengers.

For episodic releases, such as from a cough or a sneeze, the very high air exchange rates in aircraft cabins assume that contaminants released in such events are fully flushed from the cabin in as little as two to five minutes, as opposed to some six hours in a commercial or retail space complying with current codes and standards where these particles will be mixed into the large volume of the space.

11.0 CONCLUDING REMARKS

The Harvard T.H. Chan School of Public Health Aviation Public Health Initiative (APHI) developed this Phase 1 report. The multi-disciplinary academic scientific and technical team were informed by regular dialogue with a consortium of airline operators, aviation industry manufacturers, airport operators, and independent experts at universities and private research organizations. The report is an independent research-led account of the COVID-19 crisis as it affects operations across the aviation industry. It presents the scientific evidence in support of adopting a non-pharmaceutical interventions (NPI) strategy using a layered approach to control the transmission of the novel coronavirus SAR-CoV-2 on board aircraft. The report provides a series of recommendations for risk mitigation that can be adopted readily by airlines, airline passengers and crewmembers. **This layered NPI approach, of wearing face masks, disinfection of surfaces and maintenance of appropriate ventilation gate-to-gate, will ensure the risk of SARS-CoV-2 transmission onboard aircraft will be below that found in other routine activities during the pandemic, such as grocery shopping or eating out.**

The pandemic is a health crisis with profound economic impact, with efforts to control its spread exerting a devastating impact on business in general and, relevant here, to the aviation sector in particular. In the United States alone, airline capacity declined seven to 17 times more than during the 2008 global financial crisis (Boin et al. 2020). Many airports closed entirely, others shut one or more terminals and airlines suspended operations or cancelled a significant proportion of flights, with seat miles for US airlines down by 71% in April 2020 (Curley et al. 2020; Dalrymple et al. 2020). To adapt to the COVID-19 crisis, airlines have closed and/or altered routes and frequency, with the number of seats offered by airlines in 2020 some 42-52% less than originally planned (ICAO, 2020). Most airlines furloughed or laid off staff. Recognizing the economic impact of the sector, governments were quick to announce bailout and stimulus packages, with US passenger airlines calling for US$50 billion to survive the crisis (Financial Times, 2020). Reopening and recovery will focus on 'building back better', using science and the best evidence available currently to design and implement risk mitigation strategies that reduce the risk of disease transmission. Adopted widely, the recommendations in this report build upon aviation's central premise of safety.

The charge to APHI was to capture the science of SARS-CoV-2, in a field that is fast moving with new information emerging globally every day. The team then considered this information in light of the unique defined indoor environment presented by an aircraft to understand how the virus and its transmission will be affected by the conditions experienced across the passenger journey. They went on to develop strategies to mitigate transmission in the confined space of an aircraft, taking due account of behavioral change needed by crewmembers and passengers to protect themselves and others nearby them.

This Phase 1 report address the Gate-to-Gate portion, with air travel segmented into the pre-boarding, boarding, cruise and deplaning. The team's balanced view took into account the rigor of scientific studies, published and in pre-print format, and informed original investigation undertaken by the team. The recommendations also thought through the suitability of the NPI measures to routine and widespread adoption by the airlines and those traveling, including passengers and crewmembers. The layered approach proposed is thus a unique combination of engineering and physical controls as well as hygiene and physical distancing as applied to air travel.

Key findings from the report highlight the interactions of the different NPI layers to risk mitigation and include:

- Compliance with face mask-wearing and the aircraft's environmental control systems effectively diluting and removing pathogens significantly reduce the risk of passengers and crewmembers from acquiring COVID-19 during the cruise segment of their journey.
- Mask compliance reduces the dispersion of larger droplets that may deposit on surfaces, while general airline cleaning practices and passengers sanitizing hard surfaces around their seats lowers the probability of contacting SARS-CoV-2 infected surfaces (which is already low to begin with).
- Taken together, mask compliance, managed physical distancing and improved ventilation during boarding and deplaning, can effectively reduce the risk of potential transmission to the very low levels encountered during cruise conditions.
- Requiring passengers to attest to the absence of COVID-19 symptomatology, mandating they comply with all the airline's COVID-related procedures including physical distancing during boarding and deplaning provides some degree of protection (yet to be determined). The role of gate and flight crewmembers in assuring compliance will be essential and supported by airlines' policies to hold passengers accountable.

Implementing the layered risk mitigation strategies described in this report will help to ensure that air travel, with respect to SARS-CoV-2 transmission, is as safe as or substantially safer than the routine activities people undertake during these times. The potential effectiveness of any one NPI remains uncertain given that estimates of their effectiveness are based upon models. Thus, assessing the individual effects of any one intervention relative to the cumulative effect of concurrent use of multiple NPI must rely on application of the best available science at the time. Hence, the report recommends a layered NPI strategy so that additive and synergistic benefits can be harnessed to reduce the risk of disease transmission. As more information becomes available with respect to the spread of SARS-CoV-2, various control measures will continue to evolve and their effectiveness will be quantified.

Plaintiff's Exhibit 64

flightglobal.com

Eliminating passenger mask mandate is 'next step': Spirit Airlines CEO

Jon Hemmerdinger

2-3 minutes

The US government can help reduce the incidence of unruly air passenger behavior by doing away with the requirement that travellers wear face coverings, says the chief executive of Spirit Airlines.

"That's got to be the next step – when facial [covering requirements] are relaxed on airplanes," CEO Ted Christie says during the Routes Americas conference on 23 June. "That is going to take a lot of steam out of things."

Source: Max Kingsley-Jones/FlightGlobal

Frontier Airlines CEO Barry Biffle agrees: face coverings are a prime contributor to a string of recent in-flight disruptions.

"The reality is, a lot of people don't want to wear masks," says Biffle, who also spoke at the event. "You don't have to wear a mask here, you don't have to wear [masks] at Walmart, but yet you've got to do it on a plane."

“People are agitated,” he adds.

In January, the US Centers for Disease Control and Prevention mandated that air travellers must wear face masks to prevent the spread of Covid-19.

Meanwhile, the FAA has reported a surge in incidents involving allegations of unruly, even violent, passengers – events the FAA has said are often related to the face mask requirement.

“The masks make everyone uncomfortable, and it does drive a lot of friction,” Christie says. “We are going to have to make a step here, where we are creating less abrasive” conditions.

The FAA responded to the trend by instituting a “zero tolerance” policy and dishing out hefty fines – some in the tens of thousands of dollars – to a number of passengers accused of airborne outbursts.

“We are focusing on the symptom, rather than the root cause,” says Biffle, adding that such disturbances are uncommon but become high-profile thanks to social media. “The root cause is…. you’ve got to [war a mask] on a plane.”

Plaintiff's Exhibit 65

viewfromthewing.com

Southwest Airlines CEO: Let Our Vaccinated Passengers Take Off Their Masks! - View from the Wing

About Gary Leff

2-3 minutes

Southwest Airlines CEO Gary Kelly says he – and the airline lobbying group he leads – wants to see the federal transportation mask mandate end September 13 and he also says he believes airline passengers should be able to follow the same guidance set out by the CDC for everyone else – that no mask is needed if you've been vaccinated.

That would be cumbersome to enforce – think wristbands, for instance – but might actually encourage air travelers to get vaccinated.

In any case, enforcement might not be needed since the primary route of virus spread is from one unvaccinated person to another, which for most is an individual choice they're making to remain at risk. Those choosing to get the vaccine, and protect themselves and others, shouldn't have a cost imposed on them by other passengers unwilling to do so. And the paper and string that counts as a mask on board isn't very protective in any case.

While Southwest's Kelly is being reported as "the first U.S. airline executive to publicly state what is in effect support for letting the mandate expire" for comments made during the carrier's earnings call, earlier this week United Airlines CEO Scott Kirby told CNBC that he hopes the federal transportation mask mandate expires September 13 as well.

While American Airlines CEO Doug Parker dodged the question on his own earnings call this week, he has told American Airlines employees he expects the mask mandate to be lifted September 13 and that's when the airline can serve alcohol in coach again.

Parker says "we've got to get to" September 13th, and that because most inflight incidents are over masks things are going to get even harder on board as that date approaches. In the meantime they're seeing more passengers bring their own booze on board planes.

Plaintiff's Exhibit 66

usatoday.com

Will the mask mandate for flights be extended? Southwest Airlines CEO says airlines not pushing for it

3-4 minutes July 22, 2021; updated July 27

Airplanes and airports are among the few remaining places where face masks are required, but they might not be after Sept. 13if the rule isn't extended.

Southwest Airlines CEO Gary Kelly, chairman of industry lobbying group Airlines for America (A4A), said Thursday that Southwest and the trade group are not recommending another extension of the federal transportation mask mandate.

The mandate, which airlines and their unions requested to help with passenger mask compliance and to protect the health of flight crews, was put in place by President Joe Biden in January. The mandate, which applies to trains, planes and airports, buses and transportation hubs, was initially due to expire in May but was extended through Sept. 13, with the blessing of airlines.

Reports abound of passengers refusing to wear masks and becoming aggressive with flight crews.

Kelly, answering reporter questions during Southwest's quarterly earnings conference call, said airlines support following Centers for Disease Control and Prevention guidance on masks, which says vaccinated individuals don't need one but unvaccinated individuals should wear one.

New rules: CDC lifts indoor mask requirement for fully vaccinated people

Unless that advice changes, he said, "we wouldn't advocate from Southwest's perspective, or the A4A for that matter, extending the mandate."

Kelly said he doesn't know whether the mandate, enforced by the

Transportation Security Administration, will be extended or lifted.

"That's a political question, to a degree," he said.

Kelly said the government is studying the matter, given the spreading delta variant, which has caused a spike in COVID-19 cases, but he is not aware of "any efforts underway" to extend the mask mandate.

COVID-19 and travel: The delta variant is spreading. Should travelers be concerned?

The CDC has had no comment on the status of the mandate beyond Sept. 13.

"We can't comment on pending regulatory discussions as to the future of the order," spokesperson Caitlin Shockey said via email.

Kelly is the first U.S. airline executive to publicly express what is in effect support for letting the mandate expire, though United Airlines CEO Scott Kirby said he expected it to be lifted in September.

"What they decide, we'll enforce," American Airlines CEO Doug Parker said earlier Thursday on the airline's quarterly earnings conference call. "It's not for us to opine."

Last week, Delta CEO Ed Bastian told Wall Street analysts and investors he didn't know the fate of the mandate.

He said there are as many "pros to taking the mask requirement off as there are to keeping it on at the present time."

"I think it's important that medical experts make those decisions, not airline professionals, as we've learned through the pandemic," he said on the airline's earnings call. "They're the ones that have all the insight and the information and keeping people safe. I appreciate people not wanting to wear the mask. I don't like wearing the mask when I'm on board either, but it's something that we need to do to keep each other safe."

Los Angeles County, the most populated county in the USA, will once again require people to wear masks indoors – regardless of vaccination status – after a surge in COVID-19 cases.

Plaintiff's Exhibit 67

TRAVEL NEWS

A4A Won't Push for a Federal Transportation Mask Mandate Extension

John Michael Jayme | July 25, 2021

03:54 15 KEY TRAVEL ADVISO

The federal transportation mask mandate is about to end on September 13. According to this mandate, people will have to wear masks in public transportation including airports and planes. Since CDC eased on masking rules, airports and airplanes have been the few remaining places where you are required to wear a mask.

It's also the number one reason why there's an increased report of unruly passengers on planes. The majority of these unruly passengers refused to wear masks.

Southwest Airlines CEO Gary Kelly, who is also the chairman of Airlines for America (A4A), said that the trade group and Southwest are not recommending an extension of the federal transportation mask mandate.

Federal Transportation Mask Mandate Extension As Delta Variant Spreads?

President Biden announced the federal transportation mask mandate in January. The goal is to protect the passengers' and flight crews' health and improve mask compliance. This means that travelers will have to wear masks on trains, buses, planes, airports, and other transportation hubs. It was originally only up to May. But with the COVID situation in the US, it was extended until September 13.

Kelly said that airlines support the mask guidelines set by the US Centers for Disease Control and Prevention. According to the latest guidance, only unvaccinated individuals should be wearing a mask. He added though that "we wouldn't advocate from Southwest's perspective, or the A4A for that matter, extending the mandate".

03:54 **15 KEY TRAVEL ADVISO**

Kelly isn't sure if the Transportation Security Administration will extend or lift the mandate. According to Kelly, "That's a political question, to a degree".

The recent surge of COVID cases in the US is something that can affect the decision of TSA. Delta variant is now the dominant strain in the US. CDC currently has no comment regarding the status of the mask mandate. Caitlin Shockey in an email said that "We can't comment on pending regulatory discussions as to the future of the order".

American Airlines CEO Doug Parker said that "What they decide, we'll enforce".

John Michael Jayme

John Michael Jayme is a Travel Analyst for The Jet Set. He writes about news and events affecting the travel industry.

READ MORE

03:54

15 KEY TRAVEL ADVISO

Plaintiff’s Exhibit 68

Two Major Airline CEOs Question the Need for Masks on Planes

By Chris Isidore, CNN Business
Updated 11:29 PM ET, Wed December 15, 2021

New York (CNN Business)The CEOs of two of the nation's major airlines say they don't think wearing masks on planes does much to help limit exposure to Covid.

The comments from American Airlines (AAL) CEO Doug Parker — the nation's largest carrier — and Southwest (LUV) CEO Gary Kelly came during a hearing about the financial support that airlines received from the federal government in 2020 and 2021. But the topic of masks arose via a question from Sen. Roger Wicker, the ranking Republican on the Senate committee holding the hearing.

"I think the case is very strong that masks don't add much, if anything, in the air cabin environment. It is very safe and very high quality compared to any other indoor setting," said Kelly.

Both Kelly and Parker, who each have announced plans to retire as CEOs in the coming months, mentioned that high-grade HEPA air filters on planes capture virtually all airborne contamination and air quality is helped by how frequently cabin air is exchanged with fresh air from outside the cabin.

"I concur. An aircraft is the safest place you can be," said Parker. "It's true of all of our aircraft — they all have the same HEPA filters and air flow."

After the hearing, American Airlines tried to walk back Parker's remarks. It issued a statement claiming that his concurrence with Kelly was on the point about the quality of the air in the aircraft cabin, not mask requirements.

Sara Nelson, the president of the Association of Flight Attendants, testified at the hearing that not all aircraft are equipped with the same quality of air filters. For example, some older planes do not have HEPA filters, she said.

The mask requirement is still a source of controversy. Much of the steep rise of in incidents involving unruly passengers over the last two years have revolved around passengers being ordered to wear masks.

"I think that is probably for the medical community to decide rather than me," Nelson added. "What I will add is that the studies that have been done [on masks]....were done with mannequins that were sitting straight forward with masks on, not removing them, not eating."

"It is important to recognize that the safe, controlled environment on planes...includes the HEPA filters that are not on all aircraft," she concluded.

Masks on planes are required by the federal government, following the guidance of the Centers for Disease Control. The DOT did not immediately respond to a request for comment on the testimony.
The remarks by Kelly and Parker were criticized by one committee member, Sen. Ed Markey, a Massachusetts Democrat.

"I'm shocked that some of the CEOs here today have suggested we no longer need masks mandates on planes," he said. "In the face of Omicron, children under five who still cannot be vaccinated....and that we still allow unvaccinated people on planes." He said it was "immoral" to take the position that people on planes could be forced to sit next to unvaccinated people who are not wearing masks.

Nelson, who Markey was questioning, agreed that while she hopes that one day masks will not be required, she does not support lifting the mask mandate at this time.

"I believe that the government has taken a very responsible approach to this," she said. "We believe it should continue to stay in place. It's a workplace safety issue. We do need a consistent message though. It troubles me too to hear different messages. I would hope we are going to stay on the same messages and follow the medical experts and do what's necessary to keep everybody safe."
Nelson said that the confidence in the safety of air travel is the reason people are willing to buy airline tickets in near pre-pandemic levels today. She said that the mask mandate is one of the factors leading to that confidence by airline passengers.

https://www.cnn.com/2021/12/15/business/airline-ceos-question-masks-on-plane-rule/index.html dallasnews.com

Southwest Airlines CEO says face masks ‘don’t add much’ with airplane filtration systems

By Kyle Arnold3:55 PM on Dec 15, 2021 CST

4-5 minutes

Update: American Airlines CEO Doug Parker initially said "I concur" with comments from Gary Kelly in Wednesday's U.S. Senate Hearing, but American later clarified that Parker "concurred with the comments made by other witnesses about the high quality of aircraft cabin air, and did not intend to cast doubt on the necessity of face masks on planes."

Southwest Airlines CEO Gary Kelly told U.S. senators Wednesday that the air in airplane cabins is clean enough that face masks don’t provide significant additional protection to passengers from COVID-19.

“I think the case is very strong that masks don’t add much, if anything, in the air cabin,” said Kelly, who runs Dallas-based Southwest. “The environment is very safe, very high quality compared to any other indoor setting.”

“I concur,” said Doug Parker, CEO of Fort Worth-based American Airlines. “The aircraft is the safest place you can be. That’s true of all of our aircraft.”

American later clarified that Parker’s remarks were intended to agree with ”the comments made by other witnesses about the high quality of aircraft cabin air, and did not intend to cast doubt on the necessity of face masks on planes,” spokeswoman Stacy Day said.

The airline executives made the comments at a U.S. Senate committee hearing into how the airlines have used $54 billion in federal grants since March 2020 to help them financially survive the pandemic.

Kelly’s face mask comments contradict efforts by the Biden administration to require them on airplanes, in airports and on other forms of interstate transportation, such as buses and trains. President Joe Biden made airplane face mask mandates among his first executive orders when he took office in January and has since renewed the face mask mandate through March 18, 2022.

Airlines have been requiring face masks on airplanes since the summer of 2020 and then subsequently partnered with the Department of Defense and research universities such as Harvard to show that HEPA filtration systems on airplanes make it difficult for coronavirus to spread among passengers.

Over the last year, the Federal Aviation Administration and the Department of Transportation have noted a sharp uptick in reports of unruly passengers, often violent outbursts that have resulted in assaults on crew members such as flight attendants and gate agents. There have been 5,664 reports so far this year, according to the FAA’s data through Dec. 14, and 4,072 of those incidents have been tied to mask-related problems.

Kelly, who announced he is retiring in February, is also the chairman of Airlines 4 America, the main trade group for major airlines.

Parker, in a statement provided to the committee ahead of the hearing, said: “Airlines have required masks since early in the pandemic as an additive health and safety measure, and our industry strongly supported the introduction of the federal mask mandate.”

Scott Kirby, CEO of Chicago-based United Airlines, said several studies show that airplane cabins are safe. Those studies are often industry-funded.

“The conclusion of that is that effectively anywhere that you’re going to be indoors, the airplane is the safest place that you can be indoors,” Kirby said. “It’s because the air filters are safer than a theater, safer actually than an intensive care unit because we have HEPA-grade filters.”

Kirby said airplane filters cycle air 20 to 30 times an hour, as opposed to twice or three times an hour in a hospital ICU. The studies from airlines also show that the way the air flows in cabins, from the ceiling to the floor, also reduces the risk of COVID-19 spread among passengers.

However, those studies were conducted on mannequins and may not be sufficient to cover the complexity of humans, said Sara Nelson, president of the Association of Flight Attendants-CWA. She also said that not all passengers have been vaccinated or have access to vaccines.

Nelson said she believes the mask mandate should stay in place for now.

“The filtration system is different from airline to airline or from aircraft to aircraft, so not all aircraft have the HEPA filtration,” Nelson said. “What I will tell you is we look forward to the day that we no longer have the mask requirement. We are simply trying to get through this pandemic and have had to enforce this to keep everyone safe.”

foxbusiness.com

Southwest CEO: 'Masks don't add much, if anything' against COVID-19 on planes

Breck Dumas

12-15-21

4-5 minutes

Southwest Airlines CEO Gary Kelly told a U.S. Senate panel on Wednesday that "masks don't add much, if anything" in fighting the spread of COVID-19 on airplanes, calling into question the reasoning behind mask mandates on flights imposed both by airlines and the Biden administration.

Kelly made the comment during a hearing on airline oversight before the Senate Committee on Commerce, Science and Transportation, and other industry chiefs joined him in emphasizing that commercial aircraft filtration systems make them the safest indoor space there is.

Gary Kelly, chief executive officer of Southwest Airlines Co., speaks during a Senate Commerce, Science and Transportation Committee hearing in Washington, D.C., U.S., on Wednesday, Dec. 15, 2021. (Photographer: Chip Somodevilla/Getty Images/Bloomber (Photographer: Chip Somodevilla/Getty Images/Bloomberg via Getty Images / Getty Images)

AIR TRAVELERS TO US SET TO FACE TOUGHER COVID-19 TESTING

Ranking member Sen. Roger Wicker, R-Miss., asked the CEOs about air quality on planes while posing the question, "Will we ever be able, do you think, to get on an airplane without masks?"

Speaking to discussions on air quality, Kelly said, "The statistics I recall is that 99.97% of airborne pathogens are captured by the [high efficiency particulate air] filtering system, and it's turned over every two or three minutes."

"I think the case is very strong that masks don't add much, if anything, in the air cabin environment," Kelly said. "It's very safe, and very high quality compared to any other indoor setting."

Sen. Roger Wicker (R-Miss.) during hearing at the Senate Commerce, Science, and Transportation Committee on January 26, 2021, in Washington, DC. (Photo by Tom Williams-Pool/Getty Images) (Photo by Tom Williams-Pool/Getty Image / Getty Images)

FATHER SAYS AUTISTIC SON BANNED BY AIRLINE, DENIED MEDICAL MASK EXEMPTION: 'MIND-BLOWING'

Wicker then asked for a response from American Airlines CEO Doug Parker, who replied, "I concur. The aircraft is the safest place you can be – it's true of all of our aircraft. They all have these HEPA filters and the same airflow."

United Airlines CEO Scott Kirby told Wicker that, in fact, air quality on planes is "safer, actually, than an intensive care unit," adding that "being next to someone on an airplane – sitting next to them – is the equivalent of being 15 feet away from them in a typical building."

But most places in the U.S. no longer require masks indoors, save for certain Democrat-controlled jurisdictions and areas under federal oversight.

Airlines imposed mask requirements on their own in 2020 during the COVID-19 pandemic, and several welcomed President Biden's federal mandate for wearing masks on commercial flights after he took office. The federal rule was slated to expire in September, but the Transportation Security Administration extended it through Jan. 18.

President Joe Biden addresses the 76th Session of the U.N. General Assembly on September 21, 2021 at U.N. headquarters in New York City. . (Photo by Timothy A. Clary-Pool/Getty Images) ((Photo by Timothy A. Clary-Pool/Getty Images) / Getty Images)

The mask requirements have caused major headaches for airlines in the way of compliance, with mask violations being the major cause of a sharp uptick in unruly behavior from passengers. In response, the FAA has upped the fines on violations for fliers who disrupt air travel and urged airlines to "take more action" on unruly passenger incidents.

Airlines have not pushed back publicly against the mandate.

When asked by FOX Business for further explanation on Kelly's comments, Southwest said in a statement, "Southwest Airlines continues to abide by the federal mask mandate for customers and employees both within the airport environment and onboard all Southwest aircraft."

Plaintiff's Exhibit 69

reuters.com

CDC defends U.S. transit mask mandate as some call for scrapping

David Shepardson

4 minutes

Travelers board the air train ahead of the July 4th holiday, at the Newark Liberty International Airport, in Newark, New Jersey, U.S., July 2, 2021. REUTERS/Eduardo Munoz

WASHINGTON, July 16 (Reuters) - A senior U.S. health official who signed a sweeping order for masks to be worn on nearly all forms of public transport said they were a key tool in preventing COVID-19 transmission even as some lawmakers call for ending the rules.

Marty Cetron, director for the Centers for Disease Control and Prevention's (CDC) Division of Global Migration and Quarantine, told Reuters Thursday the agency's "current position" is the mandate should not be lifted.

"Masks are really powerful and we should make sure they're part of our arsenal," Cetron said in an interview. "We mask not just to protect ourselves - we mask because it's the way we take care and express our concern for each other."

The rules in place since January require masks to be worn by all travelers on airplanes, ships, trains, subways, buses, taxis, and ride-shares and at transport hubs like airports, bus or ferry terminals, train and subway stations and ports.

"The truth is that the unvaccinated portion that's out there is extremely vulnerable," Cetron said, especially in an indoor transportation hub "where the ventilation may not be optimized."

A group of Republican lawmakers this week introduced legislation to prohibit mask mandates for public transport, arguing they no longer make sense with a growing number of Americans getting vaccinated. Republican Representative Andy Biggs said transit mask rules "are only being kept in place by those who relish controlling our day-to-day lives."

In mid-May, CDC said fully vaccinated people could avoid wearing masks indoors in most places - with some exceptions like transit.

The mask mandate has been a huge source of friction on U.S. airplanes. The Federal Aviation Administration said Tuesday that since Jan. 1 it has received 3,420 unruly passenger reports, including 2,559 for refusing to wear masks.

The Transportation Security Administration (TSA) said Sunday was the single-busiest day since February 2020, with nearly 2.2 million passengers.

"I get we're all just over this emotionally but I do think we will succeed together if we realize the virus is the enemy and it's not your fellow citizen or the person sitting next to you on a plane or a piece of cloth that you have to wear over your face," Cetron said.

The CDC transit mask order has no expiration date. In April, the TSA extended its mask requirement until Sept. 13.

"As long as the CDC order is in place, the expectation is the implementing modes ... would continue with their own directives," Cetron said.

"We won't wait until September to reevaluate," Cetron said, adding CDC is regularly reviewing the mandate. "If the pandemic were to suddenly disappear before then we have the ability to take down the order."

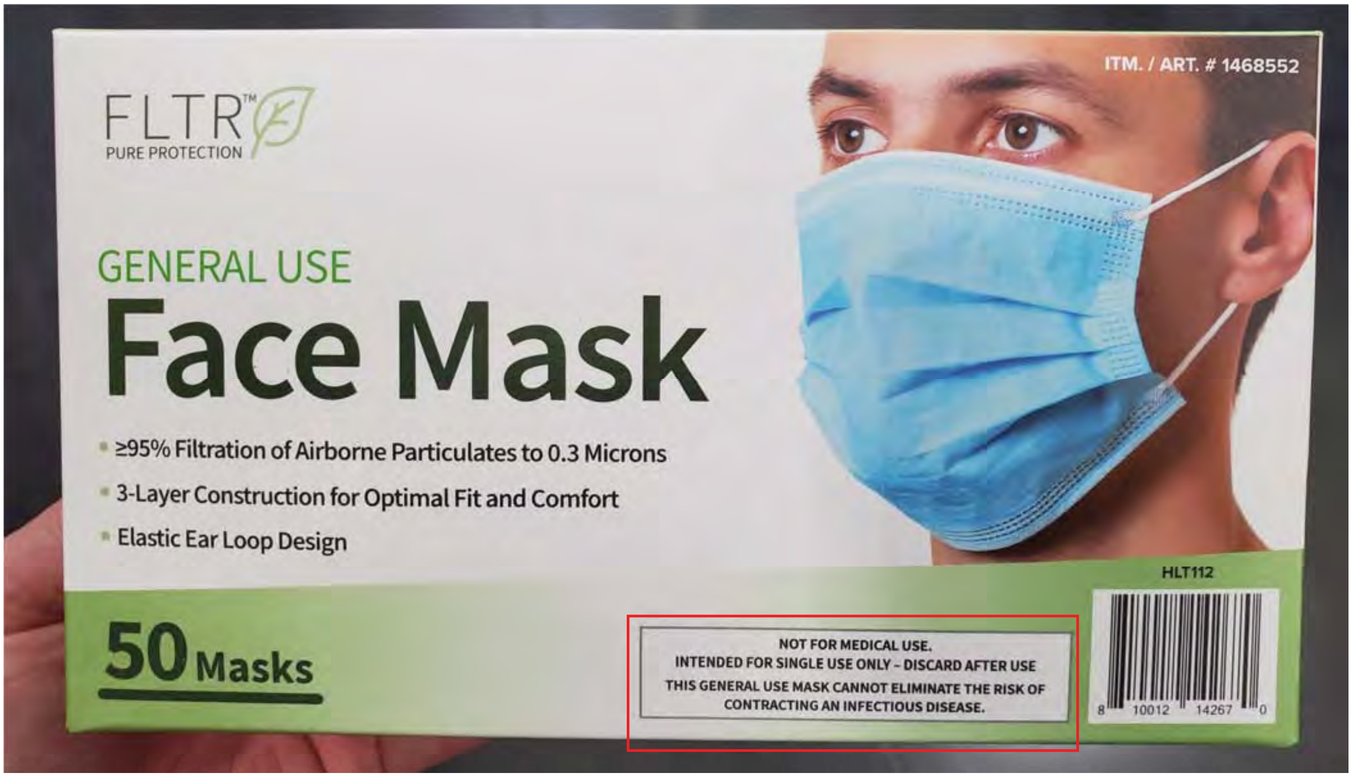
Under Donald Trump, a CDC push to mandate masks in transit was blocked.

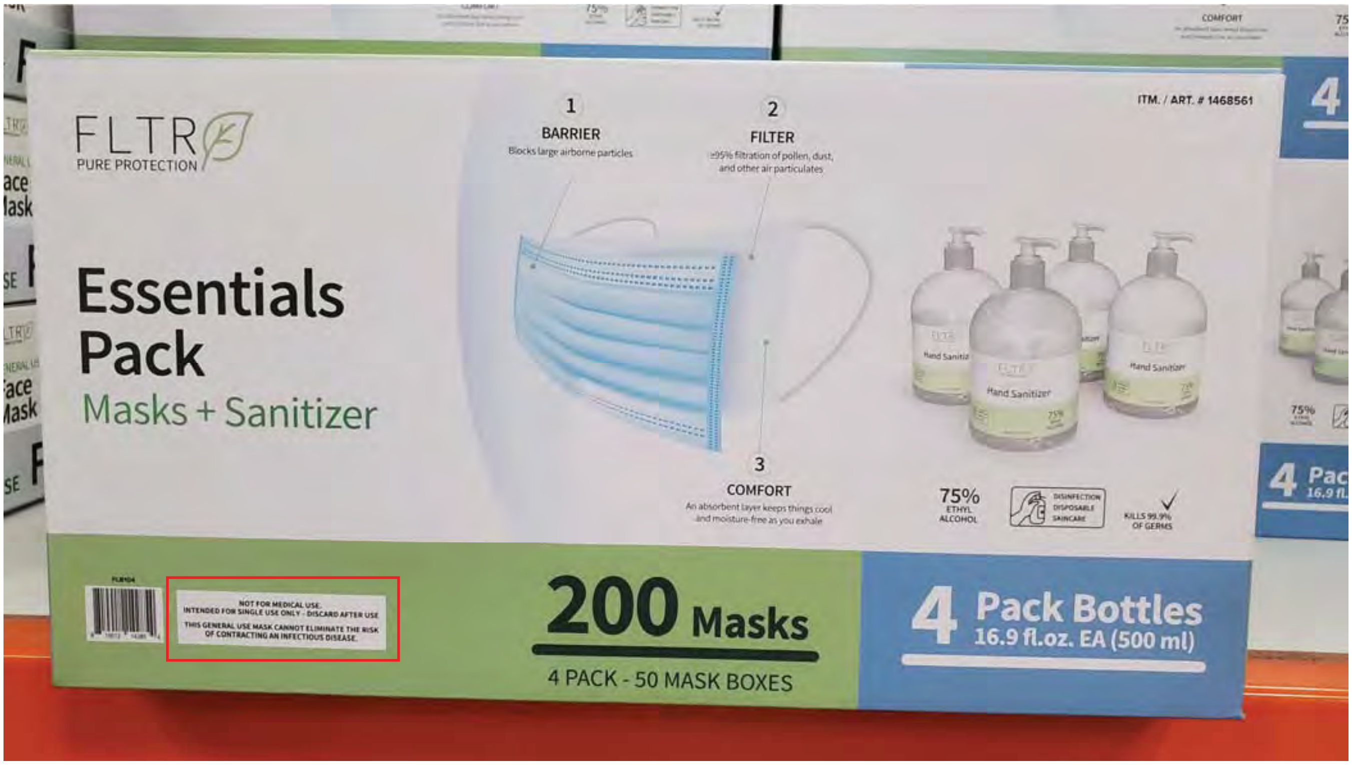
Asked if he still believes there is a scientific or public health basis for U.S. travel restrictions that bar entry from some countries in the United States, Cetron said: "I'm not going to get into the details" but said U.S. government discussions are going on.

Reporting by David Shepardson Editing by Robert Birsel

Our Standards: [The Thomson Reuters Trust Principles.](#)

Plaintiff's Exhibit 70





Plaintiff's Exhibit 71

Plaintiff's Exhibit 72

washingtonpost.com

With virus spreading fast, airlines around the world cancel flights

María Luisa Paúl, Hannah Knowles, Rachel Weiner

16-20 minutes Updated 12-24-21

Thousands of Christmastime flights have been canceled around the world as airlines say the fast-spreading omicron variant of the coronavirus is preventing staffers from working and causing travelers to rethink their plans.

As of late Friday afternoon, about 3,860 flights were canceled globally for Christmas Eve and Christmas Day, according to the website FlightAware, and 2,000 other flights were scrapped Thursday. FlightAware said about a quarter of those canceled for Friday involved travel within, into or out of the United States. Airlines cited staffing shortages and falling demand amid a new pandemic wave and other issues.

United Airlines said in a statement Thursday that it was canceling 120 flights Friday because the variant has had "a direct impact on our flight crews and the people who run our operation."

Delta Air Lines in a statement said its teams had "exhausted all options and resources — including rerouting and substitutions of aircraft and crews to cover scheduled flying." On Friday morning, it said it had canceled 135 flights on Christmas Eve because of weather and staffing problems and still had nearly 3,100 scheduled for the day.

American Airlines spokesman Derek Walls said Friday that the company was not experiencing higher-than-usual cancellations.

Travelers hastily change and scrap their plans

While some people struggled to rebook flights, others scrapped their travel plans entirely out of concerns about a new coronavirus wave driven by the omicron variant.

Elizabeth Horton of Northern Virginia was planning to fly to Missouri on Friday to see family after avoiding planes earlier during the pandemic — worried mostly about infecting her parents, who are in their 80s. She said she booked her ticket in early December and was reluctant to fly but was reassured by the fact her family is vaccinated and boosted.

"And then with the new variant coming in, it was like, 'Oh, you know what? No,' " Horton said.

She said she will stay put for Christmas and join the family festivities over Zoom.

Eliot Salant said a flight cancellation delayed his return to Israel and led him to spend nearly $180 on additional coronavirus testing, which Israel requires for reentry.

Salant, who came to visit his brother in the hospital, said he scrambled to book a flight back to Israel after rising coronavirus caseloads led the Israeli government to bar its citizens from traveling to the United States.

He said he was at a D.C.-area airport Thursday when he learned his flight to Tel Aviv was canceled. Staffers at the airport said they were stretched thin, he said, so he called his airline's customer service to discuss his options. He flew to New York and said he was able to book another flight for Friday.

He said he also wound up paying $179 for a coronavirus test at a New York airport, after delays meant he could not use his initial test.

The prices at the airport were "outrageous," he said, but "I didn't want to risk going to the free public [testing site] today, the day before for Christmas." His thinking: "Who knows if they're going to have the capacity, you know, and then how long it's going to take?"

Cancellations pale in comparison to summer stops, analyst says

Compared with cancellations this summer and fall, aviation analyst Henry Harteveldt said what he's seen today "is really small." Of course, he added, "if your flight is the one that's been canceled, the world has just ended. This is not a meltdown, as some have described it, but it is unfortunate."

Harteveldt, co-founder of Atmosphere Research Group, said he anticipates similar spikes in cancellations for the next few weeks, as long as the omicron-variant wave lasts.

"The airlines took a lot of steps to ensure their airlines would be healthy and to reduce the risk that covid would disrupt their operations, but you can't build impenetrable walls," he said Friday.

"The timeline is really dictated by the course of the virus. … No one anticipated that … we would see something like omicron."

Harteveldt said domestic flights are being canceled more often than international ones because flight routes out of the country have already been pared back by omicron-related border restrictions.

"Airlines already proactively reduced international schedules at Christmastime as a result of the more stringent entry requirements into so many countries," he said. He also noted, for those looking at websites tracking international cancellations, that some probably have nothing to do with the coronavirus. For example, he said, Chinese airlines are regularly forced to cancel flights at the last minute because of military maneuvers.

Despite new restrictions and last-minute headaches, he said, "we're seeing very strong demand for travel. … There were a lot of people who were determined to enjoy some kind of getaway for Christmas and New Year's this year."

Photos: Travelers cope with cancellations

Thousands of flights have been canceled or delayed around the world as the highly infectious omicron variant disrupts holiday travel.

Cancellations are a blip as air travel moves 'closer to normality,' analyst says

Airlines seemed headed "closer and closer to normality" this year after taking hits during the pandemic, said Robert Mann, an airline industry analyst and former airline executive. Then came "a unique factor that no one really forecast very well," he said — the omicron variant.

Mann said he expects "a lot of stress on the system" through Jan. 3, as travel peaks around the holidays. Weather does not seem to be a major factor in the latest cancellations, he said. "I would chalk them up to crew unavailability."

He noted that there are typically 20,000 flights a day in the United States and that 115,000 airline flights are expected globally on a peak day — a figure that does not include business jets and operators of general aviation aircraft. As of Friday afternoon, about 2,300 flights were canceled globally for Christmas Eve, according to the site FlightAware.

"It's more than it should be; it's more than anybody wanted it to be," Mann said of the cancellations. "But, you know, it's not the end of the Earth."

"If it's your flight, it is the end of the Earth," he added.

Airlines seek shortened isolation periods as flight attendant group pushes back

Airlines are asking federal health officials to shorten their recommended isolation period for people who have breakthrough coronavirus infections, but a flight attendants union is pushing back, saying leaders should "err on the side of caution."

Writing Thursday to the head of the Centers for Disease Control and Prevention, Airlines for America President Nicholas E. Calio suggested "an isolation period of no more than 5 days from symptom onset" for vaccinated people who contract the coronavirus. That is half the 10-day period the CDC recommends for infected people, regardless of their vaccination status.

The CDC on Thursday cut recommended isolation time for health-care workers as hospitals brace for a surge of patients. New guidance says that they can return to work after seven days with a negative test if they are asymptomatic, and that "isolation time can be cut further if there are staffing shortages."

JetBlue chief executive Robin Hayes wrote Wednesday that the "vast majority" of the company's crew members are vaccinated against the coronavirus "and like so many others are being relied upon by the American public for providing the essential service of travel."

Responding Thursday to a similar letter from Delta's chief executive, the Association of Flight Attendants-CWA — which says it represents 50,000 workers at 17 airlines — said flight attendants should not have to return to work until they are symptom-free and test negative. International President Sara Nelson wrote in a letter to the CDC that the group does "not see the justification" for reducing the isolation period.

Most crew members are vaccinated, Nelson said, but they may have not received a booster shot — which federal health officials have strongly recommended to protect against the omicron variant of the virus.

"The current climate in the passenger cabin is highly stressed. We are experiencing a record high number of aggressive passenger incidents, many of which are fueled by alcohol and refusal to comply with onboard mask rules," Nelson wrote. "Staffing flights with crewmembers who may still be symptomatic, infectious, or both by shortening them on necessary isolation time will only make this situation worse."

Hannah Sampson contributed to this report.

How to get refunds if your Christmas flight is canceled

The emotional roller coaster that accompanies life in a pandemic took another plunge Thursday night when airlines began announcing thousands of cancellations for Christmas Eve flights. After U.S. airlines navigated the Thanksgiving bump relatively unscathed, this is the "messy" holiday travel season some experts envisioned.

U.S.-based carriers such as United and Delta; Germany-based Lufthansa; and Jetstar, Qantas and Virgin in Australia are blaming the surge in omicron variant for sending their crews to sick leave or isolation after being identified in contact tracing.

Back in the summer, a chaotic travel season when airlines such as Spirit and Southwest were facing staffing shortages, By The Way compiled a guide for what to do if your flight gets canceled and how to get a refund you are owed. Here's a helpful reminder.

Staff illnesses and lack of demand are to blame for cancellations, airlines say

Some international airlines have canceled thousands of flights scheduled for this weekend and beyond, citing staff illness and lack of demand as the omicron variant spreads and prompts new travel restrictions.

Lufthansa said in a statement Friday that "a high rate of people calling in sick" and lack of demand had led it to cancel a dozen flights this holiday weekend.

Scandinavian Airlines canceled nearly five dozen flights that had been scheduled for the next week.

"We have staff who are ill, have symptoms or someone who is ill in their household, and the

Plaintiff's Exhibit 73

nytimes.com

Air Travel Is No Holiday as Covid-19 and Winter Storms Cancel Flights

Niraj Chokshi, Heather Murphy

10-12 minutes

Airlines and passengers are ending the year with many of their plans upended. And New Year's weekend may be bumpy, too.

Credit...Karsten Moran for The New York Times

Dec. 30, 2021

Airlines may have thought their pandemic troubles were behind them in the fall as a coronavirus wave subsided and travelers increasingly took to the skies. But a new virus surge and winter storms have left the carriers and their passengers in a holiday mess.

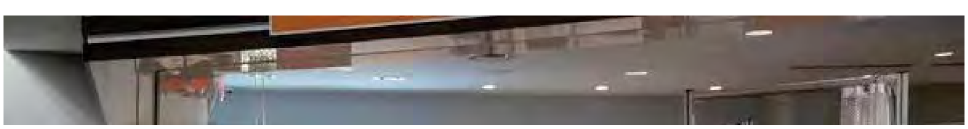
Heading into the New Year's weekend, when return flights will produce another crest in air travel, airlines have been canceling more than 1,000 flights a day to, from or within the United States. More than 1,300 flights on Friday were canceled. Carriers and their employees say the latest chapter of the pandemic, the Omicron variant, has cut deeply into the ability to staff flights, even though a vast majority of crew members are vaccinated.

"I've never seen a meltdown like this in my life," said Angelo Cucuzza, the director of organizing at the Transport Workers Union, which represents flight attendants at JetBlue. "They just can't keep up with the amount of folks that are testing positive."

JetBlue has been one of the airlines hardest hit, canceling 17 percent of its flights on Thursday, according to the air travel data site FlightAware. The carrier said Wednesday that it would cut about 1,280 flights through mid-January, citing the rise in virus cases in the Northeast, where its operations and crews are concentrated.

And then there was the weather, always a volatile element in holiday travel but particularly challenging in recent days — notably in the Pacific Northwest, where heavy snowfall and record low temperatures grounded planes last weekend.

Image



Credit...Nicole Craine for The New York Times

The next few days may be just as frustrating. Storms in Southern California and the Northwest could combine to dump snow on airline hubs in Denver and Chicago, with severe thunderstorms threatening Dallas Fort Worth International Airport, too, according to Dan DePodwin, director of forecast operations at AccuWeather.

Alaska Airlines, whose main hub is Seattle-Tacoma International Airport, went so far as to suggest that people put off nonessential travel until the new year. The carrier was hit hard again Thursday, with 14 percent of its flights canceled, as Seattle got more snow.

As many as 10 million people may fly from Thursday through Monday, according to Transportation Security Administration estimates. For months, airlines have been preparing reserves of workers for the holiday crush. But those measures were inadequate in a fast-changing situation, and many passengers were frustrated.

“Even though it’s been two years with Covid, it does not seem like they have this figured out,” said Sabine Malloy, whose plan to rendezvous with her boyfriend in Alaska to see the northern lights was upended on Tuesday when both their flights on Delta Air Lines — hers from Southern California, his from Denver — were canceled. Delta told them that it could not rebook them for several days, she said, so they canceled their plans — after her boyfriend had driven seven hours from South Dakota for his flight.

Trying to change plans before departing was also daunting. A traveler trying to rebook a family trip on American Airlines encountered a recording saying to expect a four-hour wait for a callback from an agent.

Some say airlines shoulder some of the blame for the turmoil. The industry received $54 billion in federal aid to keep workers employed throughout the pandemic, assistance that came with a ban on layoffs. But carriers were able to thin their ranks by offering buyouts and early-retirement packages to thousands of workers.

Airlines started hiring again as the travel rebound took off this year, but most have yet to fully restore their work forces: The industry employed nearly 413,000 people in October, down almost 9 percent from the same month in 2019, according to federal data. Airlines have had trouble turning a profit as passenger volumes remain about 15 percent below prepandemic levels.

Image

Credit...Karsten Moran for The New York Times

The industry looked to the Centers for Disease Control and Prevention in recent days for a partial solution to its staffing problems, lobbying for the 10-day isolation period recommended for those infected with the coronavirus to be reduced to five days. Some scientists, unaffiliated with airlines, made a similar suggestion to bolster strained work forces in other realms, like hospitals.

On Monday, the C.D.C. shifted its guidance to five days of isolation for people whose symptoms have ended or are abating, followed by five days wearing a mask. The agency said the change was motivated by findings that the coronavirus was mostly transmitted one to two days before symptoms appear and two to three days afterward.

On Tuesday, in a memo seen by The New York Times, JetBlue told employees that it would expect those "who have no symptoms, or whose symptoms are improving, to come back to work after five days." Crew members may remain on leave if they provide a doctor's note, but they won't be paid as if they were working, according to Mr. Cucuzza of the Transport Workers Union.

Asked for comment, JetBlue said, "The health and safety of our crew members and customers remains our top priority as we work through this pandemic."

Delta is providing five days' sick leave for infected workers, with two additional paid sick days if they choose to be tested on Day 5 and the results are positive.

The shorter isolation time is fueling a debate in the industry. The Association of Flight Attendants-CWA, which represents nearly 50,000 flight attendants at 17 airlines, urged maintaining a 10-day isolation period in a letter to airlines on Tuesday.

"We believe this is the wrong move for aviation as it accepts that infectious people will be put back on the job or flying as passengers on our planes," Sara Nelson, the union's president, wrote. Several flight attendants interviewed expressed concerns that potentially contagious colleagues might return to work without being tested.

Airlines always prepare for turmoil, particularly around the holidays, when bad winter weather in one place can knock an entire system off balance. But the industry has been hit especially hard this year.

Image


Credit...Nicole Craine for The New York Times

After two airlines, American and Southwest, canceled thousands of flights in October because of fierce weather and a brief shortage of air traffic controllers, they vowed to address the problems, offering bonuses to encourage employees to work throughout the holiday period, stepping up hiring and pruning flight plans. Both have avoided widespread cancellations this holiday season.

"We realized that we have got to make sure that we have staffing in place," David Seymour, American's chief operating officer, said in an interview. The airline recalled several thousand flight attendants from leave last month and this month and hired almost 600 more.

When chaos strikes, airlines engage in a complicated choreography to get out of it.

The main goal, airlines and aviation experts say, is to minimize the effect on passengers. But that's easier said than done.

Alaska Airlines spent months laying plans for this holiday season, investing in staff and equipment to deal with the winter weather and lining up backup flight crews, according to Constance von Muehlen, its chief operating officer.

The airline managed staff calling in sick at high rates by offering extra pay for others to fill in, but sustained snowfall and record low temperatures in the Seattle area forced it to cancel nearly one-third of its flights on Sunday, about one-quarter on Monday and about one-fifth on Tuesday.

"Once you get your day off poorly, there's nothing you can do to catch up," Ms. von Muehlen said.

On Tuesday, the airline issued a stark announcement. Alaska would cut about 20 percent of flights out of Seattle in the coming days to allow extra time to de-ice planes. It also "strongly" urged customers to delay nonessential travel until after this weekend.

"Our values guided our decision," she said. "We need to be as realistic as possible in what we will be able to operate and to let people know, as difficult as it is for us to do that."

Getting flight crews in place can be especially tricky, with workers dispersed throughout the country and subject to various regulations. Flight attendants are generally required to have nine hours of rest between shifts, for example.

The Omicron variant has only confounded that already complicated process.

Capt. James Belton, a spokesman for the roughly 13,500 United Airlines pilots in the Air Line Pilots

Association, confirmed that the variant is creating challenges.

Image

Credit...Karsten Moran for The New York Times

"Our sick calls are above normal," he said. Many pilots have helped fill gaps by picking up additional shifts, he said, but they are limited to flying 100 hours a month under federal law.

Operations on the ground are also being affected. The Federal Aviation Administration warned on Thursday that rising infections among employees, including air traffic control staff, might result in delays.

The Transportation Security Administration said that it was concerned about rising virus infections, too, but that it had adequate staffing. Average wait times in airport security lines were about five minutes in recent days, a spokesman said.

Getting through security, of course, is no guarantee that the rest of the trip will be smooth.

Elizabeth Barnhisel and her husband were heading off on a delayed honeymoon when a canceled connection forced an unexpected overnight layover on Tuesday at Seattle-Tacoma International Airport. Entering a baggage claim area, they found what looked like hundreds of bags lined up and crowds of miserable people — some crying, some napping, because they had been waiting so long for their bags.

Every few hours, someone would offer a different reason for the fiasco: frozen carousels, Omicron, weather. After about 10 hours, Ms. Barnhisel's bag arrived from across the airport.

The couple eventually made it to their destination, Vancouver, but it was not the honeymoon experience Ms. Barnhisel had counted on. "We're flabbergasted," she said. "We definitely took a risk by taking this trip. But at the end of the day, we've got to get back to normal somehow."

Lauren Hirsch contributed reporting.

kiro7.com

Alaska Airlines urges passengers to consider rescheduling holiday flights

Graham Johnson

2-3 minutes 12-29-21

SEATTLE — Holiday travel is such a mess at Sea-Tac Airport that on Tuesday, Alaska Airlines said passengers who don't have to fly between now and Sunday should consider rescheduling.

The airline says with more snow coming and staffing problems, it's taking at least three days to rebook passengers.

Hold times on Alaska's reservation lines are now pushing 20 hours as people try to rebook after canceled flights.

Planes and workers are scattered because of the winter storm, and the airline doesn't expect to have enough seats in the coming days to move everyone who wants to go.

"We will not get our hopes up until we are wheels up," said Kaitlin Vintertun, who was trying to get to Alaska with her husband and son to visit family.

"We've been trying to get out since Sunday," she said on Tuesday.

By 11 a.m. Tuesday, Alaska Airlines, Sea-Tac's largest carrier, canceled more than 150 flights for the day, with more expected.

Workers handed out water to people stuck in long lines for rebooking, which were not quite as dramatic as the day before.

Still, there were plenty of stories like Chris Henry's.

"It was a lot of mayhem this morning in terms of the line, and people didn't know where to go," Henry said.

After waiting in line an hour and a half to check a bag, he missed his flight to Dallas.

"I had to get in another line to get a new flight, and I waited in that for the last three and a half hours," Henry said.

He was booked to leave nearly 12 hours after his original flight, if the plane goes at all.

Alaska Airlines initially said Tuesday that de-icing each plane was taking more than an hour, and canceling flights eases congestion.

By Tuesday evening, the airline reported that de-icing time had been reduced to an average of 22 minutes.

Then there's the staffing problem.

Alaska officials said the airline had been able to backfill employees out because of COVID, but now the storm has disrupted operations to the point where all those reserves are tapped.

An Alaska Airlines blog post provides advice for passengers stuck in the mess.

Plaintiff's Exhibit 75

washingtonpost.com

Flight cancellations ease slightly, but airlines warn of more disruption ahead

Lori Aratani, Ian Duncan

6-8 minutes 12-29-21

Even as flight disruptions eased slightly Wednesday, airlines warned that cancellations and delays could continue as they struggle to rebound from coronavirus-related staffing shortages and wintry weather.

Aviation data provider FlightAware reported more than 970 cancellations of flights Wednesday evening within, out of and into the United States, down from more than 1,200 a day earlier and more than 1,400 on Sunday and Monday. United Airlines canceled the most flights among major U.S. carriers, with 161 flights — or roughly 7 percent — not departing, while regional carrier SkyWest grounded even more of its fleet.

The modest decline in Wednesday's cancellations, however, may provide little solace to travelers nearly a week into a holiday meltdown that has resulted in the cancellation of more than 6,400 flights.

Delta Air Lines, which said it was canceling 250 flights Wednesday — a number that includes regional flights operated by partner carriers — because of weather and rising coronavirus caseloads among employees. It warned of more possible disruptions because of weather forecasts for Seattle, Detroit and Salt Lake City.

Meanwhile, Alaska Airlines, which canceled 81 flights Wednesday — 12 percent of its scheduled flights — urged passengers to reconsider nonessential travel before Jan. 2 because of limited capacity to rebook travelers. In addition to staffing shortages and rising virus cases, the airline is struggling to recover after heavy weekend snow in Seattle, where it is headquartered. The city received 3.4 inches of snow Sunday, more than the amount that fell in all of 2020.

The carrier said it is reducing departures from Seattle-Tacoma International Airport by 20 percent to allow for time to de-ice planes.

U.S. airlines canceled hundreds of flights for a third day in a row on Dec. 26, as spiking coronavirus cases grounded flight crews. (Reuters)

"We deeply apologize for the inconvenience this winter storm has on our guests and employees and are working hard to return to the level of service you know and expect from us, while operating safely," said Constance von Muehlen, Alaska Airlines' chief operating officer and executive vice president.

JetBlue Airways canceled about 100 flights Wednesday, about a tenth of its schedule. The low-cost airline said in a statement it would reduce its schedule through Jan. 13, a warning that JetBlue said was intended to give customers time to make alternative plans.

The carrier said new guidance this week by the Centers for Disease Control and Prevention that shortens the recommended isolation period from 10 days to five days for people who test positive for the virus — but who do not show symptoms or whose symptoms are resolved — could ease its staffing crunch. Still, it cautioned that operations could be affected because of rapidly rising caseloads.

"While the new CDC guidelines should help get crew members back to work sooner, and our schedule reduction and other efforts will further ease day-of cancellations, we expect the number of COVID cases in the Northeast — where most of our crew members are based — to continue to surge for the next week or two," JetBlue said in a statement. "This means there is a high likelihood of additional cancellations until case counts start to come down."

Low-cost carrier Allegiant Air canceled 41 flights Wednesday, according to FlightAware, about 9 percent of its schedule. Spokeswoman Hilarie Grey said more cancellations were likely, blaming a mix of bad weather and coronavirus cases.

Airlines began preemptively canceling flights just before Christmas after employees began calling in sick with the coronavirus. While scientists are still assessing the impact of the omicron variant, indications are that it is more easily transmissible than previous variants.

On Tuesday, the United States set a record for the number of coronavirus infections, at 266,889, surpassing the 248,209 reported Jan. 12. The number could be higher since it does not include thousands of at-home tests taken by individuals who might not report positive results to health officials.

The rising number of infections has renewed questions about whether the Biden administration should require vaccination for domestic flights. Most international travelers coming to the United States must show proof of vaccination before traveling to the country.

Anthony S. Fauci, Biden's chief medical adviser, said the vaccine requirement for those traveling from international destinations was put into place to keep infections and, in particular, new variants out of the country. In the United States, he said, requirements that people wear masks when flying — combined with air filtration systems on commercial aircraft — offer "sufficient" protection for domestic travelers.

"We will seriously consider [a vaccine requirement] as new information arrives," he said Wednesday. "It's just keeping an open mind that the situation may change. But at this particular time, we do not feel that is necessary to make that a requirement for domestic flights."

After missing holiday celebrations with family and friends during the pandemic, many Americans have been eager to reunite. Travel forecasts predicted the number of people flying would be close to pre-pandemic levels. Despite the omicron variant surfacing just after Thanksgiving, many were reluctant to cancel their travel plans.

The Transportation Security Administration screened just under 2 million people Tuesday nationwide, a slight drop from Sunday and Monday.

Omicron is the fifth coronavirus variant of concern and is spreading rapidly around the world. Here's what we know. (Luis Velarde/The Washington Post)

Experts said the reluctance to cancel holiday plans was fueled by confidence in vaccines and booster shots, but also by mounting pandemic fatigue. Lisa Lee, an epidemiologist and public health expert at Virginia Tech, said battling the virus becomes more challenging this holiday travel season with more people on the move.

"You just have more chance of getting it because people are not, perhaps rightfully so, people are not shuttered in their homes anymore avoiding everyone," she said. "We are saying to ourselves as a society, we must do more than be in isolation."

Given that reality, Lee and other health experts urge people to continue practices that have become commonplace during the pandemic: mask-wearing, social distancing and frequent hand-washing. They also urged those who were able to get tested before and after travel.

Plaintiff's Exhibit 76

nytimes.com

Flight disruptions continue with thousands more cancellations as Omicron thins airline crews.

Marc Tracy, Daniel Victor, Adeel Hassan, Ana Ley

5-6 minutes 12-27-21

Credit...David Zalubowski/Associated Press

- Published Dec. 26, 2021Updated Dec. 27, 2021

Flight disruptions in the United States continued on Monday as many people embarked on their first trips in almost two years, and Dr. Anthony S. Fauci, the nation's top infectious disease expert, again raised the possibility of a vaccination requirement for air travel.

At least 2,600 more flights were canceled Monday, including about 1,000 U.S. flights, as the highly transmissible Omicron variant of the coronavirus is sending daily caseloads in parts of the United States soaring to levels higher than last winter's pandemic peak.

While the cancellations were only a small percentage of overall flights, the problem threatened to extend into the holiday week.

"When you make vaccination a requirement, that's another incentive to get more people vaccinated," Dr. Fauci said on MSNBC on Monday. "If you want to do that with domestic flights, I think that's something that seriously should be considered."

Over the holiday weekend, airlines canceled thousands of flights as the Omicron variant hit flight crews. In all, about 2,300 U.S. flights were canceled on Saturday and Sunday of Christmas weekend, with more than 3,500 more grounded globally, according to FlightAware, which provides aviation data. On Sunday alone, more than 1,300 U.S. flights and nearly 1,700 additional ones worldwide were canceled.

While some of the groundings were caused by bad weather and maintenance issues, several airlines acknowledged that the current wave of coronavirus cases had contributed significantly. A JetBlue spokesman said the airline had "seen an increasing number of sick calls from Omicron."

Twelve percent of JetBlue flights, 6 percent of Delta Air Lines flights, 5 percent of United Airlines flights and 2 percent of American Airlines flights on Sunday were canceled, according to FlightAware.

The stock prices of United, Delta, American and Southwest — the four largest U.S. carriers — were slightly lower on Monday.

Traveling rebounded sharply this year, making the situation at airports worse: Roughly two million people passed through screening checkpoints each day last week, according to the Transportation Security Administration, and on Sunday. The numbers on Christmas Eve and Christmas Day were much higher than last year, and some figures even exceeded those of the same days two years ago, when virtually no Americans were aware of a virus beginning to circulate halfway around the world.

The Omicron variant, which is now responsible for more than 70 percent of the new coronavirus cases in the United States, has already helped push daily case averages in the United States above 200,000 for the first time in nearly 12 months, according to The New York Times's coronavirus tracker.

An airline trade group has asked the Centers for Disease Control and Prevention to shorten the recommended isolation period for fully vaccinated employees who test positive to a maximum of five days, from 10 days, before they can return with a negative test.

"Swift and safe adjustments by the C.D.C. would alleviate at least some of the staffing pressures and set up airlines to help millions of travelers returning from their holidays," said Derek Dombrowski, a JetBlue spokesman.

The flight attendants' union, however, has argued that reductions in recommended isolation times should be decided on "by public health professionals, not airlines."

Some of this weekend's delays had little to do with the pandemic. Alaska Airlines had only a few cancellations related to crew exposures to the coronavirus, said a spokeswoman, Alexa Rudin. Yet it canceled 170 flights those two days, according to FlightAware, including 21 percent of its Sunday flights, because of unusually cold and snowy weather in the Pacific Northwest, which affected its hub, Seattle-Tacoma International Airport.

The pandemic has also caused a shortage of train and bus workers nationwide. In New York City, the Metropolitan Transportation Authority is also dealing with an uptick in positive cases among its staff, which is 80 percent vaccinated. It said subway service on Monday was running on a normal schedule, with scattered exceptions.

“Whatever we can do as riders to help minimize the risk to transit workers will help to reduce the spread,” said Lisa Daglian, the executive director of the Permanent Citizens Advisory Committee to the M.T.A., a watchdog group. “The M.T.A. is doing what it can with the resources it has available.”

Danny Pearlstein, a spokesman for the Riders Alliance, an advocacy group, said: “My sense is the M.T.A. is once again making the best of a bad situation.”

Plaintiff's Exhibit 77

Holiday flight cancellations hit new peak amid Covid, wintry weather

By Gregory Wallace and Matt McFarland, CNN
Updated 2:06 PM ET, Sat January 1, 2022

Thousands of US flights were canceled on New Year's Day as a combination of Covid-19 and wintry weather have slowed travel. Flight cancellations have trended up steadily since Christmas Eve, hitting a new peak Saturday morning as millions travel over the holidays.
Data from the website FlightAware shows more than 4,200 flights were canceled globally as of midday Saturday, or about 10% of the worldwide schedule.
Airlines have already been dealing with the Omicron variant, which has brought an unprecedented spike in Covid cases. Many airline employees have been unable to work. The Federal Aviation Administration has also warned more of its own employees are testing positive, which may restrict flights.

2022 is starting with a flurry of severe weather
2022 is starting with a flurry of severe weather
Now a new challenge is adding to travelers' woes: a large storm is sweeping across the Rockies and Midwest, bringing ice and heavy snow. Chicago has been especially hard hit. Airlines have canceled more than half of flights from Midway International Airport and more than 40% from O'Hare International Airport. Nearly a third of flights at Kansas City International Airport have been canceled. In Detroit, airlines canceled one in five flights.

Delta Air Lines (DAL) told CNN Business it projects between 200 and 300 of its more than 4,000 daily flights will be canceled during the holiday weekend. It also recommended people traveling in Chicago, Detroit, Salt Lake City, Seattle and the central and southern Rocky Mountain regions consider shifting their travel plans given the weather.

Southwest Airlines (LUV) told CNN Business all of its issues have been caused by weather.
More than 11,000 flights have been canceled since Christmas Eve, according to FlightAware data.

dailywire.com

Leaked Airline Memos: Majority Of Employees With Omicron Are Vaxxed, Healthy Pilots Offered More Pay To Cover Shifts

Tim Meads

3-4 minutes 1-3-22

On Monday, The Daily Wire's "Morning Wire" podcast revealed that in wake of massive absences due to COVID-19, major airlines such as United and Spirit Airlines are reportedly offering employees more pay to help cover shifts for colleagues out of commission due to the illness. In a memo obtained by The Daily Wire, United specifically cited Omicron as having caused a "significant" increase in pilot illness, making the higher pay necessary to keep flights on track. Despite the airline industry being heavily vaccinated, the Omicron variant has caused an uptick in COVID-19 absences.

As the Morning Wire reported, more than 4,000 flights were canceled just this past weekend. While a massive storm in Chicago was partly to blame, it appears the main driver has been amongst pilots.

United Airlines' CEO Scott Kirby had previously stated that the company had been forced to fire "just six of its 13,000-strong pilot group" who did not get the vaccine despite a company mandate.

Business Insider reported:

> *…Kirby said about 200 employees were terminated because they failed to get the COVID-19 vaccine, six of which were pilots, reported Reuters. Moreover, 80 pilots who received a medical or religious exemption were put on unpaid leave.*
>
> *The firings represent less than 1% of the company's 67,000-employee workforce, with most employees choosing to get the shot before the September 27 deadline.*

Likewise, Delta has bragged that more than 90% of its 80,000 employees are vaccinated. Yet, a Delta memo recently acknowledged that when it comes to "confirmed Omicron cases, including those among airline workers, the majority are occurring in fully-vaccinated individuals," according to the Morning Wire's Georgia

Howe.

“Not only is omicron making more vaccinated employees sick vs. the unvaccinated, but putting those unvaccinated employees on the street without pay means the airline doesn’t have much wiggle room when their schedules start to fall apart,” Jason Kunisch, co-founder of U.S. Freedom Flyers and a pilot for a major airline told the Morning Wire.

As The Daily Wire’s John Bickley observed, COVID-19 was called the “pandemic of the unvaccinated” just a short while ago but that term may now be obsolete given the latest news.

One of the more long-lasting ramifications of the pandemic, according to a report from “Airlines for America,” has been an increase in the use of technology in the airport.

“COVID-19 has brought about an acceleration of digital competency across demographic cohorts,” the report noted. “We have a lot of different people who fly through the airport. We are constantly thinking about the experience we present to them. And if people have become more technology savvy, more digitally competent, that means we can accelerate and roll out the contactless passenger journey across many platforms — and there will be an acceptance of and a desire for them.”

For now, though, the industry’s only recourse might be to offer more pay to those who can work, such as Spirit Airlines offering flight attendants double pay to pick up extra flights this January.

Plaintiff's Exhibit 79

thegatewaypundit.com

Over 6,000 Flights Cancelled During Christmas Weekend

Cassandra Fairbanks

2-3 minutes 12-26-21

Over 6,000 flights were canceled during Christmas weekend, primarily due to COVID-19 related complications.

Hundreds of flights were canceled on Sunday as the mass cancellation and delay count continued to rise due to people calling in sick and citing omicron.

"The nationwide spike in Omicron cases this week has had a direct impact on our flight crews and the people who run our operation. As a result, we've unfortunately had to cancel some flights and are notifying impacted customers in advance of them coming to the airport," United said in a statement. "We're sorry for the disruption and are working hard to rebook as many people as possible and get them on their way for the holidays."

United alone canceled 201 flights on Friday and 238 flights on Saturday.

Delta cancelled 173 flights just on Christmas Eve and Jet Blue cancelled 80.

“We apologize to our customers for the delay in their holiday travel plans,” Delta said in a statement. “Delta people are working hard to get them to where they need to be as quickly and as safely as possible on the next available flight.”

Across all airlines, thousands of flights were disrupted over the weekend.

“Almost 700 US flights were canceled and another 1,300 were delayed Sunday, according to FlightAware. Globally, there were over 2,000 cancellations. Delta and JetBlue each saw over 100 cancellations Sunday,” the CNN report explains.

TRENDING: Just Like Soviet Russia: T-Mobile Is Erasing Links to Gateway Pundit Articles if You Send Them by Text Message -- MORE UPDATES...

Across the globe, over 6,000 flights were canceled from Christmas Eve through Sunday — including approximately 1,700 originating in or flying to the United States.

Holiday travel was up more than double this year from last, but is still well below the pre-pandemic levels.

Plaintiff's Exhibit 80

The 3 reasons travel ground to a halt this Christmas

By Jordan Valinsky, CNN Business
Updated 11:09 AM ET, Mon December 27, 2021

Over the Christmas weekend, flying was a miserable experience for millions of travelers, as airlines canceled or delayed thousands of flights.
The problems continued Monday, with nearly 900 flights canceled within, into or out of the United States, according to FlightAware. More than 1,600 flights are delayed.
The troubles come at the busiest time of year for air travel: The US Transportation Security Administration said it screened millions of people each day over the holiday weekend, peaking at 2.19 million travelers on Thursday, December 23. Seven of the last 10 days have seen more than 2 million screenings.

A nasty brew of issues has complicated air travel, including the rapid spread of the Omicron variant, the labor shortage and a surge in travelers crowding airports and the skies.

Omicron variant

Just when airlines thought they were on the verge of normalcy and profitability again, along came the Omicron variant to put those hopes in doubt. The variant has sparked a sharp uptick in cases -- New York broke a single-day record with 49,708 new Covid-19 cases reported on Christmas Eve.
United Airlines (UAL)said last week it had to cancel hundreds of flights because it lacked enough crew members to safely fly all of its scheduled routes.
"The nationwide spike in Omicron cases this week has had a direct impact on our flight crews and the people who run our operation," said a United memo obtained by CNN.
Delta Air Lines (DAL) also said the cancellations are due to multiple issues including the Omicron variant.
"We apologize to our customers for the delay in their holiday travel plans," Delta said in a statement. "Delta people are working hard to get them to where they need to be as quickly and as safely as possible on the next available flight."
Airline travel is surging again
Leisure travel is back to near pre-Covid levels. On Friday and Saturday, TSA screened about two-thirds of the passengers it did on those days in 2019 (when Christmas fell on a Wednesday).
AAA recently estimated that more than 109 million Americans will travel over the long Christmas and New Year's week -- a number approaching the pre-pandemic record 119 million travelers of Christmas 2019.
Airlines are projected to carry 6.4 million of those passengers, AAA said. That's about triple the number from last year when the pandemic significantly curtailed holiday travel.
The labor shortage
Airlines were already having trouble finding enough crew to meet the surge in demand for travel. Omicron is making that labor shortage even worse.
Staffing shortages are leading to overworked flight crews and most of the canceled flights. Less choice in flights has led to higher ticket prices. And altercations over masks have been the cherry on the top of a miserable year for travel.
American Airlines (AAL) and Southwest (LUV) blamed service meltdowns in October and November on lacking enough pilots and flight attendants to adjust for weather-related cancellations.

Officials with various airline unions say that their members are stressed to the "breaking point" by work conditions because of understaffing. Many pilots and flight attendants say they're having trouble getting the hotel rooms they need to meet the government-mandated rest requirements while working.

Pilots at American have held informational pickets in recent weeks to complain about work conditions. And the airline unions correctly predicted that the problems would get worse with the pick-up in travel over the holidays.

Plaintiff's Exhibit 81

tsa.gov

Coronavirus (COVID-19) information | Transportation Security Administration

18-23 minutes

TSA has **3,694** employees with active COVID-19 infections. Those individuals are staying home to help keep the traveling public safe. Since the beginning of the pandemic, TSA has cumulatively had **17,252** federal employees test positive for COVID-19. **13,575** employees have recovered, and **34** have unfortunately died after contracting the virus. We have also been notified that two screening contractors have passed away due to the virus.

TSA is committed to notifying the public about airport locations where TSA employees or screening contractors have tested positive for COVID-19. The chart below lists airports with confirmed COVID-19 cases and the last date worked for the most recent screening employee who tested positive. It does not include non-airport TSA employees or contractors who have limited or no interaction with the public. Passengers who believe they may have come in contact with an infected individual within the past 14 days should follow the CDC's recommendations for travel-associated exposure.

**The chart includes TSA employees and screening contractors who may have had direct interaction with the public at an airport location.*

Airport Total Confirmed Cases TSA Screening Officers Non-Screening Employees Last work date of most recent screening officer confirmed case ABE - Lehigh Valley International 15 13 2 1/8/22 ABI - Abilene Regional 2 2 11/19/21 ABQ - Albuquerque International Sunport 51 41 10 1/6/22 ABR - Aberdeen Regional 3 3 11/9/21 ABY - Southwest Georgia Regional 5 5 12/29/21 ACK - Nantucket Memorial 2 2 3/15/21 ACT - Waco

Plaintiff's Exhibit 82

Biden grapples with a Covid-19 testing failure that could have been foreseen

Analysis by Stephen Collinson, CNN
Updated 1:25 AM ET, Tue December 28, 2021

CNN)President Joe Biden and his team repeatedly promised more Covid-19 testing, including at-home kits that deliver rapid results, but they are now admitting a virus that is more adaptable than the politicians who fight it has outpaced them again.
For many Americans, this holiday season may be remembered for hours spent in long testing lines, or fruitlessly searching pharmacy shelves for antigen tests as the Omicron variant took over the previous Delta wave. Already patchy testing has been exposed by the latest highly transmissible variant, and the US is being compared unfavorably to other developed nations where citizens have easy access to rapid tests for free.
Biden told governors in a virtual meeting Monday that his administration should have done more to speed up the availability of rapid testing, before his pledge this month for 500 million kits due to begin distribution in January, which will be too late to help this week's holiday crunch.

Are vaccine mandates for domestic flights our ticket out of the pandemic?
Are vaccine mandates for domestic flights our ticket out of the pandemic?
"It's not enough. It's clearly not enough. If we'd have known, we'd have gone harder, quicker if we could have," the President said, referring to the Omicron storm that has quickly overwhelmed existing testing capacity. In an interview with ABC News just before Christmas, Biden denied that shortfall in at-home testing represented a "failure." But he added: "You could argue that we should have known a year ago, six months ago, two months ago, a month ago." The President said he wished he had thought about ordering 500 million at-home tests "two months ago."

Such comments by the President, while candid, are unlikely to improve public confidence in a White House that vowed to shut Covid-19 down but sometimes seems to have underestimated the staying power of the virus and the scale of the challenge. The administration has had some important successes in fighting the emergency despite the politically motivated reluctance of millions of Americans to take the President's advice on the vaccines that could save their lives. And on Monday, the US Centers for Disease Control and Prevention changed its guidance in a way that may make the current outbreak less disruptive to everyday life, shortening the recommended times that people should isolate when they've tested positive for Covid-19 from 10 days to five days if they don't have symptoms -- and if they wear a mask around others for at least five more days.

But not for the first time, when it comes to testing, the White House is being forced to play catch-up following successive waves of a pandemic uncannily able to exploit political divides, slow moving bureaucracy and the impatience and weariness of the public with a crisis soon to enter its third year.
Another political blow

The frustrating search for tests endured by many Americans may also have a political consequence for Biden as he searches for a bounce back after a grim few months that saw his approval ratings tumble. He is, after all, on the record promising to fix a dearth of testing that has been laid bare by the recent viral surge.
Running on competence, he put the issue at the center of his 2020 campaign, which was partly rooted in highlighting ex-President Donald Trump's failures during the first year of the pandemic. And in an

address to the nation last March, for instance, the President said: "We continue to work on making at-home testing available."
Between Christmas and New Year's, doctors expect the US Omicron surge to grow
Between Christmas and New Year's, doctors expect the US Omicron surge to grow
More than nine months later, he is now admitting not enough has been done. Such comments make it hard to accept arguments that the White House was taken off guard by the Omicron variant. Many experts have said for months that rapid testing needs to be more available to the public. It's hardly a secret that new variants of the virus were inevitable. And a recent episode in which White House press secretary Jen Psaki mocked the idea of sending a test to all Americans -- a goal Biden has now embraced -- further muddled the administration's stance on this new phase of the pandemic.
The confusion has frustrated some public health professionals who say there simply aren't enough kits to permit people who are sick, those exposed to someone who has been infected with the virus, and people who want to travel and attend gatherings to get tested.
"It really is shameful that we don't have the amount of tests that are necessary to be able to use it as the robust containment tool that we know it is when used effectively," Dr. Chris Pernell, a public health physician and fellow of the American College of Preventive Medicine, told CNN's Alisyn Camerota on Monday.
All of this may give credence to midterm election messaging from Republicans that Biden has failed in his self-appointed number one task -- beating the virus -- even though it's the GOP's repeated attempts to politicize the struggle that have often set back the pandemic response. The party's continuing devotion to Trump, who once urged public health officials to do less testing so they would uncover fewer Covid-19 cases, also casts doubt on its sincerity on this issue.
A dangerous turn in the crisis
New controversy over testing follows another critical twist in the pandemic. There were more than 200,000 new cases of Covid-19 alone on Sunday, and some experts expect that figure to hit half a million per day soon. While there are hopeful indications that this variant causes fewer hospitalizations than previous incarnations of Covid-19, even a tiny proportion of serious cases could swamp health systems given this level of infections. This is especially the case in areas still battling a surge in the Delta variant of the virus and in parts of the country where vaccination rates remain comparatively low.
The government's top infectious diseases specialist, Dr. Anthony Fauci, admitted on CNN's "New Day" on Monday that the testing situation could be better, despite consistent warnings by experts for months that it isn't sufficiently expansive.
New Omicron variant fills up children's hospitals
New Omicron variant fills up children's hospitals
"You know, testing has always been an issue," Fauci told CNN's Kaitlan Collins, adding that the situation had been exacerbated by hordes of Americans wanting to travel during the holidays just as Omicron struck.
"It's been a very, very strong run on testing," said Fauci, director of the National Institute of Allergy and Infectious Diseases. "Obviously, not making any excuses for it: we should have had more tests available. But hopefully now as we get into the first couple of weeks in January, that'll get much better."
Biden has made several recent moves designed to fix the shortfall. At the beginning of December, he ordered health insurers to reimburse Americans for the cost of at-home testing, which can run to $20 for a kit or more. Then he promised Americans that he would make half a billion rapid tests available for free, though they will not start rolling out until at least next month. While that influx could be critical as Omicron spreads, it can't ease the Christmas surge or frustration among people who think they are infected now.
Washington caught off guard again

At-home tests are not infallible and are not a panacea for ending the pandemic. They are less important than vaccines and boosters in battling the building Omicron wave. But they are a useful tool that could allow Americans to make informed decisions about their own health and plans. They could confirm whether a sniffle is in fact Covid-19 and help people protect vulnerable relatives or decide to stay out of work to avoid infecting others.
Doctor explains how to tell the difference between Covid-19 and a cold

Doctor explains how to tell the difference between Covid-19 and a cold 01:33
The shortage of testing is all the more remarkable since the US led the world in the rapid deployment of vaccines, in a program that started under the Trump administration and was deployed by the Biden White House team.

Some companies that sought to roll out rapid tests have complained about a prohibitively difficult regulatory process at the US Food and Drug Administration. There have also been complaints about a flood of testing options, including some from abroad that have swamped the capacity to evaluate them. This is a critical issue since rushing approvals of tests or allowing those with deficiencies to get into the system could harm the credibility of testing more broadly -- and be a net negative in the drive to end the pandemic.
Yet this situation also appears to have some of the classic ingredients of a Washington screw-up. A White House consumed by crises seems to have taken its eye off the ball to some extent. It's also possible that increasingly urgent signals from the Oval Office and the suddenness of the Omicron wave haven't effectively worked their way down the bureaucratic chain. Events have overtaken the politicians and now there's a risk of a blame game. None of which is likely to move a country closer to the deliverance from the pandemic that it craves in 2022.

spectator.co.uk

Landmark Danish study finds no significant effect for facemask wearers | The Spectator

Carl Heneghan & Tom Jefferson

5-6 minutes

Masks might stop people passing on a virus. But how much measurable protection do they offer to the wearer?

Text settings

Comments

Do face masks work? Earlier this year, the UK government decided that masks could play a significant role in stopping Covid-19 and made masks mandatory in a number of public places. But are these policies backed by the scientific evidence?

Yesterday marked the publication of a long-delayed trial in Denmark which hopes to answer that very question. The 'Danmask-19 trial' was conducted in the spring with over 6,000 participants, when the public were not being told to wear masks but other public health measures were in place. Unlike other studies looking at masks, the Danmask study was a randomised controlled trial – making it the highest quality scientific evidence.

Around half of those in the trial received 50 disposable surgical face masks, which they were told to change after eight hours of use. After one month, the trial participants were tested using both PCR, antibody and lateral flow tests and compared with the trial participants who did not wear a mask.

In the end, there was no statistically significant difference between those who wore masks and those who did not when it came to being infected by Covid-19. 1.8 per cent of those wearing masks caught Covid, compared to 2.1 per cent of the control group. As a result, it seems that any effect masks have on preventing the spread of the disease in the community is small.

Some people, of course, did not wear their masks properly. Only 46 per cent of those wearing masks in the trial said they had completely adhered to the rules. But even if you only look at people who wore masks 'exactly as instructed', this did not make any difference to the results: 2 per cent of this group were also infected.

When it comes to masks, it appears there is still little good evidence they prevent the spread of airborne diseases. The results of the Danmask-19 trial mirror other reviews into influenza-like illnesses. Nine other trials looking at the efficacy of masks (two looking at healthcare workers and seven at community transmission) have found that masks make little or no difference to whether you get influenza or not.

But overall, there is a troubling lack of robust evidence on face masks and Covid-19. There have only been three community trials during the current pandemic comparing the use of masks with various alternatives – one in Guinea-Bissau, one in India and this latest trial in Denmark. The low number of studies into the effect different interventions have on the spread of Covid-19 – a subject of global importance – suggests there is a total lack of interest from governments in pursuing evidence-based medicine. And this starkly contrasts with the huge sums they have spent on 'boutique relations' consultants advising the government.

The only studies which *have* shown masks to be effective at stopping airborne diseases have been 'observational' – which observe the people who ordinarily use masks, rather than attempting to create a randomised control group. These trials include six studies carried out in the Far East during the SARS CoV-1 outbreak of 2003, which showed that masks can work, especially when they are used by healthcare workers and patients alongside hand-washing.

But observational studies are prone to recall bias: in the heat of a pandemic, not very many people will recall if and when they used masks and at what distance they kept from others. The lack of random allocation of masks can also 'confound' the results and might not account for seasonal effects. A recent observational study paper had to be withdrawn because the reported fall in infection rates over the summer was reverted when the seasonal effect took hold and rates went back up.

This is why large, randomised trials like this most recent Danish study are so important if we want to understand the impact of measures like face masks. Many people have argued that it is too difficult to wait for randomised trials – but Danmask-19 has shown that these kind of studies are more than feasible.

And now that we have properly rigorous scientific research we can rely on, the evidence shows that wearing masks in the community does not significantly reduce the rates of infection.

Due to the large number of people passing comment on the article on social media without reading it, we have updated the headline to emphasise that the study is about facemask wearers. Covid data can be found on our data hub: data.spectator.co.uk

Read next

Latest

0

theconversation.com

Face masks cut disease spread in the lab, but have less impact in the community. We need to know why

Paul Glasziou

7-9 minutes

In controlled laboratory situations, face masks appear to do a good job of reducing the spread of coronavirus (at least in hamsters) and other respiratory viruses. However, evidence shows mask-wearing *policies* seem to have had much less impact on the community spread of COVID-19.

Why this gap between the effectiveness in the lab and the effectiveness seen in the community? The real world is more complex than a controlled laboratory situation. The right people need to wear the right mask, in the right way, at the right times and places.

The real-world impact of face masks on the transmission of viruses depends not just on the behaviour of the virus but also on the behaviour of aerosol droplets in diverse settings, and on the behaviour of people themselves.

We carried out a comprehensive review of the evidence about how face masks and other physical interventions affect the spread of respiratory viruses. Based on the current evidence, we believe the community impact is modest and it may be better to focus on mask-wearing in high-risk situations.

Read more: *How a 150-year-old experiment with a beam of light showed germs exist -- and that a face mask can help filter them out*

The evidence

Simply comparing infection rates in people who wear masks with those who don't can be misleading. One problem is people who don't wear masks are more likely go to crowded spaces, and less likely to socially distance. People who are more concerned often adhere to several protective behaviours — they are likely to avoid crowds and socially distance as well as wearing masks.

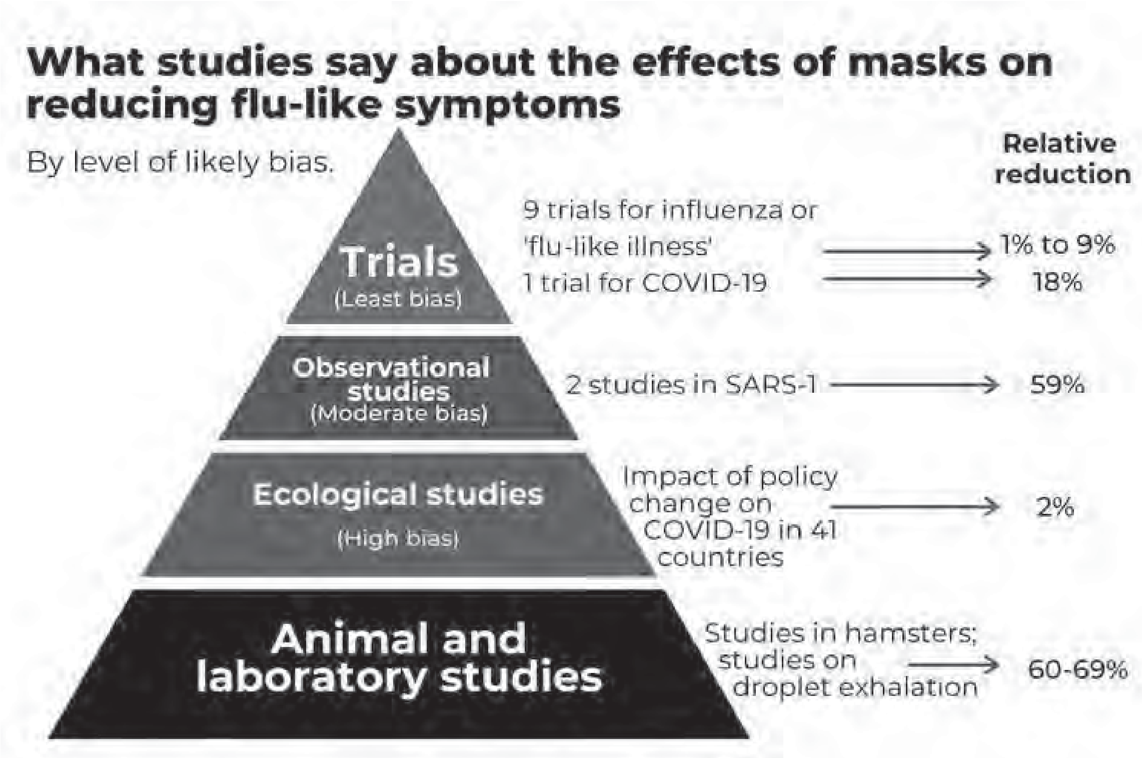
That correlation between mask wearing and other protective behaviours might explain why studies comparing mask-wearers with non-mask-wearers (known as "observational studies") show larger effects than seen in trials. Part of the effect is due to those other behaviours.

The most rigorous, but difficult, way to evaluate the effectiveness of masks is to take a large group of people and ask some to wear masks and others not to, in a so-called controlled trial. We found nine such trials have been carried out for influenza-like illness. Surprisingly, when combined, these trials found only a 1% reduction in influenza-like illness among mask-wearers compared with non-mask-wearers, and a 9% reduction in laboratory-confirmed influenza. These small reductions are not statistically significant, and are most likely due to chance.

Read more: *13 insider tips on how to wear a mask without your glasses fogging up, getting short of breath or your ears hurting*

None of these trials studied COVID-19, so we can't be sure how relevant they are to the pandemic. The SARS-CoV-2 coronavirus is a similar size to influenza, but has a different capacity to infect people, so it is possible masks might be more or less effective for COVID-19. A recently published trial in Denmark of 4,862 adults found infection with SARS-CoV-2 occurred in 42 participants randomised to masks (1.8%) compared to 53 control participants (2.1%), a (non-significant) reduction of 18%.

The most comprehensive between-country study of masks for COVID-19 infection is a comparison of policy changes, such as social distancing, travel restrictions, and mask wearing, across 41 countries. It found introducing a mask-wearing policy had little impact, but mask policies were mostly introduced after social distancing and other measures were already in place.



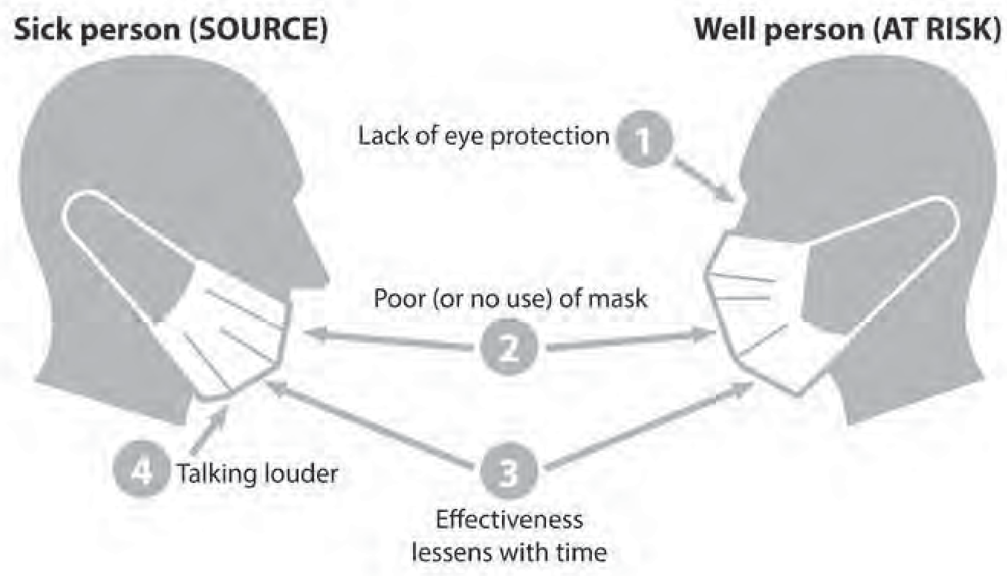
The Conversation, Author provided

What might diminish the effect of masks?

Why might masks not protect the person wearing them? There are several possibilities. Standard masks only protect your nose and mouth incompletely, for one thing. For another, masks don't protect your eyes.

The importance of eye protection is illustrated by a study of community health workers in India. Despite protection by three-layer surgical masks, alcohol hand rub, gloves, and shoe covers, 12 of 60 workers developed COVID-19. The workers were then supplied with face shields (which provide eye protection) — in addition to the personal protective equipment (PPE) described above — and none of the 50 workers became infected despite higher case load.

Why masks might fail to clearly protect others is more complex. Good masks reduce the spread of droplets and aerosols, and so should protect others.



Things that might make masks less effective. Paul Glasziou, Author provided

However, in our systematic review we found three trials that assessed how well mask wearing protects others, but none of them found an obvious effect. The two trials in households where a person with influenza wore a mask to protect others in fact found a slight increase in flu infections; and the third trial, in college dormitories, found a non-significant 10% relative reduction.

We don't know if the failure was the masks or participants' adherence. In most studies adherence was poor. In the trials very few people wear them all day (an average of about four hours by self-report, and even less when directly observed). And this adherence declined with time.

But we also have little research on how long a single mask is effective. Most guidelines suggest around four hours, but studies on bacteria show masks provide good protection for the first hour and by two hours are doing little. Unfortunately, we could not identify similar research examining viruses.

Making masks mandatory only in crowded places, close-contact settings, and confined and enclosed spaces may be more effective. Dan Himbrechts / AAP

Is it better to focus masks on the 3 Cs: covered, crowded and close contact?

In addition to the completed Danish trial, another ongoing trial in Guinea-Bissau with 66,000 participants randomised as whole villages may shed more light as it tests the idea of source control. But given the millions of cases and billions of potential masks and mask wearers, more such trials are warranted.

We know masks are effective in laboratory studies, and we know they are effective as part of personal protective equipment for health care workers. But that effect appears diminished in community usage. So in addition to the trials, new research is urgently needed to unravel each of the reasons why laboratory effectiveness does not seem to have translated into community effectiveness. We must also develop ways to overcome the discrepancy.

Until we have the needed research, we should be wary about relying on masks as the mainstay for preventing community transmission. And if we want people to wear masks regularly, we might do better to target higher-risk circumstances for shorter periods. These are generally places described by "the three Cs": crowded places, close-contact settings, and confined and enclosed spaces. These would include some workplaces and on public transport.

We are likely to be better off if we get high usage of fresh masks in the most risky settings, rather than moderate usage everywhere.

Read more: *How should I clean my cloth mask?*

One America News Network

CDC: Face Masks Don't Prevent COVID-19, Study Finds Masks Have Negligible Impact On Coronavirus Numbers

Gen Til wears a protective face mask while working out at Planet Granite climbing gym during the coronavirus pandemic in San Francisco, Thursday, March 4, 2021. The gym opened today to allow ten percent capacity. (AP Photo/Jeff Chiu)

Sen. Lee: Earmarks are a 'corrupting influence' in Congress

Honest Elections Project

OAN Newsroom (https://www.oann.com/cdc-face-masks-dont-prevent-covid-19-study-finds-masks-have-had-negligible-impact-on-coronavirus
UPDATED 9:45 PM PT – Sunday, March 7, 2021

The CDC has admitted face masks do little to prevent the spread of COVID-19 amid mounting pressure to lift mask mandates across the U.S. In a **new study**, the CDC found face masks had a negligible impact on coronavirus numbers that didn't exceed statistical margins of error.

Merchant Jesus Barajas (C) wears a face mask as he shows long stem roses for sale ahead of the Valentine's Day holiday at the Southern California Flower Market on February 12, 2021 in Los Angeles, California. (Photo by PATRICK T. FALLON/AFP via Getty Images)

The **study** found that between March and December 2020, face mask orders reduced infection rates by 1.5 percent over the rolling periods of two months each. The masks were 0.5 percent effective in the first 20 days of the mandates and less than 2 percent effective after 100 days.

A traveler wears a face mask while checking their phone on the arrivals level outside the Tom

Honest Elections Project looks to restore faith in U.S. elections

Dr. Gottlieb: COVID 'strains' will not produce new COVID surge

GOP lawmakers call on states to introduce election integrity laws

Plaintiff's Exhibit 86

thenewamerican.com

CDC Admits: No Conclusive Evidence Cloth Masks Work Against COVID - The New American

6-8 minutes

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In a recent report in *Emerging Infectious Diseases*, the U.S. Centers for Disease Control and Prevention (CDC) suggests what experts have stated all along: There is no conclusive evidence that cloth masks protects users from coronavirus, especially since most people do not use them correctly and do not keep them clean.

The report states:

> More research on cloth masks is needed to inform their use as an alternative to surgical masks/respirators in the event of shortage or high-demand situations. To our knowledge, only 1 randomized controlled trial has been conducted to examine the efficacy of cloth masks in healthcare settings, and the results do not favor use of cloth masks.
>
> More randomized controlled trials should be conducted in community settings to test the efficacy of cloth masks against respiratory infections.

There is increasing evidence that cloth masks not only may be ineffective against stopping coronavirus transmission, but that they may actually increase the spread of the virus, as well as worsening other health conditions.

A September report by the CDC found that more than 70 percent of COVID-positive patients contracted the virus in spite of faithful mask wearing while in public. Moreover, 14 percent of the patients who said they "often" wore masks were also infected. Meanwhile, just four percent of the COVID-positive patients said they "never" wore masks in the 14 days before the onset of their illness.

Likewise, the CDC's October journal report references a 2015 study on cloth mask efficacy that found that rates of infection were "consistently higher" among those in the cloth mask group versus that of the medical mask and control groups. The authors of the study suggested it was likely that the cloth masks were problematic because they retained moisture and had poor filtration.

The CDC writes of that study, "This finding suggest that risk for infection was higher for those wearing cloth masks."

The *California Globe* also observed that extensive randomized control trial (RCT) studies and meta-analysis reviews of those studies have shown that masks and respirators are ineffective against the spread of influenza-like illnesses and respiratory illnesses believed to be spread by droplet and aerosol particles. The *Globe* cited an analysis of 10 "randomized controlled tests" (RCTs) by the Center for Disease Control found "no significant reduction in influenza transmission with the use of face masks."

"There is limited evidence for their [masks] effectiveness in preventing influenza virus transmission," the studies found. This applied to masks "worn by the infected person for source control OR when worn by uninfected persons." They concluded that there was "no significant effect of face masks on transmission of laboratory-confirmed influenza."

Yet the CDC continues to recommend cloth masks for public use, even as the organization has flip-flopped on whether the virus is airborne. Their latest assertion is that airborne transmission is "sometimes" possible "under special circumstances."

However, some experts have been sounding the alarm on the widespread use of masks, asserting they may cause more harm than good.

In fact, a group of doctors in Oklahoma is suing the Tulsa mayor and the Tulsa Health Department over the city's mask mandate, asserting masks cause healthy people to become sick.

"On the OSHA website it states that employers shouldn't make employees work in an environment where they have less than a 19.5 percent oxygen level," said Clayton Clark, one of the plaintiffs. "And the mandated masks cause employees to dip below a 19.5 percent oxygen level within 10 seconds of wearing a mask, so I don't want to make my healthy employees sick."

Another plaintiff, Dr. James Meehan, MD, said he has seen an increase in patients with facial rashes, as well as fungal and bacterial infections, and has heard from colleagues around the globe that bacterial pneumonia is on the rise. He asserts this increase stems directly from mask wearing.

"Why might that be? Because untrained members of the public are wearing medical masks, repeatedly … in a non-sterile fashion…. They're becoming contaminated," he said at an August press conference. "They're pulling them off of their car seat, off the rearview mirror, out of their pocket, from their countertop, and they're reapplying a mask that should be worn fresh and sterile every single time."

"New research is showing that cloth masks may be increasing the aerosolization of the SARS-COV-2 virus into the environment causing an increased transmission of the disease," he added.

Dentists have also reported increases in oral hygiene issues, which they have dubbed "mask mouth."

"We're seeing inflammation in people's gums that have been healthy forever, and cavities in people who have never had them before," says Dr. Rob Ramondi, a dentist and co-founder of One Manhattan Dental. "About 50% of our patients are being impacted by this, [so] we decided to name it 'mask mouth' — after 'meth mouth.'"

On the other hand, Sweden has declared virtual victory over the coronavirus, absent any draconian responses to the pandemic such as mask mandates and lockdowns, opting instead for "herd immunity."

"Sweden has gone from being the country with the most infections in Europe to the safest one," Sweden's senior epidemiologist Dr. Anders Tegnell told Italian newspaper *Corriere della Sera.*

"The findings that have been produced through face masks are astonishingly weak, even though so many people around the world wear them," Tengell states.

The European Center for Disease Control and Prevention confirmed Sweden's reduction in infection rates, with just 12 cases per million, Summit News reported.

Reports by the CDC reveal that just six percent of reported COVID-19 deaths came directly from the virus, while a whopping 94 percent of the deaths attributed to the coronavirus were from people who had two to three serious underlying conditions, in addition to COVID-19.

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17-21 minutes

Posted By: Dr. Sircus (drsircus) on 05/17/2021

The Science – Facemasks Worse than Useless

https://nomaskers.org/index.cfm?key=browse_news&PostDate=all

Mask Madness – The Death of Science

Published on May 3, 2021

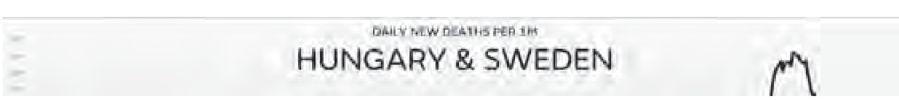
If you wanted to grow up to be a mass murderer, destroyer of health and happiness, if you wanted to inflict maximum harm on the entire human race, what profession would you choose? Besides being a CEO of a big pharmaceutical company like Pfizer or a maniac like Gates, the perfect job description with the ability to do the most harm would be a public health official.

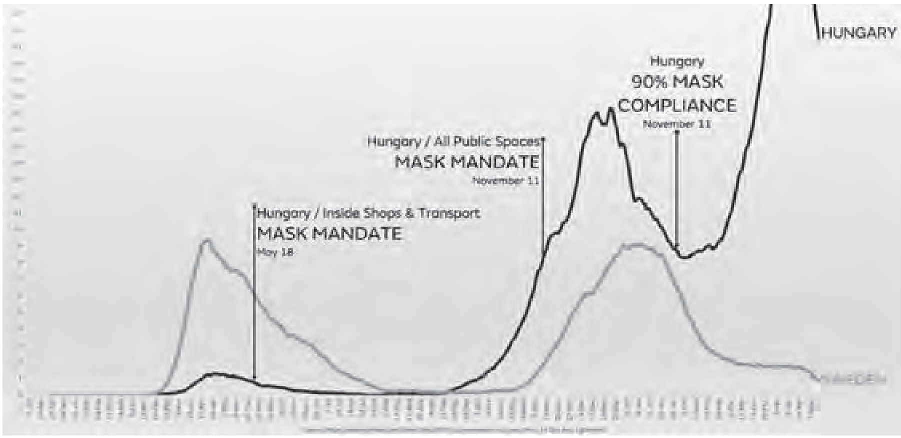
A group of men and women executed a plan under development for decades to drive people's health into the toilet. Terrorists without equal, they have armed themselves with the tools to attack the very foundations of life and health. They have deprived people, en mass, of the life/health-giving rays of the sun (depressing vitamin D levels) with their lockdowns.

Top German scientists: chemical cocktail found in some face masks.

Quebec: Potentially toxic masks distributed in schools and daycares.

Through wearing masks, public health officials forced practically the entire human race into hypoxic breathing conditions. Wearing a mask reduces the oxygen we breathe in and increases the CO2 intake. Masks are muzzling suffocation devices that science says are causing great harm. Public health officials and the politicians who ride on their coattails have not the slightest interest in science about masks or vitamin D., And they cannot admit they were wrong, dead wrong even when science tells them they are.

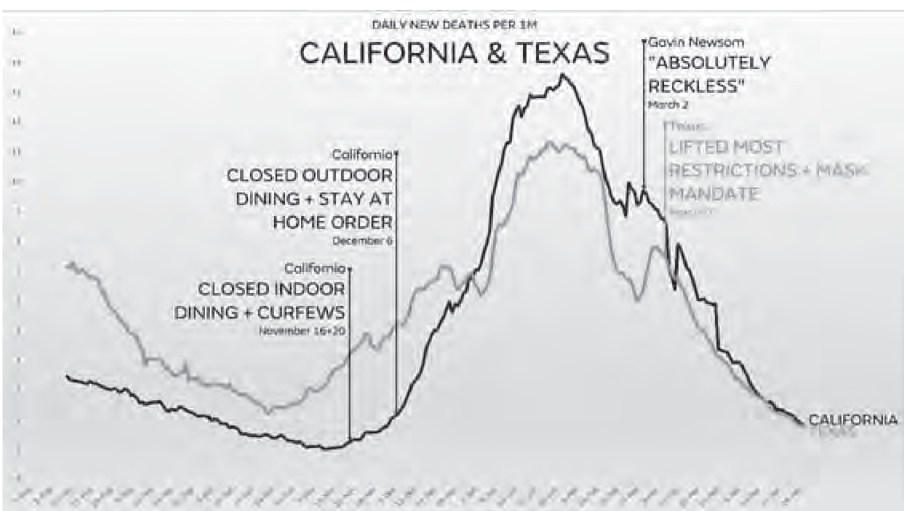




Which party has imposed the most brutal, economy-eviscerating lockdowns and the most punitive mask mandates, while steadily ratcheting up the fearmongering at every opportunity?
Mike Whitney

Special Offer: My 100 lesson course on cancer at eighty percent off the regular price of 500 dollars. So your cost will be only 99 dollars. The course is part of a doctoral program at Da Vinci University and, when taken for credit, costs 1,000 Euros for both parts. I want! »

Since the beginning of COVID, we were told to "listen to the public health experts." Dr. Fauci, Rachel Levine, Tedros Adhanom, Bill Gates (who pretends to know something about medicine), and groups like the CDC, WHO, Gates Foundation, Imperial College, etc. These people and organizations are supposedly the best resources out there for dealing with pandemics and disease spread, **but it turns out they are the worst**. They got it wrong on just about everything, and the price in terms of suffering and even death is astonishing.



The States Without Mask Mandates Have Lower COVID Rates

The number of new Texas COVID cases has dropped to record lows on the year in the weeks since the state moved to scrap mask mandates, despite hysterical warnings from mainstream media and the Biden regime that ditching the masks would result in mass casualties. One has to wonder about the scale of the harm done to the public with mask mandates. The science presented below begins to answer, but when you read that some want to have two-year-olds wearing masks, we deal with exceptional stupidity, cruelty, or both.

If you think my languaging is overstrong or that I am overblowing the case, read John Whiteheads's words, “I have studied enough of this country’s history—and world history—to know that governments (the U.S. government is no exception) are at times indistinguishable from the evil they claim to be fighting, whether that evil takes the form of terrorism, torture, drug trafficking, sex trafficking, murder, violence, theft, scientific experimentations or some other diabolical means of inflicting pain, suffering, and servitude on humanity.

Don’t think that everyone is passive about masks. People all over are demonstrating against mask mandates.

The Science – Facemasks Worse than Useless

A recent Stanford study showed that masks do absolutely nothing to help prevent the spread of COVID-19, and their use is harmful. The data suggest that both medical and non-medical facemasks are ineffective in blocking the human-to-human transmission of viral and infectious diseases such as SARS-CoV-2 and COVID-19. Wearing facemasks has been demonstrated to have substantial adverse physiological and psychological effects.

These include hypoxia, hypercapnia, shortness of breath, increased acidity and toxicity, activation of fear and stress response, rise in stress hormones, immunosuppression, fatigue, headaches, a decline in cognitive performance, predisposition for viral and infectious illnesses, chronic stress, anxiety, and depression. Long-term consequences of wearing a facemask can cause health deterioration, development and progression of chronic diseases, and premature death.

A peer-reviewed study published by the International Journal of Environmental Research and Public Health (IJERPH) in the Multidisciplinary Digital Publishing Institute (MDPI) last week and entitled *Is a Mask That Covers the Mouth and Nose Free from Undesirable Side Effects in Everyday Use and Free of Potential Hazards?* concludes that “extended mask-wearing by the general population could lead to relevant effects and consequences in many medical fields.”

Effects of mask-wearing examined in the study include an increase in breathing resistance, increase in blood carbon, dioxide decrease in blood oxygen saturation, increase in heart rate, decrease in cardiopulmonary capacity, feeling of exhaustion, increase in respiratory rate, difficulty breathing, and shortness of breath, headache, dizziness, feeling of dampness and heat, drowsiness (qualitative neurological deficits), decrease in empathy perception, impaired skin barrier function with acne, itching and skin lesions.

Gates, who pretends to be smarter than everyone, thinks there is no downside to wearing masks. He must be right, and science is wrong. Back to the dark ages is what COVID, Bill Gates, Fauci (I hate to call him a doctor), and the World Health Organization has brought us. Gates does not have the intelligence to understand why people resist wearing masks. Both he and his wife believe, "**Every single person should be wearing a mask without exception." Fauci and the CDC want us to wear two masks to double the trouble with mask side-effects, which can be quite severe.**

Who should we believe, medical scientists at Stanford or the Gates? Nick Dearden, executive director of Global Justice Now, characterized Gates' remarks — and the ideological framework behind them — as "disgusting." "Who appointed this billionaire head of global health?" asked Dearden. "Oh yeah, he did."

The pore size of cloth face coverings ranges from ~ 20-100 microns. The COVID virus is 200-1000x smaller than that, at 0.1 microns. Putting up a chain-link fence will not keep out a mosquito. Even the most esteemed medical journals admit their purpose is to calm anxiety. "Expanded masking protocols' greatest contribution may be to reduce the transmission of anxiety," writes Dr. Simonie Gold.

The publication of a long-delayed trial in Denmark was one of the first current studies in the Age of COVID to pour cold water on masks. The 'Damask-19 trial' was conducted in the spring with over 6,000 participants when the public was not being told to wear masks, but other public health measures were in place. Unlike other studies looking at masks, the Danmask study was a randomized controlled trial – making it the highest quality scientific evidence.

In the end, there was no statistically significant difference between those who wore masks and those who did not when it came to being infected by Covid-19. 1.8 percent of those wearing masks caught Covid, compared to 2.1 percent of the control group. As a result, it seems that any effect masks have on preventing the spread of the disease in the community is small.

Older Science Confirms Masks Are Worthless

A May 2020 meta-study on pandemic influenza published by the US CDC found that face masks had no effect, neither as personal protective equipment nor as a source control.

A July 2020 review by the Oxford Centre for Evidence-Based Medicine found that there is no evidence for the effectiveness of cloth masks against virus infection or transmission.

A Covid-19 cross-country study by the University of East Anglia came to the conclusion that a mask requirement was of no benefit and could even increase the risk of infection.

An April 2020 review by two U.S. professors in respiratory and infectious disease from the University of Illinois concluded that face masks have no effect in everyday life, neither as self-protection nor to protect third parties (so-called source control).

An article in the *New England Journal of Medicine* from May 2020 came to the conclusion that cloth face masks offer little to no protection in everyday life.

A July 2020 study by Japanese researchers found that cloth masks "offer zero protection against coronavirus" due to their large pore size and generally poor fit.

A 2015 study in the British Medical Journal BMJ Open found that cloth masks were penetrated by 97% of particles and may increase infection risk by retaining moisture or repeated use.

Oxygen Deprivation

In Massachusetts, people are fined if they are not wearing masks outdoors – even children as young as five are forced to do so by law. In some places like Michigan the governor wants children as young as two. She should be brought up on charges of serial child abuse.

Eric Toner, a senior scholar at the Johns Hopkins Center for Health Security, one of the inside organizations for pandemic planning, said, "I think that mask-wearing and some degree of social distancing, we will be living with — hopefully living with happily — for several years." The original title of this essay was 'Psychotic Belief in Masks.' Toner certainly qualifies in terms of being psychotic about masks.

Requiring children to wear masks does more harm than good, Dr. Jay Bhattacharya, a professor of medicine at Stanford University, told The Epoch Times. Bhattacharya advised Florida Gov. Ron DeSantis not to make children don face coverings.

What will be the effect will be of depriving oxygen to billions of people for years? How happy will that make people? Or inhaling dangerous amounts of CO2, what is that going to do to peoples' health after several years or even after only a few weeks or months.

In one study, researchers examined the blood oxygen levels in 53 surgeons using an oximeter. They measured blood oxygenation before surgery as well as at the end of surgeries.4 The researchers found that the mask reduced the blood oxygen levels (pa02) significantly. **The longer the duration of wearing the mask, the greater the fall in blood oxygen levels**.[1]

A drop in oxygen levels (hypoxia) is associated with an impairment in immunity. Studies have shown that hypoxia can inhibit the type of primary immune cells used to fight viral infections called the CD4+ T-lymphocyte. This occurs because the hypoxia increases the level of a compound called hypoxia-inducible factor-1 (HIF-1), which inhibits T-lymphocytes and stimulates a powerful immune inhibitor cell called the Tregs.

Decreasing the amount of oxygen people breathe by forcing people to wear masks is cruel and medically stupid. Under the mask, O2 readings drop from a regular 21 to an unhealthy 17.5, ringing the alarm of the official OSHA devices that measure such things. No one has mentioned or measured what happens when two masks are simultaneously worn.

The usual amount of CO2 in the air is approximately 400 ppm. When measured around the nose or the mouth, it would be higher. But wear a mask, and concentrations shoot up into thousands of ppm. This is not healthy! Carbon dioxide in the air we breathe usually is at 0.0390 percent. When we breathe out, it is 4.0 percent.

The minimum oxygen concentration in the air required for human breathing is 19.5 percent. Approximately 78 percent of the air we breathe is nitrogen gas, while only about 20.9 percent is oxygen. The Occupational Safety and Health Administration, OSHA, determined the optimal range of oxygen in the air for humans runs between 19.5 and 23.5 percent.

Not Enough Oxygen: Side Effects

Serious side effects can occur if the oxygen levels drop outside the safe zone. When oxygen concentrations drop from 19.5 to 16 percent and engage in physical activity, your cells fail to receive the oxygen needed to function correctly. So wearing masks is not indicated for any reason because masks represent slow suffocation. Not quite as bad as strangling a person or killing them outright by completely cutting off their breath, but across the board, health will be depressed, and death from all causes will increase.

In Oregon, a high school track coach, Dave Turnbull, called for an end to rules mandating mask-wearing during the competition after one of his student-athletes collapsed from "complete oxygen debt." Track star Maggie Williams was running the 800-meter race when *she collapsed to the ground* just meters short of the finish line.

Psychotic Beliefs in Masks

A vast swath of the populace has a borderline psychotic belief that a thin piece of cloth will save them from COVID flu, which will not kill 99.9% of Americans. One clear example of mask-induced mental illness is seen in a report that an extremely tolerant, mostly peaceful journalist named Kurt Eichenwald wanted to beat an anti-masker to death. He tweeted: "It's at a moment like this that I want to find an anti-masker and beat them to death. Since they believe they have the right to kill others, they have surrendered any right to object."

The CDC is on record about masks– "14 randomized controlled trials did not support a substantial effect on transmission. There is limited evidence for their effectiveness in preventing influenza virus transmission either when worn by the infected person for source control or when worn by uninfected persons to reduce exposure. Our systematic review found no significant effect of face masks on the transmission of laboratory-confirmed influenza."

More Mask Madness – Governments and Police Loose It

A judge at the Weimar District Court, Christian Dettmar, had his house searched today. His office, private premises, and car were searched. The judge's cell phone was confiscated by the police. The judge had made a sensational decision on April 8, 2021, which was very inconvenient for the government's anti Coronavirus measures policy.

Masks could be delaying development among babies.

At the suggestion of a mother, the judge had ruled in a child welfare proceeding pursuant to Section 1666 of the German Civil Code (BGB), Ref.: 9 F 148/21, that two Weimar schools were prohibited with immediate effect from requiring students to wear mouth-nose coverings of any kind.

Some places like Oregon seek to keep COVID mask mandates' indefinitely.'

American judges are removing children from parental custody for not wearing a mask.

Spain has passed a new law forcing people to wear face masks everywhere outside and even while swimming in the sea. Yes, really.

A New York City judge has removed a 6-year-old girl from her mother because she did not wear a mask while dropping her off outside of the school.

The CDC Thinks 2-Year-Olds Should Wear Masks in Schools, Even If Everyone Else Is Vaccinated

Who Cares About the Planet? Not Health Officials

Certainly not the FDA or Dr. Fauci. The planet may be facing a new plastic crisis, similar to the one brought on by bottled water, but this time involving discarded face masks. "Mass masking" continues to be recommended by most public health groups during the **COVID-19** pandemic, despite research showing masks do not significantly reduce the incidence of infection. As a result, it's estimated that 129 billion face masks are used worldwide each month, which works out to about 3 million masks a minute. Most of these are the disposable variety, made from plastic microfibers.

		Public Comment This guidance is being issued to address the Coronavirus Disease 2019 (COVID-19) public health emergency. This guidance is being implemented without prior public comment because the Food and Drug Administration (FDA or Agency) has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C) of the Federal Food, Drug, and Cosme... READ MORE
		- April 28, 2021Download the .PDF belowABSTRACTThe knowledge of biotechnology increases the risk of using biochemical weapons for mass destruction. Prions are unprecedented infectious pathogens that cause a group of fatal neurodegenerative diseases by a novel mechanism. They are transmissible particles that are devoid of nucleic acid. Due to their singular characteristics, Prions emerge as potenti... READ MORE
		- April 27, 2021(Download .PDF below)"Long-term Consequences of Wearing Facemask Can Cause Health Deterioration, Developing and Progression of Chronic Diseases, and Premature Death."Note: FactCheck.org has this to say about the study:Stanford Medicine says it "strongly supports the use of face masks to control the spread of COVID-19." Yet viral stories falsely claim a "... READ MORE

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Masking: A Careful Review of the Evidence

Paul Alexander

67-85 minutes

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The question on whether to wear a face mask or not during the Covid-19 pandemic remains emotional and contentious. Why? This question about the utility of face coverings (which has taken on a talisman-like life) is now overwrought with steep politicization regardless of political affiliation (e.g. republican or liberal/democrat).

Importantly, the evidence just is and was not there to support mask use for asymptomatic people to stop viral spread during a pandemic. While the evidence may seem conflicted, the evidence (including the peer-reviewed evidence) actually does not support its use and leans heavily toward masks having no significant impact in stopping spread of the Covid virus.

In fact, it is not unreasonable at this time to conclude that surgical and cloth masks, used as they currently are, have absolutely no impact on controlling the transmission of Covid-19 virus, and current evidence implies that face masks can be actually harmful. All this to say and as so comprehensively documented by Dr. Roger W. Koops in a recent American Institute of Economic Research (AIER) publication, there is no clear scientific evidence that masks (surgical or cloth) work to mitigate risk to the wearer or to those coming into contact with the wearer, as they are currently worn in everyday life and specifically as we refer to Covid-19.

We present the evidence in full below. We also state that should adequate evidence emerge that supports the effectiveness of surgical and cloth masks in this Covid pandemic (or any similar type masks), then we will change our position and conclude otherwise. Our focus is on face masks for Covid but we will touch gently on the issue of school closures and lockdowns, as these three issues remain the key public health policy catastrophes we have faced as global societies.

Back in August 2020, a survey by Pew indicated that 85% of Americans wore masks when in public all or most of the time. So, the public has been using masks extensively. We thus set the table in this review on the effectiveness of masking for Covid by asking, if these surgical and cloth masks are effective, why did incidence of the virus (or actual disease; and they're not the same thing) escalate so rapidly despite widespread use? Why is there no evidence across US States and global nations showing that when use is mandated (or not mandated given the general uptake of masking by the public), this contributes to reduced viral transmission? Is there any such evidence?

Orofecal transmission?

Understanding the transmission of this respiratory SARS-CoV-2 pathogen is also evolving given evidence of orofecal spread as having a potentially larger contributor role in non-respiratory transmission of Covid. As an example, a recent open-evidence review brief by Oxford researchers (Jefferson, Brassey, Heneghan) and its publication in CEBM, reveals the growing recognition that SARS-CoV-2 can infect and be shed from the gastrointestinal (GI) tract of humans. Orofecal spread demands urgent study and if orofecal spread is shown to be definitive and more consequential in Covid transmission, then this could impact mitigation strategies beyond those for respiratory transmission.

Where do we begin on masks? How about infection fatality rate/IFR?

Moreover, we are addressing here highly irrational, punitive, capricious, and groundless societal restrictions for a virus with an infection fatality rate (IFR), based on Stanford University John Ioannidis's calculations, of 0.05% in persons under 70 years old (across different global nations). Ioannidis's research was followed up recently by a reported non-institutionalized IFR in the state of Indiana (persons aged > 12 years) of 0.12% (95% CI 0.09 to 0.19) when age 40-59/60 years (reported in the Annals of Internal Medicine), and an IFR when < 40 years old of 0.01% (95% CI 0.01 to 0.02). Persons 60 or older had an IFR of 1.71% (overall IFR was 0.26%).

So why would we continue this way with these unsound and very punitive restrictive policies and for so long once the factual characteristics of this virus became evident and as alluded to above, we finally realized that its infection fatality rate (IFR) which is a more accurate and realistic reflection of mortality than CFR, was really no worse than annual influenza?

How did we get here?

How did we arrive at the confusion and misinformation surrounding mask use which is our focus, yet by extension, the crushing societal lockdowns and harmful school closures? There are serious harms and downsides due to these crushing restrictive policies and we understand that one would think reflexively if there is a pathogen, we should just lock and shut everything down and away. We understand this initial instinct.

However, there are benefits and risks to any action and the harms of these lockdowns and school closures far outweighed the benefits based on what has transpired. We even knew this soon after implementing lockdowns yet we continued catastrophic policies and are still continuing. How did we get here societally? How have our government bureaucratic leaders failed so disastrously?

We lay heavy blame on our government leaders but argue that the so-called 'medical experts' who are part of Covid Task Forces and guidance panels have been largely unscientific, illogical, and irrational in their guidance and statements.

Untethered from the reality of things. In many instances just flat out misleading and wrong! The incessant campaign by the media that has worked to drive fear and hysteria in the public is also partly to blame. There appears to be an unholy alliance between the government bureaucrats, the aforementioned 'medical experts,' and a willing print and digital media. A vast lot of what these experts say on Covid makes no sense anymore, at times unhinged and lacking of any credibility.

In such incredibly important Covid-related input and guidance, these television medical experts and many government leaders have failed in profound and often unimaginable ways and we are left asking how they got things so very wrong. Is it that these medical experts do not read the science? Or maybe cannot understand the data or science? Which? They talk about following the science but seem blinded to it. They clearly don't follow the science else we would not be here. They seem to not understand the devastation they have visited upon the lives of so many.

We argue that the messaging by the media and medical experts initially suggested that all persons are of equal risk of severe illness from Covid infection. This is where it all went wrong and where societies were greatly deceived by those who should not have done that. We were never 'all' at equal risk. This was deeply flawed and has crippled the US and global nations since day one of this pandemic. This was and remains a flat-out falsehood (untrue) and it has driven irrational fear by the public. This clearly erroneous intimation has stuck in the minds of the public and severely impacted the public's perception of their risk and how they would move forward.

School closure policy mirrors face mask policy?

What did we know? Let's address masks by first looking at school closures as it bears mentioning about the disaster the flawed school closure policies directed by our government leaders have caused in our children's lives. The school closure catastrophe mirrors the masking catastrophe and similar unsound policies. We knew early on in 2020 for example, that the key risk group was elderly persons with medical conditions (though Covid gave way to age due to serious medical conditions or obesity based on existing data). But just look at the complete disaster experts have created with our children in terms of school closures.

Look at what is now known in Ontario, Canada with the union and fees paid to 'conflicted' medical experts to drive a school closure message. This is reckless and scandalous! In spite of extremely low transmission rates and very low likelihood of spreading Covid virus among children (or of becoming severely ill from Covid), they have gone on and destroyed a year of the school lives of children due to these nonsensical medical experts and hysterical media and this will carry a huge long-term loss to our children. Who is going to pay for this?

What did CDC and NIH know about risk to children and when did they know it?

Did we have any data or science? Of course we did. Quality research "in the leading journal *Nature* estimated the Covid-19 survival rate to be approximately 99.995% in children and teens." We knew this very early on but that did not stop public health agencies and experts from deceiving or failing to inform about the true risk. A recent publication by CDC reported that among in excess of 90,000 students and staff in 11 North Carolina school districts, they found that in-school virus transmission was “very rare.” A similar finding emerged in 17 rural Wisconsin schools.

The Atlantic's Derek Thompson wrote in January 2021 that “We've known for months that young children are less susceptible to serious infection and less likely to transmit the coronavirus. Let's act like it.” This piece by Thompson was driven by CDC ‘coming’ out in the last week for school reopenings when the data was clear for a very long time that the risk was very low, if at all. Then we are, as is Thompson in his piece, provoked to ask, why did the media, our bureaucratic government leaders, and the medical experts seemingly collude to damage our children with their baseless school closures? Why did they deceive the public for so long? Catastrophic long-term losses for our children's educational but importantly, their social and emotional/psychological development has accumulated. We know that suicides among children have been escalating. Parents are struggling with the pandemic and homeschooling and children are failing out. This type of unfounded fear has been driven by the media “despite a thousandfold difference in risk between old and young.” They always knew this but continued a bold-faced lie! As a result, this has underpinned an atmosphere of gross distrust of our government officials and medical experts.

And the CDC is now in January/February 2021 racing to any open podium and microphone it can find to tell us it's time to reopen schools and it can be done safely. Yet this is not new data the CDC is stumbling upon for the first time. No, they have always known this. The CDC always knew it was safe to reopen schools for many many months now. They, like the rest of the globe, had the publicly available published pediatric-children data since mid-2020 which has been consistent and clear that there is very low risk to children and schools should not have been closed in the first place or kept closed. The data has been stable and clear just after the start of the pandemic that there is far less susceptibility for children, or severe illness for children, and very low risk of hospitalization or death for children when it comes to Covid.

Why this substantially reduced risk? We are not yet entirely sure but preliminary research points to less expression of ACE2 receptor proteins on the surface of the nasal epithelium in children (4-9 years old). This is well known globally for many, many months that children are at very low risk of spreading infection to their classmates, to their adults, teachers, or even taking it home. Secondary transmission evidence is nonexistent. Based on a high-quality McMaster University review, researchers found that “Transmission was traced back to community and home settings or adults, rather than among children within daycares or schools, even in jurisdictions where schools remained open or have since reopened.”

International research had been clear that there was no consistent relationship between in-person schooling for children and virus transmission. Any medical expert or agency implying otherwise that this is new science and ‘we now understand the data’ or ‘the data is now available’ is flat out duplicitous. But why has this happened to our children yet did not happen for seasonal influenza each year which is far more deadly than Covid for children? Or for H1N1 when it struck in 2009? Were decisions made based on evidence or other factors?

Who is at fault here? What was the reason for this very flawed policy? It surely is not based on science. Why has the CDC and other US health agencies such as the NIH been so slow to react to the known science (strong evidence from Norway, Ireland, Singapore, North Carolina etc.) and thus guide the optimal policy decisions based on this clear prior accumulated science (*Washington Post* piece September 2020, *The Atlantic*, October 2020)? These health agencies had the evidence but continued advocating devastatingly flawed school closure policies that have damaged our children. Just look at the repeated sparring between Senator Rand Paul and Dr. Anthony Fauci whereby the senator has been ongoingly pilloried by the media for calling out Dr. Fauci who has routinely changed statements and been confusing on a range of issues and particularly on the issue of school closures. Dr. Fauci replied: "We don't know everything about this virus, and we really ought to be very careful, particularly when it comes to children." Surely Dr. Fauci was aware of the global Covid data as it related to risk in children.

While children drive seasonal influenza and do take influenza home, this is not the case with Covid. We knew this very early on. We do recognize that there is risk of infection and transmission but it is very negligible when it comes to children and Covid. We cannot say zero risk but we are talking about extremely low likelihood and we knew this very early on. Yet if you turned on the daily news you will not know this because the message being sent out on practically a 24/7 basis is one of doom and gloom for our children! Surely the media and medical experts know that what they state is factually incorrect based on the science. Our governments and unions have closed schools with irrational knee-jerk nonsensical, unscientific policies similar to lockdowns, that results in known (i.e. not theoretical) immeasurable harms to our children given the losses that accrue. Again, who is going to pay for the unnecessary devastation these seemingly oblivious, arrogant, and nonsensical medical experts caused?

The truth also is that many children – and particularly those less advantaged, our minority, our African-American, Latino, and South Asian children – get their main needs met at school, including nutrition, eye tests and glasses, and hearing tests. Importantly, schools often function as a strong protective system or watchguard for children who are sexually or physically abused and the visibility of it declines with school closures.

Due to the lockdowns and the lost jobs, adult parents are very angry and bitter, and the stress and pressure in the home escalates due to lost jobs/income and loss of independence and control over their lives as well as the dysfunctional remote schooling that they often cannot optimally help with. Some are tragically reacting by lashing out at each other and their children. There are even reports that children are being taken to the ER with parents stating that they think they may have killed their child who is unresponsive.

In fact, since the Covid lockdowns were initiated in Great Britain as an example, it has been reported that incidence of abusive head trauma in children has risen by *almost 1,500%*! Similar catastrophic head trauma in babies that is linked to the Covid pandemic has been reported in Canada! There has been a devastating trend in Ottawa, Canada hospitals with a rise in the number of little children and babies being seen with catastrophic head injuries during the second wave of Covid-19. Covid-19 has cost lives and our government leaders and health agencies with television medical experts are partly to blame for their nonsensical and seemingly politicized decision-making that had no scientific basis. Look at what they have done!

Sadly, our children will bear the catastrophic consequences and not just educationally, of the deeply flawed school closure policy for decades to come (particularly our minority children who were least able to afford this). They have done this, the CDC, NIH etc. have cost children lives and done immeasurable damage to our children by increasingly recognized deeply destructive, and nonsensical policies.

These experts and agencies have known for a long time, certainly many, many months now (since summer of 2020 and before) that children are at little if any risk of spreading the infection or taking it home. They knew that schools offer a sort of vanguard safety net protection in our society for children and that children are often way better off within the school setting.

Yet despite what the available science showed, they continued their school closure positions and policies and urgings, that emboldened the unions and teachers to react and behave as they currently are despite the overwhelming science. Why wouldn't teachers and unions be petrified out of their minds based on the consistently illogical and nonsensical information emerging from our government agencies and medical experts? Yet this misguided policy continues and with mask-use and other mandates. Are we to believe that all aspects of the pandemic's response i.e. lockdowns, masking, vaccine etc., are fraught with these policy irregularities and aberrancies that are devastating to the public? As an example, we have doctors presently trying to mainstream early outpatient treatment for Covid in high-risk patients using established safe, cheap, effective, and available drugs but getting pilloried by the nihilistic medical experts and establishment. Such early ambulatory sequenced and combination treatment is a potential option that may reduce hospitalization and death.

Questions on masking mirrors questions on social distancing?

Specifically, from what sources did the CDC rely upon to designate that a distance of 6 feet between individuals is needed to mitigate Covid viral spread? And why, for example, do Europeans from various countries only have to stand about 1 meter apart (approximately 3 feet)? Do they know something that we don't? Or were both values arrived at arbitrarily? Were these recommendations based on evidence or were they set arbitrarily? If the latter, then why not 4 feet, 10 feet or 20 feet? Turns out "the World Health Organization recommends a distance of "at least one meter (3.3 feet)." China, France, Denmark and Hong Kong went with one meter. South Korea opted for 1.4 meters; Germany, Italy and Australia for 1.5 meters.

The CDC said 6 feet and we still don't know how they arrived at this distance and yet this pandemic has been active since at least February 2020. Unfortunately, then we can similarly at best only make unsound and disingenuous statements in favor of the use of masks but which are not backed with evidence or data. Yet the issues at hand are so serious given large societal implications and reorganization that it is difficult to reconcile with logic the absence of any such studies.

Focusing on face masks

With a focus on facial masks, where do we stand? Well, our position is based on the science. We contend that surgical and cloth masks are basically facial coverings that lack any scientific data to support their use. And that they are largely cosmetic and function more to give the user a sense of confidence and security as it pertains to the Covid pandemic. We are basing this on an examination of the totality of the evidence to date presented below. Except for the N95 masks (typically for hospital and high-risk settings and usually accompanied by gowns, gloves and other PPE) and only when properly fitted to allow for an optimal seal to the face, and only when changed often, is there effectiveness in mitigating respiratory virus spread.

And in relation to this, such protection is generally required only when clinicians treat highly infectious patients and under isolation conditions! Effectiveness also depends on a filter that could effectively deal with virus-sized particles. The Covid-19 virus is 120 nanometers in size while the filtration potential of a N95 mask is 150-300 nanometers. We also suggest that such fitting would actually be needed as a person places a fresh mask on their face, in order to retain functionality of the N95 respirator. Perhaps, it is important to note that the "N95" terminology means that the mask filters 95%

of the particulate material. Moreover, prolonged use of fitted N95 type masks (particulate filtering facepiece respirators) are uncomfortable, and can potentially cause harm.

In light of the above we hold that most of the populace would favor the use of the typical surgical 'blue' masks (or worse; cloth masks or home-made cloth masks) and even considering the fit issues discussed here regarding N95 masks, they cannot provide similar protection (from being infected or passing on infection) as might N95s.

There is simply no defensible rationale to treat this pandemic other than using an age and risk-targeted approach and fostering optimal hand washing hygiene. The vastly rational and sensible way is to target high-risk people (i.e. those at risk of developing severe disease and/or dying) and allow everyone else to get on with their lives. We ensure hospitals are well prepared (we hope) and we have had one year to do this as outlined by our governments when they asked us to help 'bend the curve,' and we simultaneously triple down on protecting the high-risk persons.

With this in place, we strive to safely and with sensible precautions, reopen society and schools in full. It is as simple as that, and on top of this, we have strong evidence of the use early on of repurposed existing, safe, cheap, and effective therapeutics in higher-risk Covid positive persons in private homes or nursing home settings who are showing initial symptoms. When used early in the outpatient setting, these drugs (sequenced combined antivirals, corticosteroids, and anti-thrombotic anti-clotting drugs) can help reduce isolation, mitigate transmission, and cut hospitalization and death significantly.

The implications of the policies like restrictions and masking are far-reaching and such policies must be based on evidence. The current policies cause crushing harms to our societies and cannot be based on the notion of stopping Covid at all costs. Stopping Covid at all costs without factoring in the implication societally is a completely illogical, irrational, damaging, and unattainable goal.

Asymptomatic spread and masks?

Before proceeding to the key evidence on the effectiveness (or not) of face coverings (masks), we wish to highlight research that is highly applicable. This surrounds recently emerging evidence that Covid-19 spread is so exceedingly rare in asymptomatic persons as to have virtually no impact in the grand scheme. Given that there are very strong data to support this contention, then we state at the outset that universal masking has no merit and cannot be supported by reliable data or research.

In an article published in *Nature Communications* (November 2020) that studied 10 million eligible persons, it was demonstrated that asymptomatic spread was not merely rare but in fact, does not appear to happen at all! Not one instance was found in the study whereby researchers reported that there were positive tests emerging even amongst close contacts of asymptomatic cases in this sample of 10 million. Why would we even consider then the need for universal masking when there is evidence like this of limited asymptomatic spread?

We also point out (and we also recognize and appreciate that this argument is far from being one based in strong evidence *per* se) that if ten's of studies or more are required to prove, one way or another, whether a procedure is effective or not (and to therefore lead to changes in standard of care), and there are still no reliable data, the effects are either minimal or nonexistent. Hence it can be reasoned that there is no meaningful effect in the first place; such an argument can be used for the masking dilemma.

All this is to say that there is and was no scientific justification to mandate or call for 'voluntary' masking of healthy people. None! And we also suggest that this straightforward reasoning can be applied to most of the other 'mitigation' efforts being implemented to date; specifically societal lockdowns, and school closures. In fact, we can find no definitive research-based evidence to support masking, societal lockdowns, or school closures at the time of writing this piece. We continue to argue that most of this has been arbitrarily construed by the government leaders and their medical experts.

These policies are not merely misguided, but they are also not without serious and adverse consequences; they have caused crushing harms and have been very injurious at a personal and societal level. Restrictive policies have not been thought through as to the implications at large! The benefits have not been assessed or considered alongside the potential (and documented) harms and this is a catastrophic omission from the perspective of sound public health policy and principles. In short, the bureaucracy has provided us with confused and often contradictory policy supported by a lack of clarity, sheer assumptions, and nonsense in general, and in this case, in relation to universal masking. Our leadership and 'experts' have failed to recognize the crushing harms that result from their arbitrary and even worse, capricious policies that lack any reliable evidentiary support!

It might also be expected that in light of the apparent groundbreaking seminal research to which we alluded above, this would not only be covered widely by the mainstream media and of course our experts but that this would clarify and help settle issues pertaining to asymptomatic spread, lockdowns in general, school closures, and of course in this case, masking. Amazingly though, there has been no acknowledgement of this work. And yet such findings that could bear on evidence-informed decision-making were ignored entirely.

Double masking?

Moreover, Dr. Anthony Fauci of the NIAID is now supporting (or at the least not discouraging) the call for the use of double masks! To paraphrase him, it makes 'common sense' to wear two masks instead of one. Yet this flies in the face of the extant data showing that the use of single masks has not provided any protection insofar as progress of the pandemic is concerned (in fact just the opposite… in virtually every jurisdiction in which mask wearing was mandated, there were very large increases in the rates of infection or at least PCR positivity to be more accurate). Despite this Dr. Fauci has responded by raising the double-mask approach, stating that "it likely does" work in relation to offering more protection.

What happened to "following the science" and the need for randomized controlled trials on the use of double masks? It seems that we follow the science only when it supports preconceived notions or goals. What was stated on double masking was utter nonsense. Dr. Fauci likely did not read the marine recruit CHARM NEJM study whereby the recruits consistently wore double layered masks yet there was still spread in the most heavily, monitored for compliance, and restricted to military environments.

Did Dr. Fauci also consider the possibility that with double masks, wearers will likely experience more difficulty in simply breathing comfortably? And what would be the consequences for those with pulmonary diseases, upper respiratory infections, others with difficulty breathing without a mask, and most importantly for children? Wearing a mask, let alone two, potentially simulates COPD/chronic obstructive pulmonary disease, akin to what smokers commonly get. Masks can make it difficult for one to breathe out, especially during stressful situations. We cannot say here because we don't know, absent scientific data, but neither does Dr. Fauci. At worst the advice regarding the use of double masking (why not triple or even four or five masks?) is arbitrary and has no scientific basis. Then why put it out there? This reflects a dissonance to anything that disrupts the set narrative that at this stage of the pandemic happens to be more political in our view than scientific or evidence-based. To add to the confusion, Dr. Fauci followed this up by stating when questioned about this statement by the media, that there is no data to show that double masks work. So, what then is the public to believe? We cannot claim to think for Dr. Fauci and similar medical experts, but why do medical experts with a podium consistently in this Covid pandemic lend so much misinformation and confusion to the public? They consistently make statements with no data or evidence to back it up. They cause great confusion and distrust by this.

Mask mandates?

As noted above, the data show that Dr. Fauci's confusing about-faces concerning advice as to management of the pandemic issues, including on masking, was perhaps arbitrary at best. As regards to masking, it is simply impossible to understand ongoing recommendations for this when we know that there are multiple US States where it can be shown clearly that *after* implementing mask mandates (indoor and outdoor), the number of cases went up! We are not suggesting that the addition of mask mandates in any way caused case numbers to soar, but clearly they had no positive or beneficial effects either. There are 37 US states including but not limited to California, Texas, Hawaii, Maine, Delaware, Florida, Oregon, and Pennsylvania that currently mandate face coverings in public. Outside of the USA, there are also global data showing that when mask mandates were implemented in Austria, Germany, France, Spain, UK, Belgium, Italy, to name only a few, case numbers went up, not down.

Moreover, the EPOCH Times reported that "in states (US) with a mandate in effect, there were 9,605,256 confirmed Covid-19 cases, which works out to an average of 27 cases per 100,000 people per day. When states didn't have a statewide order—including states that never had mandates, coupled with the period of time masking states didn't have the mandate in place—there were 5,781,716 cases, averaging 17 cases per 100,000 people per day; a notable reduction as compared to the number of cases observed during mask mandates! States with mandates in place produced an average of 10 more reported infections per 100,000 people per day than states without mandates." The blind acceptance of the current unsupported dogma that has become so entrenched that if cases do go up, the experts wedded to the universal use of masks claim that this is good news such that the masking prevented even more cases from occurring; this is truly incredible.

The reality is that there is significant evidence that masks are not effective for controlling a pandemic. To reiterate we agree, though, that within the context of a clinician treating an obviously infected patient (with any communicable disease), the use of masks is important but even then this must also be augmented by the use of other PPE (goggles, and even hazmat clothing with isolated oxygen supplies for example) and this simply cannot be compared to population wide use of masks The effects on populations are catastrophic and masks, perhaps unintentionally have constrained our ability to return to a semblance of normal life!

What is the actual Evidence on Masking?

What does the best overall body of evidence show at this time as to the effectiveness of masks? To answer this, we refer to a recent tantalizing piece by Jenin Younes published in the American Institute for Economic Research (AIER) that sets the table for making a strong argument against the effectiveness of masks and also raises very troubling questions. Given what is available, we must also draw on data derived from the study of other respiratory viruses (e.g. influenza) in regard to the use of masks to prevent spread of disease, and we also argue that this evidence is very pertinent to the virus (SARS CoV-2) associated with Covid-19 disease.

Overall, the available research on the use of masks to mitigate transmission of pathogens in a pandemic is of very poor methodological quality using largely indirect unadjusted evidence, and not the optimal clinical research that is needed. A major limitation is the use of the same evidence base by all reviews and thus arrival at similar findings. However, this low-quality evidence is what we have and is, we believe, still useful enough to guide and inform us.

At the same time, we do recognize the urgent need for well-designed clinical research in order to address as definitively as possible questions pertaining to the utility of face masks in curtailing or stopping spread of Covid-19 (and future similar respiratory 'pandemic' pathogens). In fact, we find it remarkable that researchers have not been commissioned to develop adequate studies on the use of face masks to prevent the spread of SARS CoV-2 by asymptomatic people. It's also noteworthy that there have also been no reliable studies that can demonstrate one way or the other whether social distancing truly can be used to impede viral spread, especially in asymptomatic people.

It appears that this issue is now fraught with politics and agendas promulgated by a wide array of medical experts on television and the media as opposed to being related to a reliable base of knowledge. We suggest that various populations are being hurt by this type of 'academic sloppiness,' which feeds into what we would call the reckless behavior of many experts and ill-informed media outlets who rely on these authorities. Conclusions around the use of masks during the Covid pandemic (and other actions that have been taken but are not addressed here in detail such as lockdowns and school closures) are often baseless and we submit that the research community has not studied the mask issue appropriately, principally because they are reticent and possibly even wary as to what the findings might reveal. After all, those who object to masking are often immediately labeled as 'deniers' and heretics.

The public remains confused by the messaging from senior medical experts across the US. This can be exemplified by comments made by Dr. Anthony Fauci early on in the pandemic (March 2020) as part of his Covid-19 Task Force role when he stated categorically that (para), "wearing a mask might make people feel a little bit better" but "it's not providing the perfect protection that people think it is." Then and now, he actually echoed the current scientific consensus and this was in line with the World Health Organization's guidance.

However, as we know, the guidance coming from experts was still somewhat confusing at best and downright unscientific and flawed at worst. Interestingly, this type of advice (also given by others including Canada's Chief Medical Officer, Dr. Theresa Tam), was changed (initially dismissive of mask use) under the notion that in fact the experts were intentionally saying these things so as to prevent runs on surgical masks that were in short supply at the time and needed by healthcare workers. We put forward the notion that this is not the case and that in fact at that time, the experts actually *were* relying on available data as alluded to above. All this is to say that such changes in advice provided by top medical experts only served to confuse a public desperately in need of honesty and optimal guidance.

In relation to the above we point out that the World Health Organization (WHO) stated that "the widespread use of masks by healthy people in the community setting is not yet supported by high quality or direct scientific evidence and there are potential benefits and harms to consider."

A strong argument against the use of masks in the current Covid-19 pandemic gained traction when a recent CDC case-control study reported that well over 80% of cases always or often wore masks.

This CDC study further called into question the utility of masks in the Covid-19 emergency.

A recent publication asserts that face masks become nonconsequential and do not work after 20 minutes due to saturation. "Those masks are only effective so long as they are dry," said Professor Yvonne Cossart of the Department of Infectious Diseases at the University of Sydney." As soon as they become saturated with the moisture in your breath they stop doing their job and pass on the droplets." In a similar light, there are indications that wearing a mask that is already used is riskier that if one wore no mask.

Moreover, accumulating data and evidence *in toto* suggests a lack of evidence to support mask use (in adults or children) including any broad mask mandate. For example, the CDC in its examination of Nonpharmaceutical Measures (NPIs) for Pandemic Influenza in Nonhealthcare Settings, Oxford's CEBM, CIDRAP and policy questions unsound mask data, Klompas (NEJM) and universal masking, Jefferson et al., CDC 2, Brainard et al.'s research on preventing respiratory illness (Norwich School of Medicine), Marks's Covid-19 transmission clusters in Catalonia (*Lancet*), Spain, Jenin Younes's persuasive AIER piece on masking in the US, and research evidence by Hunter et al. regarding NPIs.

More specifically, research done by the CDC (May 2020) and published in *Emerging Infectious Diseases* (EID) examined personal protective measures and environmental hygiene measures for the effectiveness of such measures in reducing transmission of laboratory-confirmed influenza in the community. Researchers focused on disposable surgical or medical (typical blue coloured) face masks and identified 7 studies involving influenza and influenza-like illness (ILI) and reported that there was in fact no significant reduction in the transmission of influenza when face masks were used. Overall, the CDC reported that there is no significant effect of face masks in the transmission of laboratory-confirmed influenza and we hold that these findings could be extrapolated to SARS-CoV-2.

Researchers from the University of Oxford's Center for Evidence-Based Medicine (CEBM) examined the data regarding the effectiveness of the use of masks within the current highly charged backdrop of politics. They concluded that after nearly 20 years of preparedness for coming pandemics, the evidence on face mask use remains very conflicted. They examined evidence that revealed that "masks alone have no significant effect in interrupting the spread of ILI or influenza in the general population, nor in healthcare workers." They ask why had the correct applicable comparative effectiveness research not been conducted and we agree, that is, until the recent marine study (NEJM publication (CHARM study) and the Danish study published in the Annals of Internal Medicine which we describe. The Oxford researchers also speculate that there is likely and elevated rate of harm (infection) when using cloth face masks. They looked specifically at 6 RCTs in 2010 that examined face masks in respiratory viruses whereby 2 studies were in healthcare employees and 4 were in family and student groups. The trials for ILI showed very poor mask wearing compliance and seldom reported the harms that might be associated with the use of masks (harm evidence to be presented later in this discussion). Taken together though this fits with the premise outlined above where we state that if masking could be used to effectively prevent viral spread, there would have been clear evidence by now.

In 2013, the Canadian Agency for Drugs and Technologies in Health (an Agency specializing in Systematic Review/Meta-Analysis), stated: "No evidence was found on the effectiveness of wearing surgical face masks to protect staff from infectious material in the operating room, no evidence was found to support the use of surgical face masks to reduce the frequency of surgical site infections, and guidelines recommend the use of surgical face masks by staff in the operating room to protect both operating room staff and patients (despite the lack of evidence).”

Similarly, Jefferson et al. studied physical interventions to interrupt or reduce the spread of respiratory viruses (updating a prior Cochrane review (2011) to include 15 RCTs (n=13,259 persons) exploring the impact of masks (14 trials) in healthcare workers, the general population and those in quarantine (1 trial)). When compared to non-masking, researchers found no significant reduction of ILI cases or influenza when masks were used in the general population and in healthcare workers. Somewhat surprisingly, there was also no difference between surgical masks and N95 respirators for ILI or for influenza.

However, this might comport with the fact that although N95 masks can be effective at filtering 95% of the particulate matter, the masks must be properly fitted. And in this regard, when an individual places a fresh mask on their face, there is no guarantee whatsoever that it will be placed in the precise location used when fit tests were done. This would mean therefore, that the filtering effectiveness of N95 masks can’t really be predicted or guaranteed. The body of evidence was considered to be of ‘low’ quality based on included study limitation, even though these were RCTs, and they were plagued with serious methodological concerns.

Marks et al. reported on transmission clusters of Covid-19 in Catalonia, Spain (post-hoc analysis of data collected in the BCN PEP CoV-2 Study), looking at a cohort that was part of a RCT (314 patients with Covid-19, with 282 (90%) having at least one contact, 753 contacts in total, resulting in 282 clusters. Ninety (32%) of 282 clusters had at least one transmission event). Researchers reported no association of risk of transmission with mask usage by contacts.

The New England Journal of Medicine (NEJM) recently published an article on Covid-19 and masks which appeared to suggest that masks have become no more than a psychological crutch, and stated that “We know that wearing a mask outside health care facilities offers little, if any, protection from infection. Public health authorities define a significant exposure to Covid-19 as face-to-face contact within 6 feet with a patient with symptomatic Covid-19 that is sustained for at least a few minutes (and some say more than 10 minutes or even 30 minutes).

The chance of catching Covid-19 from a passing interaction in a public space is therefore minimal. In many cases, the desire for widespread masking is a reflexive reaction to anxiety over the pandemic.” They also stated that “it is also clear that masks serve symbolic roles. Masks are not only tools, they are also talismans that may help increase health care workers’ ‘perceived’ sense of safety, well-being, and trust in their hospitals. Although such reactions may not be strictly logical, we are all subject to fear and anxiety, especially during times of crisis. One might argue that fear and anxiety are better countered with data and education than with a marginally beneficial mask.”

A recent WHO-sponsored systematic review and meta-analysis published in the *Lancet* included 39 nonrandomized observational studies (weaker study designs) that were not always adjusted fully for confounders and reported that face masks *could* be effective. These studies had small sample sizes with small event numbers, and were plagued with potential selection bias and residual confounding bias. The body of evidence was judged to be of low quality and was also open to the risk of recall, and measurement bias. The studies focused principally on mask use in households or contacts of cases that arose from investigations of the SARS and MERS epidemics (but with limited date for Covid-19 too). The researchers argued though that this indirect evidence can be regarded as the most direct information that would apply also to Covid-19.

Following publication in the *Lancet* of the WHO-sponsored review, researchers led by University of

Toronto epidemiology professor Peter Jueni, have now come forward asking *Lancet* to retract the study, citing numerous serious methodological flaws such as (but not limited to):

i) 7 studies being unpublished and non-peer-reviewed observational studies

ii) failure to consider the randomized evidence

iii) 25 included studies are about the SARS-1 virus or the MERS coronavirus, both of which have very different transmission characteristics than SARS-CoV-2: they were transmitted almost exclusively by severely ill hospitalized patients and there was no assessment of community transmission; a serious concern in regard to the issues being discussed in this document

iv) of the 4 studies relating to the SARS-CoV-2, 2 were misinterpreted by the authors of the *Lancet* meta-study, 1 is inconclusive, and 1 focused on the impact of using N95 (FFP2) respirators which is irrelevant insofar as community transmission, especially in regard to asymptomatic people and also did not address the use of medical grade or cloth masks

v) this review is being used to guide global face mask policy for the general population whereby one included study was judged to be misclassified (relating to masks in a hospital environment), one showed no benefit of face masks, and one is a poorly designed retrospective study about SARS-1 in Beijing based on telephone interviews. None of the studies refer to SARS-CoV-2.

Similarly, a recent study published in *PNAS* surrounding airborne transmission and face masks has also provoked substantial consternation and argued to be a politically motivated study more than a scientific one. It has led to over 40 leading scientists calling for its withdrawal due to it being very flawed because of the use of very suboptimal statistical analyses.

A review by the Norwich School of Medicine (preprint) studied the effectiveness of wearing face masks and examined 31 published studies of all research designs. They reported that "the evidence is not sufficiently strong to support widespread use of face masks as a protective measure against Covid-19. However, there is enough evidence to support the use of face masks for short periods of time by particularly vulnerable individuals when in transient higher risk situations."

A recent Danish Study published in the *Annals of Internal Medicine* sought to assess whether recommending surgical mask utilization outside of the home would help reduce the wearer's risks of acquiring SARS-CoV-2 infection in a setting where masks were uncommon and not among recommended public health measures. The sample included a total of 3,030 participants who were assigned randomly to wear masks, and 2,994 who were told to not wear masks (i.e. the control arm). The researchers reported that 4,862 persons completed the study. Infection with SARS-CoV-2 occurred in 42 participants who wore masks (1.8%) while 53 participants in the control group developed infection (2.1%). The between-group difference was −0.3 percentage point in favor of mask-use (95% CI, −1.2 to 0.4 percentage point; $p = 0.38$). Based on the analysis of the findings though, the authors concluded that there was no statistically or clinically significant impact of mask-use in regard to the rate of infection with SARS CoV-2.

Interestingly, these results emerged in a setting where social distancing and other public health measures were in effect, *except* for mask-wearing. In point of fact, the use of masks in this population was in general quite low. In any case, based on these findings it might be expected on the basis of this study alone that there would be serious doubt raised as to the need for the initiation and maintenance of mandatory use of masks in the public domain. Unfortunately, as of this date, this does not seem to be the case and is inexplicable quite frankly.

Additionally, with a focus on cloth face masks, recent reports suggest that they should never be used as a protective barrier as they offer no transmission protection (as PPE or as source control; see Tokyo report and BMJ study).

In the BMJ cluster randomized study, researchers sought to compare the efficacy of cloth masks to medical masks in hospital workers (in 14 Vietnamese hospitals utilizing 1,607 workers over 18 years of age). Wards were randomized so that in some, medical masks were worn while in other wards cloth masks were used. Another ward was assigned as a control group for 'usual practice' which included the use of masks on every shift for 4 consecutive weeks. The rates of all infection outcomes were highest in the cloth mask arm, with the rate of ILI significantly higher in the cloth mask arm (relative risk (RR)=13.00, 95% CI 1.69 to 100.07) compared with the medical mask arm. There were also significantly higher rates of ILI in the cloth mask group as compared with the control arm.

An analysis by mask use showed that ILI (RR=6.64, 95% CI 1.45 to 28.65) and laboratory-confirmed virus (RR=1.72, 95% CI 1.01 to 2.94) were significantly higher in the cloth mask group compared with the medical mask group. Researchers found that penetration of the cloth masks by particles was in the range of 97% (filtering out only 3% of viral particles) and for medical masks, it was still only 44%. This being the first RCT of cloth masks, the researchers cautioned against the use of cloth masks. There is extensive moisture retention and poor filtration with reuse which results in increased risk of infection, including by bacterial microorganisms. They concluded that cloth masks should not be recommended for healthcare workers, especially in high-risk settings.

The Norwegian Institute of Public Health (NIPH) conducted a recent rapid review to assess if individuals in the community without respiratory symptoms should wear face masks to reduce the spread of Covid-19. They proceeded on the assumption that 20% of 'infected' people are asymptomatic and that with a risk reduction of 40% when wearing masks, approximately 200,000 persons would need to wear a mask to prevent one new infection per week. Researchers concluded that based on the existing epidemic/pandemic in Norway, "wearing face masks to reduce the spread of Covid-19 is not recommended for individuals in the community without respiratory symptoms who are not in near contact with people who are known to be infected."

In a May 2020 communication report in *Nature* (Medicine), Leung et al. examined the importance of respiratory droplets as well as aerosol routes of spread with a specific focus on coronaviruses, influenza viruses, and rhinoviruses. They measured the quantity of respiratory virus in exhaled breath of participants with acute respiratory infections (ARIs) and determined the possible efficacy of surgical face masks to prevent respiratory virus transmission.

As part of the study, they screened 3,363 persons in two study phases, eventually enrolling 246 participants with ARI who provided exhaled breath samples, with 122 (50%) of the participants being randomized to either not wearing a face mask during the first exhaled breath collection or randomized to wearing a face mask (n=124 (50%)). Seasonal human coronaviruses, influenza viruses and rhinoviruses within exhaled breath and coughs of children as well as adults with ARI were identified. In this study, it was found that surgical face masks can significantly reduce detection of influenza virus RNA in respiratory droplets and coronavirus RNA in aerosols, and with a trend toward reduced detection of coronavirus RNA in respiratory droplets. Their results suggest that surgical masks can potentially reduce the release of influenza virus particles into the environment in respiratory droplets, but not in aerosols. And it must be emphasized that this study relied on people who had symptomatic disease, something vastly different from the issues under consideration here.

Perhaps one of the most seminal and rigorous studies (along with the Danish study published in the

Annals of Internal Medicine) emerged from a United States Marine Corps study performed in an isolated location; Parris Island. As reported in a recent NEJM publication (CHARM study), researchers studied SARS-CoV-2 transmission among Marine recruits during quarantine. Marine recruits at Parris Island (n=1,848 of 3,143 eligible recruits) who volunteered underwent a 2-week quarantine at home that was followed by a 2nd 2-week quarantine in a closed college campus setting.

As part of the study, participants wore masks and socially distanced while symptoms were monitored with daily checks of temperature. RT-PCR testing was used to assess the effectiveness of these strategies insofar as the presence or absence of SARS CoV-2 mRNA was concerned. Samples were obtained by the use of nasal swabs which were collected between arrival and the 2nd day of supervised quarantine and on days 7 and 14 (the 2nd quarantine used to mitigate infection among recruits). All recruits were required to have a negative RT-PCR result prior to entering Parris Island. It was found that within 2 days following arrival on the closed campus, 16 participants now tested positive for SARS-CoV-2 mRNA (15 being asymptomatic) and 35 more tested positive on day 7 or on day 14 (n=51 in total).

More specifically, of the 1,801 recruits who tested negative with PCR at study enrollment, 24 (1.3%) tested positive on day 7. On day 14, a total of 11 of 1,760 (0.6%) of the previously PCR-test negative participants tested positive; none of these participants were seropositive on day 0. As such, 35 participants who had had negative PCR test results within the first 2 days post arrival at the campus then became positive during the strict supervised quarantine. Of the 51 total participants who had at least one positive PCR test, 22 had positive tests on more than 1 day. Phylogenetic analysis was conducted whereby 6 independent monophyletic transmission clusters (independent viral strains) indicative of local transmission were uncovered during the supervised quarantine. The majority of clusters principally included members of the same platoon, and numerous infected recruits had an infected roommate.

The authors reported that about 2% who had earlier negative tests for SARS-CoV-2 at the beginning of strict supervised quarantine (we ask the reader to think; *military grade supervision*), and less than 2% of recruits who had unknown prior status, tested positive by day 14. Positive volunteers were mainly asymptomatic and transmission clusters occurred within platoons. The predominant finding was that despite the very strict and enforced quarantine (including 2 full weeks of supervised confinement and then forced social distancing and masking protocols), the rate of transmission was not reduced and in fact seemed to be higher than expected! Hence, we point out that not only was masking ineffective in preventing the spread of disease, but even *made things worse*. Despite quarantines, social distancing, and masking, in this cohort of mainly young male recruits, roughly 2% still went on to become infected and tested positive for SARS-CoV-2. Sharing of rooms and platoon membership were reported risk factors for viral transmission.

As with the Danish investigation this study of Marine recruits who were kept under stringent military level supervision raises serious questions about the utility of quarantines, as it appears that not only do masks appear to be ineffective in preventing communal disease spread but also that quarantines do not work even when supervised for 2 weeks in a closed college. As we have stated elsewhere, it seems that quarantines are ineffective and that would also seem to include enforced social distancing! At the risk of repeating ourselves, all this is to say that in this study where compliance was monitored and enforced, and the conditions are favourable enough to support a rigorous study, so called ‘mitigation’ strategies just *do not work and cannot work amongst the general population*. This study stands as one of the higher-quality and more robust studies on the question of masking.

A 1981 British publication by Dr. Neil Orr reported on a trial in patients in a 40-bed surgical ward that focused on cholecystectomies, gastrectomies, thyroidectomies, bowel resections, prostatectomies, herniorrhaphies as well as cystoscopies, bronchoscopies, and gastroscopies. The analysis looked at throughput, wounds, and infection rates during a 6-month period (March-August) each year from 1976 to 1980. Remarkably it was concluded that the effectiveness of a mask in reducing contamination varied with the mask's shape, the materials of which the masks were made, and the way the masks were worn. Importantly, it was shown that wearing a mask did not reduce incidents of contamination in the theatre. In fact, results suggested the opposite in that wearing no mask correlated with the greatest reductions in contamination (also associated with performing the operations under conditions of silence… no speaking by the staff during any of the procedures).

A publication in Annals of Internal Medicine by Bae et al. "Effectiveness of Surgical and Cotton Masks in Blocking SARS-CoV-2" was retracted on a request by the ACP journal. We are thus unable to comment on the findings.

Based on the foregoing evidence cited above, we find no conclusive evidence to support the use of masks for Covid-19 (except N-95 type masks in a hospital setting and when appropriately fitted and utilized). In fact, masking appears to carry substantial risks to the user. And we reiterate that our conclusions are not based on the absence of evidence for ineffectiveness alone, *but actual evidence of ineffectiveness*.

And we reiterate that our conclusions are not based on the absence of evidence for ineffectiveness alone, *but actual evidence of ineffectiveness*.

Possibly the one study that could only be construed as pseudo-science, is based on a recent MMWR by the CDC on the use of double masks, this even after Dr. Anthony Fauci backtracked and said there is no evidence that this is effective. This is why this study was left for last in our review. Along comes the CDC with a study on maximizing fit for cloth and medical procedure masks by placing a cloth mask over a surgical mask and knotting the ear loops of a medical procedure mask and then tucking in and flattening the extra material close to the face. A pliable elastomeric head form was used to simulate a person under various conditions e.g. coughing etc. CDC reported that "the unknotted medical procedure mask alone blocked 42.0% of the particles from a simulated cough (standard deviation [SD] = 6.70), and the cloth mask alone blocked 44.3% (SD = 14.0). The combination of the cloth mask covering the medical procedure mask (double mask) blocked 92.5% of the cough particles (SD = 1.9)".

Incredulously, CDC then went on to declare that "the findings of these simulations should neither be generalized to the effectiveness of all medical procedure masks or cloths masks nor interpreted as being representative of the effectiveness of these masks when worn in real-world settings" and findings are not to be extrapolated to children "because of their smaller size or to men with beards and other facial hair, which interfere with fit". In addition, CDC stated "although use of double masking or knotting and tucking are two of many options that can optimize fit and enhance mask performance for source control and for wearer protection, double masking might impede breathing or obstruct peripheral vision for some wearers, and knotting and tucking can change the shape of the mask such that it no longer covers fully both the nose and the mouth of persons with larger faces". We are then left to ask, what was the purpose of this publication if it cannot be generalized to real-world settings and may impact breathing? Incidentally, in the SARS-CoV-2 Transmission among Marine Recruits during Quarantine (CHARM) study on Parris Island, the military recruits used double-layered masks and findings were that masks and social distancing did not stop spread of COVID infection.

What about possible harms from wearing masks?

But what about harms from mask use? The information that is accumulating involves mask wearers within a Covid-19 environment and raises many concerns especially regarding psychological damage and especially to infants and children, with potential catastrophic impacts on the cognitive development of children. This is even more critical in relation to children with special needs or who are on the autism spectrum who need to be able to recognize facial expressions as part of their ongoing development. The accumulating evidence also suggests that prolonged mask use in children or adults can cause harms:

i) difficulty with breathing

ii) inhalation of toxic substances such as microplastics and chlorine compounds located in the masks (these are potentially serious risks)

iii) CO_2 intoxication

iv) sudden cardiac arrest seen in children

v) a reduction in blood oxygenation (hypoxia) or an elevation in blood CO2 (hypercapnia)

vi) psychological damage

vii) (N95 masks) a reduction in the PaO2 level, increases in respiratory rate, and increases the occurrence of chest discomfort and respiratory distress with prolonged use

viii) dizziness and light-headedness, headaches especially among healthcare workers

ix) bacterial and mould buildup in children's masks that can then be inhaled

x) anxiety and sleep problems, behavioral disorders and fear of contamination in children

xi) deoxygenation during surgery

xii) potentially life-threatening damage to the lungs (e.g. Stanford engineers report that masks can make it much more difficult to breathe, estimating that N95 masks as an example, reduce oxygen intake from 5% to 20% and if worn for a prolonged period)

xiii) as reported by Koops, facial skin infections, nose/throat and sinus infections, a change in breathing patterns.

Predominant finding?

The predominant conclusion is that face masks have a very important role in places such as hospitals, but there exists very little evidence of widespread benefit for members of the public (adults or children) as well as evidence that masking is truly an ineffectual way to manage pandemic-related spread of viral disease. As Kolstoe stated, it has become less about the science and more about politics and a symbol of solidarity.

Our view is that masks as they are worn now, and the masks that are in use, offer zero protection. They can be viewed as ineffective while others consider them as being better than nothing but without evidence to support that view. Masks are not sealed properly to the face and do not effectively stop *virion* penetration. We state emphatically that public health policy, or any policy for that matter, must be undergirded by sound data and evidence. As we have said, the reality is that widespread use of masks is *not* supported by science and in fact just the opposite. This mask hysteria is driving unnecessary fear in the population and must end. Those who deliver statements relentlessly on the use of masks are doing so without the luxury of any credible evidence to support those views. They speak on assumption or speculation and this is *not* science! However, it is important to understand that as we await definitive research, given the situation and the desire to prevent spread to higher-risk persons (e.g. elderly), when consistent social distancing is not possible (our previous concerns about distancing notwithstanding), and out of an abundance of caution, face coverings among symptomatic individuals *might reduce the spread* of droplets with SARS-CoV-2 infection to others.

This must also be considered when a setting is experiencing elevated transmission rates. Moreover, this is sensible to the degree that it does not support generalized mask wearing by the entire population! We urge always common-sense reasonable precautions to be taken and on an individual basis, as the case may be, with an age and hazard targeted approach to reducing risk, always endeavoring to do our utmost in order to protect the high-risk persons among us.

It is very sensible that one would use a face mask when visiting an elderly person who is high-risk or even if the setting is controlled such as a healthcare setting in a nursing home. This makes complete sense (even though again, we know that evidence does not support this notion)! It is reasonable to be cautious, even in the light of limited or nonexistent evidence (especially strong peer-review evidence) of effectiveness and the increasing information suggesting that there's now evidence of harms related to mask (over)use. Situation-by-situation decisions can be made that depend on the risk at hand. The full context must be considered but if you are adequately socially distanced, there is no reason to wear a mask. There is no evidence for this. Though we would also contend that one should wear a mask if that is what is expected but adhere to meticulous hand hygiene and socially isolate if ill.

Danish reporting of a higher-quality mask study on Covid and masks that was actually rejected or sidelined by top journals including *Lancet, New England Journal of Medicine*, and the American Association's *JAMA* is alarming if true and suggests a pattern of politicization of research and of the medical community, journal editors and the peer-reviewers. We look forward to its future publication.

Conclusion

In closing, perhaps Yinon Weiss, who is a U.S. military veteran, and who holds a degree in bioengineering from U.C. Berkeley, captures our current face mask calamity by reminding us how masks constrain our return to a more normal life. As outlandish as this might seem could this be the aim of those using the pandemic for the purpose of advancing various political ideologies? Masking drives fear in the population and a perennial sense of 'illness' that is crippling. As stated eloquently by Weiss, "Our universal use of unscientific face coverings is therefore closer to medieval superstition than it is to science, but many powerful institutions have too much political capital invested in the mask narrative at this point, so the dogma is perpetuated."

Our paper sought to examine the complete and most updated mask-related scientific evidence, along with anecdotal data and reports. Our current belief remains that asymptomatic individuals do not drive the pandemic and that the time-tested method of Ignaz Philipp Semmelweis of washing hands remains the best-established mechanism of limiting most microbial infections. People with symptomatic disease should not go into work! Unfortunately, since the economic downturn around 2008, the incidence of 'presenteeism' has increased due to the fear of losing one's job if one does not show up to work, even if ill. This behaviour has to be taken very seriously and must be stopped.

We also agree with the words of Klompas in the NEJM publication: "What is clear, however, is that universal masking alone is not a panacea. A mask will not protect providers caring for a patient with active Covid-19 if it's not accompanied by meticulous hand hygiene, eye protection, gloves, and a gown. A mask alone will not prevent health care workers with early Covid-19 from contaminating their hands and spreading the virus to patients and colleagues. **Focusing on universal masking alone may, paradoxically, lead to more transmission of Covid-19 if it diverts attention from implementing more fundamental infection-control measures."**

In sum, when we look at the science, there is emerging and troubling evidence of harms from mask use in the absence of any benefits. This is also related to things as mundane as simple incorrect use of masking, as well as the development of complacency that emerges due to mask use and thus the relaxation of other mitigation steps, as well as mask contamination.

We also cannot discount the possible harms on our immune systems and general health from such constant and prolonged use of masks, given we have never done this before. We are in uncharted territory and especially so with the possible implications for our children. Their immune systems are still being developed and we are forcing lockdowns, school closures, and masking on a developing child and we have no prior experience on the subsequent outcomes pertaining to children's development, health, and well-being.

Most discomforting is that those government bureaucrats in charge and particularly the 'medical experts' continue to fail to admit they were exceptionally incorrect with regard to most of what they have stated in terms of pandemic policies and response related to the Covid pandemic. They have harmed the very societies they are supposed to help protect. They have failed to look at the evidence or follow it, and continue to operate in an arbitrary nonscientific, nonevidence informed manner. They 'attack,' with the assistance of the mass media, those of us who question their policies and actions despite the disastrous outcomes of those public health policies. Indeed, we are often blamed for the failures (called 'deniers' or 'heretics') and crushing harms of all of their policies when it has actually been their specious, illogical, and unsound actions and recommendations that deserve public outcry.

Suggested points to consider

In line with Koops and as published in the journal of the AIER, we embrace and suggest the following in terms of mask use for this Covid pandemic (based on individual decision-making):

i) Persons who have been infected and experienced Covid, are not required to wear any facial coverings

ii) No facial covering/masking is needed when in ventilated, open air surroundings; the risk for becoming infected with SARS CoV-2 is extremely small to non-existent

iii.) Facial coverings/masks are potentially of use when in close proximity to a high-risk person, e.g. elderly or if you are in a health care setting e.g. hospital or nursing home, long-term care facility, assisted-living facility, care home etc. This will also limit the spread of bacteria etc. to high-risk persons but again it must be stressed that this pertains most specifically to those visitors who have active symptomatic disease as opposed to those who are entirely asymptomatic

iv.) Children are at very low risk of acquiring SARS-CoVC-2 virus, or getting severely ill from infection; they are at also very low risk of spreading to other children, or to adults, and their teachers etc. Children should not be masked under any condition and only in instances when they are high-risk (immunocompromised), have contributory medical conditions.

v) Children must be allowed to interface with their natural environments (environments in general) so that their immune systems remain constantly taxed and 'tuned up' and is optimal for immune system development as well as their cognitive development, particularly in children with special needs such as autism

vi) People who are "post-convalescent" Covid should not wear masks. People with Covid-19, if they must be in the presence of others, should wear masks, although only minorly helpful at best.

vii) We implore that all government leaders and so-called medical experts include risk-benefit analyses each and any time they seek to advocate for or implement societal policies. We must have evidence of the benefits as well as harms and examine the trade-offs and most importantly, consider the implications to the public. If the policy is destructive, you end it!

Contributing Authors

- **Paul E Alexander MSc PhD**, McMaster University and GUIDE Research Methods Group, Hamilton, Ontario, Canada elias98_99@yahoo.com
- **Howard C. Tenenbaum DDS, Dip. Perio., PhD**, FRCD(C) Centre for Advanced Dental Research and Care, Mount Sinai Hospital, and Faculties of Medicine and Dentistry, University of Toronto, Toronto, ON, Canada
- **Ramin Oskoui, MD**, CEO, Foxhall Cardiology, PC, Washington, DC oskouimd@gmail.com
- **Harvey A. Risch, MD, PhD**, Yale School of Public Health, New Haven, CT USA harvey.risch@yale.edu
- **Peter A. McCullough, MD, MPH**, Baylor University Medical Center, Baylor Heart and Vascular Institute, Baylor Jack and Jane Hamilton Heart and Vascular Hospital, Dallas, TX, USA peteramccullough@gmail.com
- **Nicholas E. Alexander**

Paul E. Alexander

Paul E. Alexander received his bachelor's degree in epidemiology from McMaster University in Hamilton, Ontario, a master's degree from Oxford University, and a PhD from McMaster University's Department of Health Research Methods, Evidence, and Impact.

Plaintiff's Exhibit 89

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Review

Is a Mask That Covers the Mouth and Nose Free from Undesirable Side Effects in Everyday Use and Free of Potential Hazards?

Kai Kisielinski [1], Paul Giboni [2], Andreas Prescher [3], Bernd Klosterhalfen [4], David Graessel [5], Stefan Funken [6], Oliver Kempski [7] and Oliver Hirsch [8,*]

1 Private Practice, 40212 Düsseldorf, Germany; kaikisielinski@yahoo.de
2 Private Practice, 22763 Hamburg, Germany; pgiboni@gmx.de
3 Institute of Molecular and Cellular Anatomy (MOCA), Wendlingweg 2, 52074 Aachen, Germany; aprescher@ukaachen.de
4 Institute of Pathology, Dueren Hospital, Roonstrasse 30, 52351 Dueren, Germany; bernd.klosterhalfen@web.de
5 Institute of Neuroscience and Medicine, Forschungszentrum Jülich, 52425 Jülich, Germany; d.graessel@fz-juelich.de
6 Private Practice, 47803 Krefeld, Germany; dr_funken@colita.net
7 Institute of Neurosurgical Pathophysiology, University Medical Centre of the Johannes Gutenberg University of Mainz Langenbeckstr. 1, 55131 Mainz, Germany; oliver.kempski@unimedizin-mainz.de
8 Department of Psychology, FOM University of Applied Sciences, 57078 Siegen, Germany
* Correspondence: oliver.hirsch@fom.de

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Abstract: Many countries introduced the requirement to wear masks in public spaces for containing SARS-CoV-2 making it commonplace in 2020. Up until now, there has been no comprehensive investigation as to the adverse health effects masks can cause. The aim was to find, test, evaluate and compile scientifically proven related side effects of wearing masks. For a quantitative evaluation, 44 mostly experimental studies were referenced, and for a substantive evaluation, 65 publications were found. The literature revealed relevant adverse effects of masks in numerous disciplines. In this paper, we refer to the psychological and physical deterioration as well as multiple symptoms described because of their consistent, recurrent and uniform presentation from different disciplines as a Mask-Induced Exhaustion Syndrome (MIES). We objectified evaluation evidenced changes in respiratory physiology of mask wearers with significant correlation of O_2 drop and fatigue ($p < 0.05$), a clustered co-occurrence of respiratory impairment and O_2 drop (67%), N95 mask and CO_2 rise (82%), N95 mask and O_2 drop (72%), N95 mask and headache (60%), respiratory impairment and temperature rise (88%), but also temperature rise and moisture (100%) under the masks. Extended mask-wearing by the general population could lead to relevant effects and consequences in many medical fields.

Keywords: personal protective equipment; masks; N95 face mask; surgical mask; risk; adverse effects; long-term adverse effects; contraindications; health risk assessment; hypercapnia; hypoxia; headache; dyspnea; physical exertion; MIES syndrome

1. Introduction

At the beginning of the spread of the novel pathogen SARS-CoV-2, it was necessary to make far-reaching decisions even without available explicit scientific data. The initial assumption was that the pandemic emergency measures were set in place to reduce the acute threat of the public health system effectively and swiftly.

In April 2020, the World Health Organization (WHO) recommended the use of masks only for symptomatic, ill individuals and health care workers and did not recommend its widespread use.

In June 2020, they changed this recommendation to endorse the general use of masks in, e.g., crowded places [1,2]. In a meta-analysis study commissioned by the WHO (evidence level Ia), no clear, scientifically graspable benefit of moderate or strong evidence was derived from wearing masks [3].

While maintaining a distance of at least one meter showed moderate evidence with regard to the spreading of SARS-CoV-2, only weak evidence at best could be found for masks alone in everyday use (non-medical setting) [3]. Another meta-analysis conducted in the same year confirmed the weak scientific evidence for masks [4].

Accordingly, the WHO did not recommend general or uncritical use of masks for the general population and expanded its risk and hazard list within just two months. While the April 2020 guideline highlighted the dangers of self-contamination, possible breathing difficulties and false sense of security, the June 2020 guideline found additional potential adverse effects such as headache, development of facial skin lesions, irritant dermatitis, acne or increased risk of contamination in public spaces due to improper mask disposal [1,2].

However, under pressure from increasing absolute numbers of positive SARS-CoV-2 tests, many prescribers further extended mask-wearing according to certain times and situations, always justified by the desire to limit the spread of the virus [5]. The media, numerous institutions and most of the population supported this approach.

Among the medical profession and scientists, the users and observers of medical devices, there have been simultaneous calls for a more nuanced approach [6–8]. While there has been a controversial scientific discussion worldwide about the benefits and risks of masks in public spaces, they became the new social appearance in everyday life in many countries at the same time.

Although there seems to be a consensus among the decision makers who have introduced mandatory masks that medical exemptions are warranted, it is ultimately the responsibility of individual clinicians to weigh up when to recommend exemption from mandatory masks. Physicians are in a conflict of interest concerning this matter. On the one hand, doctors have a leading role in supporting the authorities in the fight against a pandemic. On the other hand, doctors must, in accordance with the medical ethos, protect the interests, welfare and rights of their patient's third parties with the necessary care and in accordance with the recognized state of medical knowledge [9–11].

A careful risk–benefit analysis is becoming increasingly relevant for patients and their practitioners regarding the potential long-term effects of masks. The lack of knowledge of legal legitimacy on the one hand and of the medical scientific facts on the other is a reason for uncertainty among clinically active colleagues.

The aim of this paper is to provide a first, rapid, scientific presentation of the risks of general mandatory mask use by focusing on the possible adverse medical effects of masks, especially in certain diagnostic, patient and user groups.

2. Materials and Methods

The objective was to search for documented adverse effects and risks of different types of mouth–nose-covering masks. Of interest here were, on the one hand, readymade and self-manufactured fabric masks, including so-called community masks and, on the other hand medical, surgical and N95 masks (FFP2 masks).

Our approach of limiting the focus to negative effects seems surprising at first glance. However, such an approach helps toprovide us with more information. This methodology is in line with the strategy of Villalonga-Olives and Kawachi, who also conducted a review exclusively on the negative effects [12].

For an analysis of the literature, we defined the risk of mouth–nose protection as the description of symptoms or the negative effects of masks. Reviews and expert presentations from which no measurable values could be extracted, but which clearly present the research situation and describe negative effects, also fulfill this criterion.

Additionally, we defined the quantifiable, negative effect of masks as the presentation of a measured, statistically significant change in a physiological parameter in a pathological direction ($p < 0.05$), a statistically significant detection of symptoms ($p < 0.05$) or the occurrence of symptoms in at least 50% of those examined in a sample ($n \geq 50\%$).

Up to and including 31 October 2020, we conducted a database search in PubMed/MEDLINE on scientific studies and publications on adverse effects and risks of different types of mouth–nose-covering masks according to the criteria mentioned above (see Figure 1: Review flowchart). Terms searched were "face masks", "surgical mask" and "N95" in combination with the terms "risk" and "adverse effects" as well as "side effects". The selection criteria of the papers were based on our above definition of risk and adverse effect of masks. Mainly English- and German-language publications of evidence levels I to III according to the recommendations of the Agency for Healthcare Research and Quality (AHQR) that were not older than 20 years at the time of the review were considered. The evaluation also excluded level IV evidence, such as case reports and irrelevant letters to the editor that exclusively reflect opinions without scientific evidence.

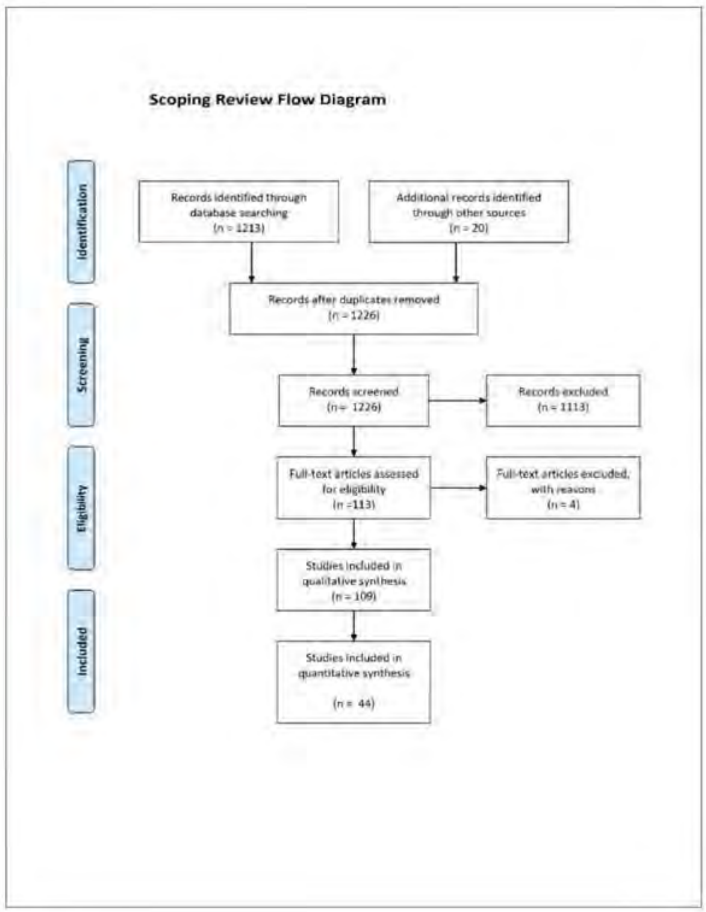

Figure 1. Scoping review flow diagram according to the PRISMA scheme.

After excluding 1113 papers that were irrelevant to the research question and did not meet the criteria mentioned (quantifiable, negative effects of masks, description of symptoms or the negative effects of masks), a total of 109 relevant publications were found for evaluation in the context of our scoping review (see Figure 1: Flow chart).

Sixty-five relevant publications concerning masks were considered being within the scope of the content-related evaluation. These included 14 reviews and 2 meta-analyses from the primary research. For the quantitative evaluation, 44 presentations of negative effects from the years 2004 to 2020 were eligible. Thirty-one of these studies were experimental (70%), and 13 studies were data collection studies in the sense of simple observational studies, especially in the dermatological field (30%). The observed study parameters and significant results from these 44 publications ($p < 0.05$ or $n \geq 50\%$) were compiled in an overall display (Figure 2). Based on this data, a correlation analysis of the observed mask effects was performed. This included a correlation calculation of the recorded symptoms and physiological changes (for nominally scaled, dichotomous variables according to Fisher using R, R Foundation for Statistical Computing, Vienna, Austria, version 4.0.2).

significantly measured mask-induced changes in scientific studies 2004-2020: • = p<0.05 ■ = n≥50 %	Fabric Mask	Surgical Mask	N95-Mask	O2↓	CO2↑	Humidity↑	Temperature↑	Breathing Resistance↑	Respiratory Rate↑	Blood Pressure↑	Cerebral Vasodilation	Heart Rate↑	Respiratory Impairment	Exhaustion & Fatigue	Drowsiness	Dizziness	Headache	Psycho-vegetative Effect	Decrease in Empathy	Itch	Skin Irritation	Acne	Rhinitis	Voice Disorder	False Sense of Security	Bacterial Contamination	Fungal Contamination	Viral Conatmination
Beder 2008		X		•								•																
Bharatendu 2020			X		•						•						•											
Butz 2005		X			•																							
Chughtai 2019		X																										•
Epstein 2020		X	X		•																							
Fikenzer 2020		X	X	•		•	•	•					•	•						•								
Foo 2006			X																	■	■	■						
Georgi 2020	X	X	X	•	•				•				•	•														
Goh 2019			X		■																							
Heider 2020		X	X																					•				
Hua 2020		X	X			•														■	•							
Jacobs 2009		X															•											
Jagim 2018	X			•										•	•													
Kao 2004			X	•					•				•	•														
Klimek 2020																							•					
Kyung 2020			X	•	•				•			•	•															
Lan 2020			X																	■	•							
Lee 2011			X					•																				
Li 2005		X	X			•	•	•		•		•	•	•						•								
Lim 2006			X														•											
Liu 2020	X	X	X	•		•	•					•	•	•	•	•					•							
Luckman 2020	X	X	X																						•			
Luksamijarulkul 2014		X																								•	•	
Matusiak 2020	X	X	X			•	•						•							•	•			•				
Mo 2020		X			•					•			•															
Monalisa 2017		X																								•	•	
Ong 2020			X														•											
Person 2018		X											•															
Pifarre 2020		X	X	•	•																							
Porcari 2016	X			•										•														
Prousa 2020	X	X	X															•										
Ramirez 2020		X	X														•											
Rebmann 2013		X	X	•	•							•	•	•	•		•											
Roberge 2012		X			•	•	•		•			•	•															
Roberge 2014			X		•		•																					
Rosner 2020		X	X														■				■	■						
Scarano 2020		X	X			•	•						•								•							
Shenal 2012	X	X	X											•														
Smart 2020		X	X				•						•															
Szepietkowski 2020	X	X	X																	•								
Techasatian 2020	X	X	X																		■							
Tong 2015			X	•	•																							
Wong 2013		X																	•									
Zhiqing 2018		X																								•		

Figure 2. Overview including all 44 considered studies with quantified, significant adverse effects of masks (black dots and black rectangles). Not all studies examined each mentioned parameter, as focused or subject-related questions were often in the foreground. Gray fields correspond to a lack of coverage in the primary studies, white fields represent measured effects. We found an often combination of significant chemical, physical, physiological parameters and complaints. Drowsiness summarizes the symptom for any qualitative neurological deficits described in the scientific literature examined.

In addition, another 64 publications with a neighboring range of topics were consulted in connection with the mask effects we found. These included declarations, guidelines and legal principles. In order to expand the amount of data for the discussion, we proceeded according to the "snowball principle" by locating citations of selected papers in the bibliographies and including them where appropriate.

Since the findings from the topics presented for discussion were to an unexpected degree subject-related, we decided to divide the results according to the fields of medicine. Of course, there are overlaps between the respective fields, which we point out in detail.

3. Results

A total of 65 scientific papers on masks qualified for a purely content-based evaluation. These included 14 reviews and two meta-analyses.

Of the mathematically evaluable, groundbreaking 44 papers with significant negative mask effects ($p < 0.05$ or $n \geq 50\%$), 22 were published in 2020 (50%), and 22 were published before the COVID-19 pandemic. Of these 44 publications, 31 (70%) were of experimental nature, and the remainder were observational studies (30%). Most of the publications in question were English (98%). Thirty papers referred to surgical masks (68%), 30 publications related to N95 masks (68%), and only 10 studies pertained to fabric masks (23%).

Despite the differences between the primary studies, we were able to demonstrate a statistically significant correlation in the quantitative analysis between the negative side effects of blood-oxygen depletion and fatigue in mask wearers with $p = 0.0454$.

In addition, we found a mathematically grouped common appearance of statistically significant confirmed effects of masks in the primary studies ($p < 0.05$ and $n \geq 50\%$) as shown in Figure 2. In nine of the 11 scientific papers (82%), we found a combined onset of N95 respiratory protection and carbon dioxide rise when wearing a mask. We found a similar result for the decrease in oxygen saturation and respiratory impairment with synchronous evidence in six of the nine relevant studies (67%). N95 masks were associated with headaches in six of the 10 studies (60%). For oxygen deprivation under N95 respiratory protectors, we found a common occurrence in eight of 11 primary studies (72%). Skin temperature rise under masks was associated with fatigue in 50% (three out of six primary studies). The dual occurrence of the physical parameter temperature rise and respiratory impairment was found in seven of the eight studies (88%). A combined occurrence of the physical parameters temperature rise and humidity/moisture under the mask was found in 100% within six of six studies, with significant readings of these parameters (Figure 2).

The literature review confirms that relevant, undesired medical, organ and organ system-related phenomena accompanied by wearing masks occur in the fields of internal medicine (at least 11 publications, Section 3.2). The list covers neurology (seven publications, Section 3.3), psychology (more than 10 publications, Section 3.4), psychiatry (three publications, Section 3.5), gynecology (three publications, Section 3.6), dermatology (at least 10 publications, Section 3.7), ENT medicine (four publications, Section 3.8), dentistry (one publication, Section 3.8), sports medicine (four publications, Section 3.9), sociology (more than five publications, Section 3.10), occupational medicine (more than 14 publications, Section 3.11), microbiology (at least four publications, Section 3.12), epidemiology (more than 16 publications, Section 3.13), and pediatrics (four publications, Section 3.14) as well as environmental medicine (four publications, Section 3.15).

We will present the general physiological effects as a basis for all disciplines. This will be followed by a description of the results from the different medical fields of expertise and closing off with pediatrics the final paragraph.

3.1. General Physiological and Pathophysiological Effects for the Wearer

As early as 2005, an experimental dissertation (randomized crossover study) demonstrated that wearing surgical masks in healthy medical personnel (15 subjects, 18–40 years old) leads to measurable physical effects with elevated transcutaneous carbon dioxide values after 30 min [13]. The role of dead space volume and CO_2 retention as a cause of the significant change ($p < 0.05$) in blood gases on the way to hypercapnia, which was still within the limits, was discussed in this article. Masks expand the natural dead space (nose, throat, trachea, bronchi) outwards and beyond the mouth and nose.

An experimental increase in the dead space volume during breathing increases carbon dioxide (CO_2) retention at rest and under exertion and correspondingly the carbon dioxide partial pressure pCO_2 in the blood ($p < 0.05$) [14].

As well as addressing the increased rebreathing of carbon dioxide (CO_2) due to the dead space, scientists also debate the influence of the increased breathing resistance when using masks [15–17].

According to the scientific data, mask wearers as a whole show a striking frequency of typical, measurable, physiological changes associated with masks.

In a recent intervention study conducted on eight subjects, measurements of the gas content for oxygen (measured in O_2 Vol%) and carbon dioxide (measured in CO_2 ppm) in the air under a mask showed a lower oxygen availability even at rest than without a mask. A Multi-Rae gas analyzer was used for the measurements (RaeSystems®) (Sunnyvale, California CA, United States). At the time of the study, the device was the most advanced portable multivariant real-time gas analyzer. It is also used in rescue medicine and operational emergencies. The absolute concentration of oxygen (O_2 Vol%) in the air under the masks was significantly lower (minus 12.4 Vol% O_2 in absolute terms, statistically significant with $p < 0.001$) at 18.3% compared to 20.9% room air concentration. Simultaneously, a health-critical value of carbon dioxide concentration (CO_2 Vol%) increased by a factor of 30 compared to normal room air was measured (ppm with mask versus 464 ppm without mask, statistically significant with $p < 0.001$) [18].

These phenomena are responsible for a statistically significant increase in carbon dioxide (CO_2) blood content in mask wearers [19,20], on the one hand, measured transcutaneously via an increased $PtcCO_2$ value [15,17,19,21,22], on the other hand, via end-expiratory partial pressure of carbon dioxide ($PETCO_2$) [23,24] or, respectively, the arterial partial pressure of carbon dioxide ($PaCO_2$) [25].

In addition to the increase in the wearer's blood carbon dioxide (CO_2) levels ($p < 0.05$) [13,15,17,19,21–28], another consequence of masks that has often been experimentally proven is a statistically significant drop in blood oxygen saturation (SpO_2) ($p < 0.05$) [18,19,21,23,29–34]. A drop in blood oxygen partial pressure (PaO_2) with the effect of an accompanying increase in heart rate ($p < 0.05$) [15,23,29,30,34] as well as an increase in respiratory rate ($p < 0.05$) [15,21,23,35,36] have been proven.

A statistically significant measurable increase in pulse rate ($p < 0.05$) and decrease in oxygen saturation SpO_2 after the first ($p < 0.01$) and second hour ($p < 0.0001$) under a disposable mask (surgical mask) were reported by researchers in a mask intervention study they conducted on 53 employed neurosurgeons [30].

In another experimental study (comparative study), surgical and N95 masks caused a significant increase in heart rate ($p < 0.01$) as well as a corresponding feeling of exhaustion ($p < 0.05$). These symptoms were accompanied by a sensation of heat ($p < 0.0001$) and itching ($p < 0.01$) due to moisture penetration of the masks ($p < 0.0001$) in 10 healthy volunteers of both sexes after only 90 min of physical activity [35]. Moisture penetration was determined via sensors by evaluating logs (SCXI-1461, National Instruments, Austin, TX, USA).

These phenomena were reproduced in another experiment on 20 healthy subjects wearing surgical masks. The masked subjects showed statistically significant increases in heart rate ($p < 0.001$) and respiratory rate ($p < 0.02$) accompanied by a significant measurable increase in transcutaneous carbon dioxide $PtcCO_2$ ($p < 0.0006$). They also complained of breathing difficulties during the exercise [15].

The increased rebreathing of carbon dioxide (CO_2) from the enlarged dead space volume in mask wearers can reflectively trigger increased respiratory activity with increased muscular work as well as the resulting additional oxygen demand and oxygen consumption [17]. This is a reaction to pathological changes in the sense of an adaptation effect. A mask-induced drop in blood oxygen saturation value (SpO_2) [30] or the blood oxygen partial pressure (PaO_2) [34] can in turn additionally intensify subjective chest complaints [25,34].

The documented mask-induced changes in blood gases towards hypercapnia (increased carbon dioxide/CO_2 blood levels) and hypoxia (decreased oxygen/O_2 blood levels) may result in additional nonphysical effects such as confusion, decreased thinking ability and disorientation [23,36–39], including overall impaired cognitive abilities and decrease in psychomotoric abilities [19,32,38–41]. This highlights the importance of changes in blood gas parameters (O_2 and CO_2) as a cause of clinically relevant psychological and neurological effects. The above parameters and effects (oxygen saturation, carbon dioxide content, cognitive abilities) were measured in a study on saturation sensors (Semi-Tec AG, Therwil, Switzerland), using a Borg Rating Scale, Frank Scale, Roberge Respirator Comfort Scale and Roberge Subjective Symptoms-during-Work Scale, as well as with a Likert scale [19]. In the other main study, conventional ECG, capnography and symptom questionnaires were used in measuring carbon dioxide levels, pulse and cognitive abilities [23]. Other physiological data collection was done with pulse oximeters (Allegiance, MCGaw, USA), subjective complaints were assessed with a 5-point Likert scale and motoric speed was recorded with linear-position transducers (Tendo-Fitrodyne, Sport Machins, Trencin, Slovakia) [32]. Some researchers used standardized, anonymized questionnaires to collect data on subjective complaints associated with masks [37].

In an experimental setting with different mask types (community, surgical, N95) a significant increase in heart rate ($p < 0.04$), a decrease in oxygen saturation SpO_2 ($p < 0.05$) with an increase in skin temperature under the mask (face) and difficulty of breathing ($p < 0.002$) were recorded in 12 healthy young subjects (students). In addition, the investigators observed dizziness ($p < 0.03$), listlessness ($p < 0.05$), impaired thinking ($p < 0.03$) and concentration problems ($p < 0.02$), which were also statistically significant when wearing masks [29].

According to other researchers and their publications, masks also interfere with temperature regulation, impair the field of vision and of non-verbal and verbal communication [15,17,19,36,37,42–45].

The above-mentioned measurable and qualitative physiological effects of masks can have implications in various areas of expertise in medicine.

It is known from pathology that not only supra-threshold stimuli exceeding normal limits have disease-relevant consequences. Subthreshold stimuli are also capable of causing pathological changes if the exposure time is long enough. Examples occur from the slightest air pollution by hydrogen sulfide resulting in respiratory problems (throat irritation, coughing, reduced absorption of oxygen) and neurological diseases (headaches, dizziness) [46]. Furthermore, subthreshold but prolonged exposure to nitrogen oxides and particulate matter is associated with an increased risk of asthma, hospitalization and higher overall mortality [47,48]. Low concentrations of pesticides are also associated with disease-relevant consequences for humans such as mutations, development of cancer and neurological disorders [49]. Likewise, the chronic subthreshold intake of arsenic is associated with an increased risk of cancer [50], subthreshold intake of cadmium with the promotion of heart failure [51], subthreshold intake of lead is associated with hypertension, renal metabolic disorders and cognitive impairment [52] or subthreshold intake of mercury with immune deficiency and neurological disorders [53]. Subliminal UV radiation exposure over long periods is also known to cause mutation-promoting carcinogenic effects (especially white skin cancer) [54].

The mask-induced adverse changes are relatively minor at first glance, but repeated exposure over longer periods in accordance with the above-mentioned pathogenetic principle is relevant. Long-term disease-relevant consequences of masks are to be expected. Insofar, the statistically significant results found in the studies with mathematically tangible differences between mask wearers and people without masks are clinically relevant. They give an indication that with correspondingly repeated and prolonged exposure to physical, chemical, biological, physiological and psychological conditions, some of which are subliminal, but which are significantly shifted towards pathological areas, health-reducing changes and clinical pictures can develop such as high blood pressure and arteriosclerosis, including coronary heart disease (metabolic syndrome) as well as neurological diseases. For small increases in carbon dioxide in the inhaled air, this disease-promoting effect has been proven with the creation of headaches, irritation of the respiratory tract up to asthma as well as an increase in blood pressure and heart rate with vascular damage and, finally, neuropathological and cardiovascular consequences [38]. Even slightly but persistently increased heart rates encourage oxidative stress with endothelial dysfunction, via increased inflammatory messengers, and finally, the stimulation of arteriosclerosis of the blood vessels has been proven [55]. A similar effect with the stimulation of high blood pressure, cardiac dysfunction and damage to blood vessels supplying the brain is suggested for slightly increased breathing rates over long periods [56,57]. Masks are responsible for the aforementioned physiological changes with rises in inhaled carbon dioxide [18–28], small sustained increases in heart rate [15,23,29,30,35] and mild but sustained increases in respiratory rates [15,21,23,34,36].

For a better understanding of the side effects and dangers of masks presented in this literature review, it is possible to refer to well-known principles of respiratory physiology (Figure 3).

The average dead space volume during breathing in adults is approximately 150–180 mL and is significantly increased when wearing a mask covering the mouth and nose [58]. With an N95 mask, for example, the dead space volume of approximately 98–168 mL was determined in an experimental study [59]. This corresponds to a mask-related dead space increase of approximately 65 to 112% for adults and, thus, almost a doubling. At a respiratory rate of 12 per minute, the pendulum volume respiration with such a mask would, thus, be at least 2.9–3.8 L per minute. Therefore, the dead space amassed by the mask causes a relative reduction in the gas exchange volume available to the lungs per breath by 37% [60]. This largely explains the impairment of respiratory physiology reported in our work and the resulting side effects of all types of masks in everyday use in healthy and sick people (increase in respiratory rate, increase in heart rate, decrease in oxygen saturation, increase in carbon dioxide partial pressure, fatigue, headaches, dizziness, impaired thinking, etc.) [36,58].

In addition to the effect of increased dead space volume breathing, however, mask-related breathing resistance is also of exceptional importance (Figure 3) [23,36].

Experiments show an increase in airway resistance by a remarkable 126% on inhalation and 122% on exhalation with an N95 mask [60]. Experimental studies have also shown that moisturization of the mask (N95) increases the breathing resistance by a further 3% [61] and can, thus, increase the airway resistance up to 2.3 times the normal value.

This clearly shows the importance of the airway resistance of a mask. Here, the mask acts as a disturbance factor in breathing and makes the observed compensatory reactions with an increase in breathing frequency and simultaneous feeling of breathlessness plausible (increased work of the respiratory muscles). This extra strain due to the amplified work of breathing against bigger resistance caused by the masks also leads to intensified exhaustion with a rise in heart rate and increased CO_2 production. Fittingly, in our review of the studies on side effects of masks (Figure 2), we also found a percentage clustering of significant respiratory impairment and a significant drop in oxygen saturation (in about 75% of all study results).

In the evaluation of the primary papers, we also determined a statically significant correlation of the drop in oxygen saturation (SpO_2) and fatigue with a common occurrence in 58% of the mask use studies with significant results (Figure 2, $p < 0.05$).

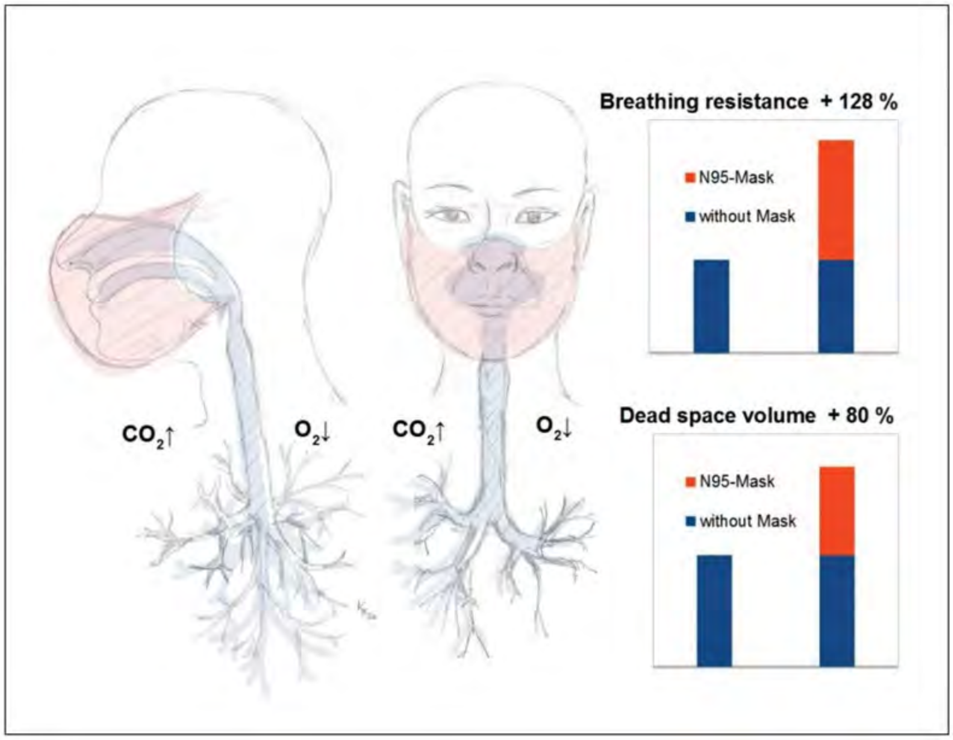

Figure 3. Pathophysiology of the mask (important physical and chemical effects): Illustration of the breathing resistance* and of the dead space volume of an N95 mask in an adult. When breathing, there is an overall significantly reduced possible gas exchange volume of the lungs of minus 37% caused by the mask (Lee 2011) [60] according to a decrease in breathing depth and volume due to the greater breathing resistance of plus128%* (exertion when inhaling greater than when exhaling) and due to the increased dead space volume of plus80%**, which does not participate directly in the gas exchange and is being only partially mixed with the environment. (* = averaged inspiration and expiration according to Lee 2011 [60] including moisture penetration according to Roberge 2010 [61], ** = averaged values according to Xu 2015 [59]).

3.2. Internistic Side Effects and Dangers

As early as 2012, an experiment showed that walking in the 20 masked subjects compared to the identical activity without masks significantly increased heart rates (average +9.4 beats per minute, $p < 0.001$) and breathing rates ($p < 0.02$). These physiological changes were accompanied by transcutaneous significantly measurable increased transcutaneous carbon dioxide ($PtcCO_2$) levels ($p < 0.0006$) as well as respiratory difficulties in the mask wearers compared to the control group [15].

In a recent experimental comparative study from 2020, 12 healthy volunteers under surgical masks as well as under N95 masks experienced measurable impairments in the measured lung function parameters as well as cardiopulmonary capacity (lower maximum blood lactate response) during moderate to heavy physical exertion compared to exertion without masks ($p < 0.001$) [31]. The mask-induced increased airway resistance led to increased respiratory work with increased oxygen consumption and demand, both of the respiratory muscles and the heart. Breathing was significantly impeded ($p < 0.001$) and participants reported mild pain. The scientists concluded from their results that the cardiac compensation of the pulmonary, mask-induced restrictions, which still functioned in healthy people, was probably no longer possible in patients with reduced cardiac output [31].

In another recent study, researchers tested fabric masks (community masks), surgical masks and FFP2/N95 masks in 26 healthy people during exercise on a cycle ergometer. All masks also showed a measurable carbon dioxide (CO_2) retention ($PtcCO_2$) (statistically significant with $p < 0.001$) and, for N95 masks, a decrease in the oxygen saturation value SpO_2 (statistically significant at 75 and 100 W with $p < 0.02$ and $p < 0.005$, respectively). The clinical relevance of these changes was shown in an increase in breathing frequency with fabric masks ($p < 0.04$) as well as in the occurrence of the previously described mask-specific complaints such as a feeling of heat, shortness of breath and headaches. The stress perception was recorded on a Borg scale from 1 to 20. During physical exertion under an N95 mask, the group with masks showed a significant increase in the feeling of exhaustion compared to the group without with 14.6 versus 11.9 on the scale of 20. During the exposure, 14 of the 24 subjects wearing masks complained of shortness of breath (58%), four of headaches and two of a feeling of heat. Most of the complaints concerned FFP2 masks (72%) [21].

The aforementioned physiological and subjective physical effects of masks on healthy people at rest and under exertion [21,31] give an indication of the effect of masks on sick and elderly people even without exertion.

In an observational study of ten 20 to 50 year-old nurses wearing N95 masks during their shift work, side effects such as breathing difficulties ("I can't breathe"), feelings of exhaustion, headache ($p < 0.001$), drowsiness ($p < 0.001$) and a decrease in oxygen saturation SpO_2 ($p < 0.05$) as well as an increase in heart rate ($p < 0.001$) were statistically significant in association with an increase in obesity (BMI) [19]. The occurrence of symptoms under masks was also associated with older age (statistically significant correlation of fatigue and drowsiness with $p < 0.01$ each, nausea with $p < 0.05$, an increase in blood pressure with $p < 0.01$, headache with $p < 0.05$, breathing difficulties with $p < 0.001$) [19].

In an intervention study involving 97 patients with advanced chronic obstructive pulmonary disease (COPD) the respiratory rate, oxygen saturation and exhaled carbon dioxide equivalents (capnometry) changed unfavorably and significantly after the use of N95 masks (FFP2 equivalent) with an initial 10-minute rest and subsequent 6-minute walking. Seven patients discontinued the experiment due to serious complaints with a decrease in the oxygen saturation value SpO_2 and a pathological carbon dioxide (CO_2) retention as well as increased end-expiratory partial pressure of carbon dioxide ($PETCO_2$) [23]. In two patients, the $PETCO_2$ exceeded the normal limits and reached values of >50 mmHg. An FEV1 < 30% and a modified Medical Research Council (mMRC) Dyspnea Scale Score of $\geq$3, both indicators of advanced COPD, correlated with mask intolerance overall in this study. The most common symptom under mask was breathlessness at 86%. In the dropouts of the study, dizziness (57%) and headaches were also often recorded. In the mask-tolerant COPD patients, significant increases in heart rate, respiratory rate and end-expiratory carbon dioxide partial pressure $PETCO_2$ could be objectified even at rest, after only 10 min of mask-wearing ($p < 0.001$), accompanied by a decrease in oxygen saturation SpO_2 ($p < 0.001$) [23]. The results of this study with an evidence level IIa are indicative for COPD mask wearers.

In another retrospective comparative study on COPD and surgical masks, examiners were able to demonstrate statistically an increase in arterial partial pressure of carbon dioxide ($PaCO_2$) of approximately +8 mmHg ($p < 0.005$) and a concomitant mask-related increase in systolic blood pressure of +11 mmHg ($p < 0.02$) [25]. This increase is relevant in hypertensive patients, but also in healthy people with borderline blood pressure values as pathological value range triggered by mask-wearing can be induced.

In 39 hemodialysis patients with end-stage renal disease, a type N95 mask (FFP2 equivalent) caused a significant drop in blood oxygen partial pressure (PaO_2) in 70% of patients at rest (on hemodialysis) within only 4 h ($p = 0.006$). Despite a compensatory increased respiratory rate ($p < 0.001$), malaise with chest pain occurred ($p < 0.001$) and even resulted in hypoxemia (drop in oxygen below the normal limit) in 19% of the subjects [34]. The researchers concluded from their findings that elderly or patients with reduced cardiopulmonary function have a higher risk of developing a severe respiratory failure while wearing a mask [34].

In a review paper on the risks and benefits of masks worn during the COVID-19 crisis, other authors provide an equally critical assessment of mandatory mask use for patients with pneumonia, both with and without COVID-19 pneumonia disease [16].

3.3. Neurological Side Effects and Dangers

In a scientific evaluation of syncope in the operating theatre, 36 of 77 affected persons (47%) were associated with wearing a mask [62]. However, other factors could not be ruled out as contributory causes.

In their level III evidence review, neurologists from Israel, the UK and the USA state that a mask is unsuitable for epileptics because it can trigger hyperventilation [63]. The use of a mask significantly increases the respiratory rate by about plus 15 to 20% [15,21,23,34,64]. However, an increase in breathing frequency leading to hyperventilation is known to be used for provocation in the diagnosis of epilepsy and causes seizure-equivalent EEG changes in 80% of patients with generalized epilepsy and in up to 28% of focal epileptics [65].

Physicians from New York studied the effects of wearing masks of the surgical-type mask and N95 among medical personnel in a sample of 343 participants (surveyed using standardized, anonymized questionnaires). Wearing the masks caused detectable physical adverse effects such as impaired cognition (24% of wearers) and headaches in 71.4% of the participants. Of these, 28% persisted and required medication. Headache occurred in 15.2% under 1 h of wear, in 30.6% after 1 h of wear and in 29.7% after 3 h of wear. Thus, the effect intensified with increasing wearing time [37].

Confusion, disorientation and even drowsiness (Likert scale questionnaire) and reduced motoric abilities (measured with a linear position transducer) with reduced reactivity and overall impaired performance (measured with the Roberge Subjective Symptoms-during-Work Scale) as a result of mask use have also been documented in other studies [19,23,29,32,36,37].

The scientists explain these neurological impairments with a mask-induced latent drop in blood gas oxygen levels O_2 (towards hypoxia) or a latent increase in blood gas carbon dioxide levels CO_2 (towards hypercapnia) [36]. In view of the scientific data, this connection also appears to be indisputable [38–41].

In a mask experiment from 2020, significant impaired thinking ($p < 0.03$) and impaired concentration ($p < 0.02$) were found for all mask types used (fabric, surgical and N95 masks) after only 100 min of wearing the mask [29]. The thought disorders correlated significantly with a drop in oxygen saturation ($p < 0.001$) during mask use.

Initial headaches ($p < 0.05$) were experienced by up to 82% of 158, 21–35 year-old mask wearers in another study of N95 respiratory protection with one third (34%) experiencing headaches up to four times daily. Participants wore the mask for 18.3 days over a 30-day period with a mean of 5.9 h per day [66].

Significantly increased headache ($p < 0.05$) could be observed not only for N95 but also for surgical masks in participants of another observational study of health care workers [67].

In another study, the researchers classified 306 users with an average age of 43 years and wearing different types of masks, of whom 51% had an initial headache as a specific symptom related exclusively to increased surgical and N95 mask use (1 to 4 h, $p = 0.008$) [68].

Researchers from Singapore were able to demonstrate in a trial involving 154 healthy N95 health service mask wearers that a significant increase in mask-induced blood carbon dioxide levels (measured by end-expiratory partial pressure of carbon dioxide $PETCO_2$) and a measurably greater vasodilatation with an increase in cerebral artery flow in the cerebri media resulted. This was associated with headaches in the trial group ($p < 0.001$) [27].

According to the researchers, the aforementioned changes also contribute to headaches during the prolonged use of masks with a shift towards hypoxia and hypercapnia. Furthermore, stress and mechanical factors such as the irritation of cervical nerves in the neck and head area caused by the tight mask straps pressuring the nerve strands also contribute to headaches [66].

In the analysis of the primary studies, we were able to detect an association between the N95 mask and headaches. In six out of 10 studies, the significant headache appeared in conjunction with the N95 mask (60% of all studies, Figure 2).

3.4. Psychological Side Effects and Dangers

According to an experimental study, wearing surgical masks and N95 masks can also lead to a reduced quality of life owing to reduced cardiopulmonary capacity [31]. Masks, along with causing physiological changes and discomfort with progressive length of use, can also lead to significant discomfort ($p < 0.03$ to $p < 0.0001$) and a feeling of exhaustion ($p < 0.05$ to 0.0001) [69].

Besides the shift in blood gases towards hypercapnia (increase in CO_2) and hypoxia (decrease in O_2), detailed under general physiological effects (Section 3.1), masks also restrict the cognitive abilities of the individual (measured using a Likert scale survey) accompanied by a decline in psycho-motoric abilities and consequently a reduced responsiveness (measured using a linear position transducer) as well as an overall reduced performance capability (measured with the Roberge Subjective Symptoms-during-Work Scale) [29,32,38,39,41].

The mask also causes an impaired field of vision (especially affecting the ground and obstacles on the ground) and also presents an inhibition to habitual actions such as eating, drinking, touching, scratching and cleaning the otherwise uncovered part of the face, which is consciously and subconsciously perceived as a permanent disturbance, obstruction and restriction [36]. Wearing masks, thus, entails a feeling of deprivation of freedom and loss of autonomy and self-determination, which can lead to suppressed anger and subconscious constant distraction, especially as the wearing of masks is mostly dictated and ordered by others [70,71]. These perceived interferences of integrity, self-determination and autonomy, coupled with discomfort, often contribute to substantial distraction and may ultimately be combined with the physiologically mask-related decline in psycho-motoric abilities, reduced responsiveness and an overall impaired cognitive performance. It leads to misjudging situations as well as delayed, incorrect and inappropriate behavior and a decline in the effectiveness of the mask wearer [36,37,39–41].

The use of masks for several hours often causes further detectable adverse effects such as headaches, local acne, mask-associated skin irritation, itching, sensations of heat and dampness, impairments and discomfort predominantly affecting the head and face [19,29,35–37,71–73]. However, the head and face are significant for well-being due to their large representation in the sensitive cerebral cortex (homunculus) [36].

According to a questionnaire survey, masks also frequently cause anxiety and psycho-vegetative stress reactions in children—as well as in adults—with an increase in psychosomatic and stress-related illnesses and depressive self-experience, reduced participation, social withdrawal and lowered health-related self-care [74]. Over 50% of the mask wearers studied had at least mild depressive feelings [74]. Additional fear-inducing and often exaggerated media coverage can further intensify this. A recent retrospective analysis of the general media in the context of the 2014 Ebola epidemic showed a scientific truth content of only 38% of all publicly published information [75]. Researchers classified a total of 28% of the information as provocative and polarizing and 42% as exaggerating risks. In addition, 72% of the media content aimed to stir up health-related negative feelings. The feeling of fear, combined with insecurity and the primal human need to belong [76], causes a social dynamic that seems partly unfounded from a medical and scientific point of view.

The mask, which originally served purely hygienic purpose, has been transformed into a symbol of conformity and pseudo-solidarity. The WHO, for example, lists the advantages of the use of masks by healthy people in public to include a potentially reduced stigmatization of mask wearers, a sense of contribution to preventing the spread of the virus and a reminder to comply with other measures [2].

3.5. Psychiatric Side Effects and Dangers

As explained earlier, masks can cause increased rebreathing with an accumulation of carbon dioxide in the wearer due to increased dead space volume [16–18,20] (Figure 3), with often statistically significant measurable elevated blood carbon dioxide (CO2) levels in sufferers [13,15,17,19–28] (Figure 2). However, changes that lead to hypercapnia are known to trigger panic attacks [77,78]. This makes the significantly measurable increase in CO_2 caused by wearing a mask clinically relevant.

Interestingly, breath provocation tests by inhaling CO_2 are used to differentiate anxiety states in panic disorders and premenstrual dysphoria from other psychiatric clinical pictures. Here, absolute concentrations of 5% CO_2 already suffice to trigger panic reactions within 15–16 min [77]. The normal exhaled air content of CO_2 is about 4%.

It is obvious from experimental studies on masked subjects that concentration changes in the respiratory gases in the above-mentioned range with values above 4% could occur during rebreathing with prolonged mask use [18,23].

The activation of the locus coeruleus by CO_2 is used to generate panic reactions via respiratory gases [78,79]. This is because the locus coeruleus is an important part of the system of vegetative noradrenergic neurons, a control center in the brainstem, which reacts to an appropriate stimulus and changes in the gas concentrations in the blood by releasing the stress hormone noradrenaline [78].

From the physiological, neurological and psychological side effects and dangers described above (Sections 3.1, 3.3 and 3.4), additional problems can be derived for the use of masks in psychiatric cases. People undergoing treatment for dementia, paranoid schizophrenia, personality disorders with anxiety and panic attacks, but also panic disorders with claustrophobic components, are difficult to reconcile with a mask requirement, because even small increases in CO_2 can cause and intensify panic attacks [44,77–79].

According to a psychiatric study, patients with moderate to severe dementia have no understanding of COVID-19 protection measures and have to be persuaded to wear masks constantly [80].

According to a comparative study, patients with schizophrenia have a lower acceptance of mask-wearing (54.9% agreement) than ordinary practice patients (61.6%) [81]. The extent to which mask-wearing can lead to an exacerbation of schizophrenia symptoms has not yet been researched in detail.

When wearing masks, confusion, impaired thinking, disorientation (standardized recording via special rating and Likert scales, $p < 0.05$) and in some cases a decrease in maximum speed and reaction time (measured with the linear-position transducer, $p < 0.05$) were observed [19,32,36,38–41]. Psychotropic drugs reduce psycho-motoric functions in psychiatric patients. This can become clinically relevant especially with regard to the further reduced ability to react and the additional increased susceptibility to accidents of such patients when wearing masks.

In order to avoid an unintentional CO_2-triggered anesthesia [39], fixed and medically sedated patients, without the possibility of continuous monitoring, should not be masked according to the criteria of the Centers for Disease Control and Prevention, USA (CDC). This is because of the possible CO_2 retention described above, as there is a risk of unconsciousness, aspiration and asphyxia [16,17,20,38,82,83].

3.6. Gynaecological Side Effects and Dangers

As a critical variable, a low blood carbon dioxide level in pregnant women is maintained via an increased respiratory minute volume, stimulated by progesterone [22]. For a pregnant woman and her unborn child, there is a metabolic need for a fetal–maternal carbon dioxide (CO_2) gradient. The mother's blood carbon dioxide level should always be lower than that of the unborn child in order to ensure the diffusion of CO_2 from the fetal blood into the maternal circulation via the placenta.

Therefore, mask-related phenomena described above (Sections 3.1 and 3.2), such as the measurable changes in respiratory physiology with increased breathing resistance, increased dead space volume (Figure 3) and the retention of exhaled carbon dioxide (CO_2) are of importance. If CO_2 is increasingly rebreathed under masks, this manifestation could, even with subliminal carbon dioxide increases, act as a disturbing variable of the fetal–maternal CO_2 gradient increasing over time of exposure and, thus, develop clinical relevance, also with regard to a reduced compensation reserve of the expectant mothers [20,22,28].

In a comparative study, 22 pregnant women wearing N95 masks during 20 min of exercise showed significantly higher percutaneous CO_2 values, with average $PtcCO_2$ values of 33.3 mmHg compared to 31.3 mmHg than in 22 pregnant women without masks ($p = 0.04$) [22]. The heat sensation of the expectant mothers was also significantly increased with masks, with $p < 0.001$ [22].

Accordingly, in another intervention study, researchers demonstrated that breathing through an N95 mask (FFP2 equivalent) impeded gas exchange in 20 pregnant women at rest and during exercise, causing additional stress on their metabolic system [28]. Thus, under an N95 mask, 20 pregnant women showed a decrease in oxygen uptake capacity VO_2 of about 14% (statistically significant, $p = 0.013$) and a decrease in carbon dioxide output capacity VCO_2 of about 18% (statistically significant, $p = 0.001$). Corresponding significant changes in exhaled oxygen and carbon dioxide equivalents were also documented with increases in exhaled carbon dioxide ($FeCO_2$) ($p < 0.001$) and decreases in exhaled oxygen (FeO_2) ($p < 0.001$), which were explained by an altered metabolism due to respiratory mask obstruction [28].

In experiments with predominantly short mask application times, neither the mothers nor the fetuses showed statistically significant increases in heart rates or changes in respiratory rates and oxygen saturation values. However, the exact effects of prolonged mask use in pregnant women remain unclear overall. Therefore, in pregnant women, extended use of surgical and N95 masks is viewed critically [20].

In addition, it is unclear whether the substances contained in industrially manufactured masks that can be inhaled over longer periods of time (e.g., formaldehyde as an ingredient of the textile and thiram as an ingredient of the ear bands) are teratogenic [20,84].

3.7. Dermatological Side Effects and Dangers

Unlike garments worn over closed skin, masks cover body areas close to the mouth and nose, i.e., body parts that are involved with respiration.

Inevitably, this leads not only to a measurable temperature rise [15,44,85], but also to a severe increase in humidity due to condensation of the exhaled air, which in turn changes the natural skin milieu considerably of perioral and perinasal areas [36,61,82]. It also increases the redness, pH-value, fluid loss through the skin epithelium, increased hydration and sebum production measurably [73]. Preexisting skin diseases are not only perpetuated by these changes, but also exacerbated. In general, the skin becomes more susceptible to infections and acne.

The authors of an experimental study were able to prove a disturbed barrier function of the skin after only 4 h of wearing a mask in 20 healthy volunteers, both for surgical masks and for N95 masks [73]. In addition, germs (bacteria, fungi and viruses) accumulate on the outside and inside of the masks due to the warm and moist environment [86–89]. They can cause clinically relevant fungal, bacterial or viral infections. The unusual increase in the detection of rhinoviruses in the sentinel studies of the German Robert Koch Institute (RKI) from 2020 [90] could be another indication of this phenomenon.

In addition, a region of the skin that is not evolutionarily adapted to such stimuli is subjected to increased mechanical stress. All in all, the above-mentioned facts cause the unfavorable dermatological effects with mask related adverse skin reactions like acne, rashes on the face and itch symptoms [91].

A Chinese research group reported skin irritation and itching when using N95 masks among 542 test participants and also a correlation between the skin damage that occurred and the time of exposure (68.9% at $\leq$6 h/day and 81.7% at >6 h/day) [92].

A New York study evaluated in a random sample of 343 participants the effects of frequent wearing of surgical mask type and N95 masks among healthcare workers during the COVID-19 pandemic. Wearing the masks caused headache in 71.4% of participants, in addition to drowsiness in 23.6%, detectable skin damage in 51% and acne in 53% of mask users [37].

On the one hand, direct mechanical skin lesions occur on the nose and cheekbones due to shear force, especially when masks are frequently put on and taken off [37,92].

On the other hand, masks create an unnaturally moist and warm local skin environment [29,36,82]. In fact, scientists were able to demonstrate a significant increase in humidity and temperature in the covered facial area in another study in which the test individuals wore masks for one hour [85]. The relative humidity under the masks was measured with a sensor (Atmo-Tube, San Francisco, CA, USA). The sensation of humidity and temperature in the facial area is more crucial for well-being than other body regions [36,44]. This can increase discomfort under the masks. In addition, the increase in temperature favors bacterial optimization.

The pressure of the masks also causes an obstruction of the flow physiology of lymph and blood vessels in the face, with the consequence of increased disturbance of skin function [73] and ultimately also contributing to acne in up to 53% of all wearers and other skin irritations in up to 51% of all wearers [36,37,82].

Other researchers examined 322 participants with N95 masks in an observational study and detected acne in up to 59.6% of them, itching in 51.4% and redness in 35.8% as side effects [72].

In up to 19.6% (273) of the 1393 wearers of different masks (community masks, surgical, N95 masks), itching could be objectified in one study, in 9% even severely. An atopic predisposition (allergy tendency) correlated with the risk of itching. The length of use was significantly related to the risk of itching ($p < 0.0001$) [93].

In another dermatological study from 2020, 96.9% of 876 users of all mask types (community masks, surgical masks, N95 masks) confirmed adverse problems with a significant increase in itching (7.7%), accompanied by fogging-up of glasses (21.3%), flushing (21.3%), slurred speech (12.3%) and difficulty breathing (35.9%) ($p < 0.01$) [71].

Apart from an increased incidence of acne [37,72,91] under masks, contact eczema and urticaria [94] are generally described in connection with hypersensitivities to ingredients of the industrially manufactured masks (surgical mask and N95) such as formaldehyde (ingredient of the textile) and thiram (ingredient of the ear bands) [73,84]. The hazardous substance thiram, originally a pesticide and corrosive, is used in the rubber industry as a optimization accelerator. Formaldehyde is a biocide and carcinogen and is used as a disinfectant in the industry.

Even isolated permanent hyperpigmentation as a result of post-inflammatory or pigmented contact dermatitis has been described by dermatologists after prolonged mask use [72,91].

3.8. ENT and Dental Side Effects and Dangers

There are reports from dental communities about negative effects of masks and are accordingly titled "mask mouth" [95]. Provocation of gingivitis (inflammation of the gums), halitosis (bad breath), candidiasis (fungal infestation of the mucous membranes with Candida albicans) and cheilitis (inflammation of the lips), especially of the corners of the mouth, and even plaque and caries are attributed to the excessive and improper use of masks. The main trigger of the oral diseases mentioned is an increased dry mouth due to a reduced saliva flow and increased breathing through the open mouth under the mask. Mouth breathing causes surface dehydration and reduced salivary flow rate (SFR) [95]. Dry mouth is scientifically proven due to mask wear [29]. The bad habit of breathing through the open mouth while wearing a mask seems plausible because such breathing pattern compensates for the increased breathing resistance, especially when inhaling through the masks [60,61]. In turn, the outer skin moisture [71,73,85] with altered skin flora, which has already been described under dermatological side effects (Section 3.7), is held responsible as an explanation for the inflammation of the lips and corners of the mouth (cheilitis) [95]. This clearly shows the disease-promoting reversal of the natural conditions caused by masks. The physiological internal moisture with external dryness in the oral cavity converts into internal dryness with external moisture.

ENT physicians recently discovered a new form of irritant rhinitis due to N95 mask use in 46 patients. They performed endoscopies and nasal irrigations on mask wearers, which were subsequently assessed pathologically. Clinical problems were recorded with standardized questionnaires. They found statistically significant evidence of mask-induced rhinitis and itching and swelling of the mucous membranes as well as increased sneezing ($p < 0.01$). Endoscopically, it showed an increased secretion and evidence of inhaled mask polypropylene fibers as the trigger of mucosal irritation [96].

In a study of 221 health care workers, ENT physicians objectified a voice disorder in 33% of mask users. The VHI-10 score of 1 to 10, which measures voice disorders, was on average 5.72 higher in these mask users (statistically significant with $p < 0.001$). The mask not only acted as an acoustic filter, provoking excessively loud speech, it also seems to trigger impaired vocal cord coordination because the mask compromises the pressure gradients required for undisturbed speech [43]. The researchers concluded from their findings that masks could pose a potential risk of triggering new voice disorders as well as exacerbating existing ones.

3.9. Sports Medicine Side Effects and Dangers

According to the literature, performance-enhancing effects of masks regarding cardiovascular optimization and improvement of oxygen uptake capacity cannot be proven.

For example, in an experimental reference study (12 subjects per group), the training mask that supposedly mimics altitude training (ETM: elevation training mask) only had training effects on the respiratory muscles. However, mask wearers showed significantly lower oxygen saturation values (SpO_2%) during exercise (SpO_2 of 94% for mask wearers versus 96% for mask-less, $p < 0.05$) [33], which can be explained by an increased dead space volume and increased resistance during breathing. The measured oxygen saturation values were significantly lower than the normal values in the group of mask wearers, which indicates a clinical relevance.

The proven adaptation effect of the respiratory muscles in healthy athletes [33] clearly suggests that masks have a disruptive effect on respiratory physiology.

In another intervention study on mask use in weightlifters, researchers documented statistically significant effects of reduced attention (questionnaire recording, Likert scale) and a slowed maximum speed of movement detectable by means of sensors (both significant at $p < 0.001$), leading the researchers to conclude that mask use in sport is not without risks. As a secondary finding, they also detected a significant decrease in oxygen saturation SpO_2 when performing special weight-lifting exercises ("back squats") in the mask group after only 1 min of exercise compared to the mask-free group ($p < 0.001$) [32]. The proven tendency of the masks to shift the chemical parameter oxygen saturation SpO_2 in a pathological direction (lower limit value 95%) may well have clinical relevance in untrained or sick individuals.

Sports medicine confirmed an increase in carbon dioxide (CO_2) retention, with an elevation in CO_2 partial pressure in the blood with larger respiratory dead space volumes [14].

In fact, dead space-induced CO_2 retention while wearing a mask during exercise was also experimentally proven. The effects of a short aerobic exercise under N95 masks were tested on 16 healthy volunteers. A significantly increased end-expiratory partial pressure of carbon dioxide ($PETCO_2$) with plus 8 mmHg ($p < 0.001$) was found [24]. The increase in blood carbon dioxide (CO_2) in the mask wearers under maximum load was plus 14% CO_2 for surgical masks and plus 23% CO_2 for N95 masks, an effect that may well have clinical relevance in the pre-diseased, elderly and children, as these values strongly approached the pathological range [24].

In an interesting endurance study with eight middle-aged subjects (19–66), the gas content for O_2 and CO_2 under the masks was determined before and after exercise. Even at rest, the oxygen availability under the masks was 13% lower than without the masks and the carbon dioxide (CO_2) concentration was 30 times higher. Under stress (Ruffier test), the oxygen concentration (% O_2) below the mask dropped significantly by a further 3.7%, while the carbon dioxide concentration (% CO_2) increased significantly by a further 20% (statistically significant with $p < 0.001$). Correspondingly, the oxygen saturation of the blood (SpO_2) of the test persons also decreased significantly from 97.6 to 92.1% ($p < 0.02$) [18]. The drop in the oxygen saturation value (SpO_2) to 92%, clearly below the normal limit of 95%, is to be classified as clinically relevant and detrimental to health.

These facts are an indication that the use of masks also triggers the effects described above leading to hypoxia and hypercapnia in sports. Accordingly, the WHO and Centers for Disease Control and Prevention, GA, USA (CDC) advise against wearing masks during physical exercise [82,97].

3.10. Social and Sociological Side Effects and Dangers

The results of a Chilean study with health care workers show that masks act like an acoustic filter and provoke excessively loud speech. This causes a voice disorder [43]. The increased volume of speech also contributes to increased aerosol production by the mask wearer [98]. These experimental data measured with the Aerodynamic Particle Sizer (APS, TSI, model 332, TSI Incorporated, Minnesota, MI, USA) are highly relevant.

Moreover, mask wearers are prevented from interacting normally in everyday life due to impaired clarity of speech [45], which tempts them to get closer to each other.

This results in a distorted prioritization in the general public, which counteracts the recommended measures associated with the COVID-19 pandemic. The WHO prioritizes social distancing and hand hygiene with moderate evidence and recommends wearing a mask with weak evidence, especially in situations where individuals are unable to maintain a physical distance of at least 1 m [3].

The disruption of non-verbal communication due to the loss of facial expression recognition under the mask can increase feelings of insecurity, discouragement and numbness as well as isolation, which can be extremely stressful for the mentally and hearing-impaired [16].

Experts point out that masks disrupt the basics of human communication (verbal and nonverbal). The limited facial recognition caused by masks leads to a suppression of emotional signals. Masks, therefore, disrupt social interaction, erasing the positive effect of smiles and laughter but at the same time greatly increasing the likelihood of misunderstandings because negative emotions are also less evident under masks [42].

A decrease in empathy perception through mask use with disruption of the doctor–patient relationship has already been scientifically proven on the basis of a randomized study (statistically significant, with $p = 0.04$) [99]. In this study, the Consultation Empathy Care Measury, the Patient Enablement Instrument (PEI) Score and a Satisfaction Rating Scale were assessed in 1030 patients. The 516 doctors, who wore masks throughout, conveyed reduced empathy towards the patients and, thus, nullified the positive health-promoting effects of a dynamic relationship. These results demonstrate a disruption of interpersonal interaction and relationship dynamics caused by masks.

The WHO guidance on the use of masks in children in the community, published in August 2020, points out that the benefits of mask use in children must be weighed up against the potential harms, including social and communicational concerns [100].

Fears that widespread pandemic measures will lead to dysfunctional social life with degraded social, cultural and psychological interactions have also been expressed by other experts [6–8,42].

3.11. Social and Occupational Medicine Side Effects and Hazards

In addition to mask-specific complaints such as a feeling of heat, dampness, shortness of breath and headache, various physiological phenomena were documented, such as the significant increase in heart and respiratory rate, the impairment of lung function parameters, the decrease in cardiopulmonary capacity (e.g., lower maximum blood lactate response) [15,19,21,23,29–31], as well as the changes in oxygen and carbon dioxide both in the end-expiratory and the air under the mask that was measured in the blood of the individuals [13,15,18,19,21–25,27–34]. The significant changes were measurable after only a few minutes of wearing a mask and in some cases reached magnitudes of minus 13% reduced O_2 concentration and 30-fold increased CO_2 concentration of the inhaled air under masks ($p < 0.001$) [18]. The changes observed were not only statistically significant, but also clinically relevant; the subjects also showed pathological oxygen saturation after exposure to masks ($p < 0.02$) [18].

Shortness of breath during light exertion (6 min walking) under surgical masks has been recorded with statistical significance in 44 healthy subjects in a prospective experimental intervention study ($p < 0.001$) [101]. Here, the complaints were assessed using a subjective, visual analogue scale.

In another study from 2011, all tested masks caused a significantly measurable increase in discomfort and a feeling of exhaustion in the 27 subjects during prolonged usage ($p < 0.0001$) [69].

These symptoms lead to additional stress for the occupational mask wearer and, thus, in relation to the feeling of exhaustion, contribute to the self-perpetuating vicious circle caused by the vegetative sympathetic activation, which further increases the respiratory and heart rate, blood pressure and increased sense of exhaustion [16,20,35,83].

Other studies showed that the psychological and physical effects of the masks can lead to an additional reduction in work performance (measured with the Roberge Subjective Symptoms-during-Work Scale, a Likert scale of 1–5) via increased feelings of fatigue, dissatisfaction and anxiety [58,102,103].

Wearing masks over a longer period of time also led to physiological and psychological impairments in other studies and, thus, reduced work performance [19,36,58,69]. In experiments on respiratory-protective equipment, an increase in the dead space volume by 350 mL leads to a reduction in the possible performance time by approx. −19%, furthermore to a decrease in breathing comfort by −18% (measured via a subjective rating scale) [58]. In addition, the time spent working and the flow of work is interrupted and reduced by putting on and taking off the masks and changing them. The reduced work performance has been recorded in the literature found as described above (especially in Sections 3.1 and 3.2) but has not been quantified further in detail [36,58].

Surgical mask type and N95 protective equipment frequently caused adverse effects in medical personnel such as headaches, breathing difficulties, acne, skin irritation, itching, decreased alertness, decreased mental performance and feelings of dampness and heat [19,29,37,71,85]. Subjective, work performance-reducing, mask-related impairments in users, measured with special survey scores and Likert scales, have also been described in other studies [15,21,27,32,35,43,66–68,72,96,99].

In Section 3.7 on dermatology, we already mentioned a paper that demonstrated a significant temperature increase of 1.9 °C on average (to over 34.5 °C) in the mask-covered facial area ($p < 0.05$) [85]. Due to the relatively larger representation in the sensitive cerebral cortex (homunculus), the temperature sensation in the face is more decisive for the feeling of well-being than other body regions [36,44]. The perception of discomfort when wearing a mask can, thus, be intensified. Interestingly, in our analysis, we found a combined occurrence of the physical variable temperature rise under the mask and the symptom respiratory impairment in seven of eight studies concerned, with a mutual significantly measured occurrence in 88%. We also detected a combined occurrence of significantly measured temperature rise under the mask and significantly measured fatigue in 50% of the relevant primary studies (three of six papers, Figure 2). These clustered associations of temperature rise with symptoms of respiratory impairment and fatigue suggest a clinical relevance of the detected temperature rise under masks. In the worst case scenario, the effects mentioned can reinforce each other and lead to decompensation, especially in the presence of COPD, heart failure and respiratory insufficiency.

The sum of the disturbances and discomforts that can be caused by a mask also contributes to distraction (see also psychological impairment). These, in conjunction with a decrease in psycho-motoric skills, reduced responsiveness and overall impaired cognitive performance (all of which are pathophysiological effects of wearing a mask) [19,29,32,39–41] can lead to a failure to recognize hazards and, thus, to accidents or avoidable errors at work [19,36,37]. Of particular note here are mask-induced listlessness ($p < 0.05$), impaired thinking ($p < 0.05$) and concentration problems ($p < 0.02$) as measured by a Likert scale (1–5) [29]. Accordingly, occupational health regulations take action against such scenarios. The German Industrial Accident Insurance (DGUV) has precise and extensive regulations for respiratory protective equipment where they document the limitation of wearing time, levels of work intensity and defined instruction obligation [104].

The standards and norms prescribed in many countries regarding different types of masks to protect their workers are also significant from an occupational health point of view [105]. In Germany, for example, there are very strict safety specifications for masks from other international countries. These specify the requirements for the protection of the wearer [106]. All these standards and the accompanying certification procedures were increasingly relaxed with the introduction of mandatory masks for the general public. This meant that non-certified masks such as community masks were also used on a large scale in the work and school sectors for longer periods during the pandemic measures [107]. Most recently, in October 2020, the German Social Accident Insurance (DGUV) recommended the same usage time limits for community masks as for filtering half masks, namely, a maximum of three shifts of 120 min per day with recovery breaks of 30 min in between. In Germany, FFP2 (N95) masks must be worn for 75 min, followed by a 30-minute break. An additional suitability examination by specialized physicians is also obligatory and stipulated for occupationally used respirators [104].

3.12. Microbiological Consequences for Wearer and Environment: Foreign/Self-Contamination

Masks cause retention of moisture [61]. Poor filtration performance and incorrect use of surgical masks and community masks, as well as their frequent reuse, imply an increased risk of infection [108–110]. The warm and humid environment created by and in masks without the presence of protective mechanisms such as antibodies, the complement system, defense cells and pathogen-inhibiting and on a mucous membrane paves the way for unimpeded growth and, thus, an ideal growth and breeding ground for various pathogens such as bacteria and fungi [88] and also allows viruses to accumulate [87]. The warm and humid mask microclimate favors the accumulation of various germs on and underneath the masks [86], and the germ density is measurably proportional to the length of time the mask is worn. After only 2 h of wearing the mask, the pathogen density increases almost tenfold in experimental observation studies [87,89].

From a microbiological and epidemiological point of view, masks in everyday use pose a risk of contamination. This can occur as foreign contamination but also as self-contamination. On the one hand, germs are sucked in or attach themselves to the masks through convection currents. On the other hand, potential infectious agents from the nasopharynx accumulate excessively on both the outside and inside of the mask during breathing [5,88]. This is compounded by contact with contaminated hands. Since masks are constantly penetrated by germ-containing breath and the pathogen reproduction rate is higher outside mucous membranes, potential infectious pathogens accumulate excessively on the outside and inside of masks. On and in the masks, there are quite serious, potentially disease-causing bacteria and fungi such as *E. coli* (54% of all germs detected), Staphylococcus aureus (25% of all germs detected), Candida (6%), Klebsiella (5%), Enterococci (4%), Pseudomonads (3%), Enterobacter (2%) and Micrococcus (1%) even detectable in large quantities [88].

In another microbiological study, the bacterium Staphylococcus aureus (57% of all bacteria detected) and the fungus Aspergillus (31% of all fungi detected) were found to be the dominant germs on 230 surgical masks examined [86].

After more than six hours of use, the following viruses were found in descending order on 148 masks worn by medical personnel: adenovirus, bocavirus, respiratory syncytial virus and influenza viruses [87].

From this aspect, it is also problematic that moisture distributes these potential pathogens in the form of tiny droplets via capillary action on and in the mask, whereby further proliferation in the sense of self- and foreign contamination by the aerosols can then occur internally and externally with every breath [35]. In this regard, it is also known from the literature that masks are responsible for a proportionally disproportionate production of fine particles in the environment and, surprisingly, much more so than in people without masks [98].

It was shown that all mask-wearing subjects released significantly more smaller particles of size 0.3–0.5 μm into the air than mask-less people, both when breathing, speaking and coughing (fabric, surgical, N95 masks, measured with the Aerodynamic Particle Sizer, APS, TS, model 3329) [98]. The increase in the detection of rhinoviruses in the sentinel studies of the German RKI from 2020 [90] could be a further indication of this phenomenon, as masks were consistently used by the general population in public spaces in that year.

3.13. Epidemiological Consequences

The possible side effects and dangers of masks described in this paper are based on studies of different types of masks. These include the professional masks of the surgical mask type and N95/KN95 (FFP2 equivalent) that are commonly used in everyday life, but also the community fabric masks that were initially used. In the case of N95, the N stands for National Institute for Occupational Safety and Health of the United States (NIOSH), and 95 indicates the 95 per cent filtering capacity for fine particles up to at least 0.3 μm [82].

A major risk of mask use in the general public is the creation of a false sense of security with regard to protection against viral infections, especially in the sense of a falsely assumed strong self-protection. Disregarding infection risks may not only neglect aspects of source control, but also result in other disadvantages. Although there are quite a few professional positive accounts of the widespread use of masks in the general populace [111], most of the serious and evident scientific reports conclude that the general obligation to wear masks conveys a false sense of security [4,5]. However, this leads to a neglect of those measures that, according to the WHO, have a higher level of effectiveness than mask-wearing: social distancing and hand hygiene [2,112]. Researchers were able to provide statistically significant evidence of a false sense of security and more risky behavior when wearing masks in an experimental setting [112].

Decision makers in many countries informed their citizens early on in the pandemic in March 2020 that people without symptoms should not use a medical mask, as this created a false sense of security [113]. The recommendation was ultimately changed in many countries. At least Germany pointed out that wearers of certain types of masks such as the common fabric masks (community masks) cannot rely on them to protect them or others from transmission of SARS-CoV-2 [114].

However, scientists not only complain about the lack of evidence for fabric masks in the scope of a pandemic [16,110], but also about the high permeability of fabric masks with particles and the potential risk of infection they pose [108,109]. Ordinary fabric masks with a 97% penetration for particle dimensions of $\geq$0.3 μm are in stark contrast to medical-type surgical masks with a 44% penetration. In contrast, the N95 mask has a penetration rate of less than 0.01% for particles $\geq$ 0.3 μm in the laboratory experiment [108,115].

For the clinical setting in hospitals and outpatient clinics, the WHO guidelines recommend only surgical masks for influenza viruses for the entire patient treatment except for the strongly aerosol-generating measures, for which finer filtering masks of the type N95 are suggested. However, the WHO's endorsement of specific mask types is not entirely evidence-based due to the lack of high-quality studies in the health sector [108,109,116,117].

In a laboratory experiment (evidence level IIa study), it was demonstrated that both surgical masks and N95 masks have deficits in protection against SARS-CoV-2 and influenza viruses using virus-free aerosols [118]. In this study, the FFP2-equivalent N95 mask performed significantly better in protection (8–12 times more effective) than the surgical mask, but neither mask type established reliable, hypothesis-generated protection against corona and influenza viruses. Both mask types could be penetrated unhindered by aerosol particles with a diameter of 0.08 to 0.2 μm. Both the SARS-CoV-2 pathogens with a size of 0.06 to 0.14 μm [119] and the influenza viruses with 0.08 to 0.12 μm are unfortunately well below the mask pore sizes [118].

The filtering capacity of the N95 mask up to 0.3 μm [82] is usually not achieved by surgical masks and community masks. However, aerosol droplets, which have a diameter of 0.09 to 3 μm in size, are supposed to serve as a transport medium for viruses. These also penetrate the medical masks by 40%. Often, there is also a poor fit between the face and the mask, which further impairs their function and safety [120]. The accumulation of aerosol droplets on the mask is problematic. Not only do they absorb nanoparticles such as viruses [6], but they also follow the airflow when inhaling and exhaling, causing them to be carried further. In addition, a physical decay process has been described for aerosol droplets at increasing temperatures, as also occurs under a mask [15,44,85]. This process can lead to a decrease in size of the fine water droplets up to the diameter of a virus [121,122]. The masks filter larger aerosol droplets but cannot retain viruses themselves and such smaller, potentially virus-containing aerosol droplets of less than 0.2 μm and hence cannot stop the spread of virus [123].

Similarly, in an in vivo comparative studies of N95 and surgical masks, there were no significant differences in influenza virus infection rates [124,125]. Although this contrasts with encouraging in vitro laboratory results with virus-free aerosols under non-natural conditions, even with fabric masks [126], it should be noted that under natural in-vivo conditions, the promising filtration functions of fabric masks based on electrostatic effects also rapidly diminish under increasing humidity [127]. A Swiss textile lab test of various masks available on the market to the general public recently confirmed that most mask types filter aerosols insufficiently. For all but one of the eight reusable fabric mask types tested, the filtration efficacy according to EN149 was always less than 70% for particles of 1 μm in size. For disposable masks, only half of all eight mask types tested were efficient enough at filtering to retain 70% of particles 1 μm in size [128].

A recent experimental study even demonstrated that all mask-wearing people (surgical, N95, fabric masks) release significantly and proportionately smaller particles of size 0.3 to 0.5 μm into the air than mask-less people, both when breathing, speaking and coughing [98]. According to this, the masks act like nebulizers and contribute to the production of very fine aerosols. Smaller particles, however, spread faster and further than large ones for physical reasons. Of particular interest in this experimental reference study was the finding that a test subject wearing a single-layer fabric mask was also able to release a total of 384% more particles (of various sizes) when breathing than a person without [98].

It is not only the aforementioned functional weaknesses of the masks themselves that lead to problems, but also their use. This increases the risk of a false sense of security. According to the literature, mistakes are made by both healthcare workers and lay people when using masks as hygienically correct mask use is by no means intuitive. Overall, 65% of healthcare professionals and as many as 78% of the general population, use masks incorrectly [116]. With both surgical masks and N95 masks, adherence to the rules of use is impaired and not adequately followed due to reduced wearability with heat discomfort and skin irritation [29,35,116,129]. This is exacerbated by the accumulation of carbon dioxide due to the dead space (especially under the N95 masks) with the resulting headaches described [19,27,37,66–68,83]. Increased heart rate, itching and feelings of dampness [15,29,30,35,71] also lead to reduced safety and quality during use (see also social and occupational health side effects and hazards). For this reason, (everyday) masks are even considered a general risk for infection in the general population, which does not come close to imitating the strict hygiene rules of hospitals and doctors' offices: the supposed safety, thus, becomes a safety risk itself [5].

In a meta-analysis of evidence level Ia commissioned by the WHO, no effect of masks in the context of influenza virus pandemic prevention could be demonstrated [130]. In 14 randomized controlled trials, no reduction in the transmission of laboratory-confirmed influenza infections was shown. Due to the similar size and distribution pathways of the virus species (influenza and Corona, see above), the data can also be transferred to SARS-CoV-2 [118]. Nevertheless, a combination of occasional mask-wearing with adequate hand-washing caused a slight reduction in infections for influenza in one study [131]. However, since no separation of hand hygiene and masks was achieved in this study, the protective effect can rather be attributed to hand hygiene in view of the aforementioned data [131].

A recently published large prospective Danish comparative study comparing mask wearers and non-mask wearers in terms of their infection rates with SARS-CoV2 could not demonstrate any statistically significant differences between the groups [132].

3.14. Paediatric Side Effects and Hazards

Children are particularly vulnerable and may be more likely to receive inappropriate treatment or additional harm. It can be assumed that the potential adverse mask effects described for adults are all the more valid for children (see Section 3.1 to Section 3.13: physiological internal, neurological, psychological, psychiatric, dermatological, ENT, dental, sociological, occupational and social medical, microbiological and epidemiological impairments and also Figures 2 and 3).

Special attention must be paid to the respiration of children, which represents a critical and vulnerable physiological variable due to higher oxygen demand, increased hypoxia susceptibility of the CNS, lower respiratory reserve, smaller airways with a stronger increase in resistance when the lumen is narrowed. The diving reflex caused by stimulating the nose and upper lip can cause respiratory arrest to bradycardia in the event of oxygen deficiency.

The masks currently used for children are exclusively adult masks manufactured in smaller geometric dimensions and had neither been specially tested nor approved for this purpose [133].

In an experimental British research study, the masks frequently led to feelings of heat ($p < 0.0001$) and breathing problems ($p < 0.03$) in 100 school children between 8 and 11 years of age especially during physical exertion, which is why the protective equipment was taken off by 24% of the children during physical activity [133]. The exclusion criteria for this mask experiment were lung disease, cardiovascular impairment and claustrophobia [133].

Scientists from Singapore were able to demonstrate in their level Ib study published in the renowned journal "nature" that 106 children aged between 7 and 14 years who wore FFP2 masks for only 5 min showed an increase in the inspiratory and expiratory CO_2 levels, indicating disturbed respiratory physiology [26].

However, a disturbed respiratory physiology in children can have long-term disease-relevant consequences. Slightly elevated CO_2 levels are known to increase heart rate, blood pressure, headache, fatigue and concentration disorders [38].

Accordingly, the following conditions were listed as exclusion criteria for mask use [26]: any cardiopulmonary disease including but not limited to: asthma, bronchitis, cystic fibrosis, congenital heart disease, emphysema; any condition that may be aggravated by physical exertion, including but not limited to: exercise-induced asthma; lower respiratory tract infections (pneumonia, bronchitis within the last 2 weeks), anxiety disorders, diabetes, hypertension or epilepsy/attack disorder; any physical disability due to medical, orthopedic or neuromuscular disease; any acute upper respiratory illness or symptomatic rhinitis (nasal obstruction, runny nose or sneezing); any condition with deformity that affects the fit of the mask (e.g., increased facial hair, craniofacial deformities, etc.).

It is also important to emphasize the possible effects of masks in neurological diseases, as described earlier (Section 3.3).

Both masks and face shields caused fear in 46% of children (37 out of 80) in a scientific study. If children are given the choice of whether the doctor examining them should wear a mask they reject this in 49% of the cases. Along with their parents, the children prefer the practitioner to wear a face visor (statistically significant with $p < 0.0001$) [134].

A recent observational study of tens of thousands of mask-wearing children in Germany helped the investigators objectify complaints of headaches (53%), difficulty concentrating (50%), joylessness (49%), learning difficulties (38%) and fatigue in 37% of the 25,930 children evaluated. Of the children observed, 25% had new onset anxiety and even nightmares [135]. In children, the threat scenarios generated by the environment are further maintained via masks, in some cases, even further intensified, and in this way, existing stress is intensified (presence of subconscious fears) [16,35,136,137].

This can in turn lead to an increase in psychosomatic and stress-related illnesses [74,75]. For example, according to an evaluation, 60% of mask wearers showed stress levels of the highest grade 10 on a scale of 1 to a maximum of 10. Less than 10% of the mask wearers surveyed had a stress level lower than 8 out of a possible 10 [74].

As children are considered a special group, the WHO also issued a separate guideline on the use of masks in children in the community in August 2020, explicitly advising policy makers and national authorities, given the limited evidence, that the benefits of mask use in children must be weighed up against the potential harms associated with mask use. This includes feasibility and discomfort, as well as social and communication concerns [100].

According to experts, masks block the foundation of human communication and the exchange of emotions and not only hinder learning but deprive children of the positive effects of smiling, laughing and emotional mimicry [42]. The effectiveness of masks in children as a viral protection is controversial, and there is a lack of evidence for their widespread use in children; this is also addressed in more detail by the scientists of the German University of Bremen in their thesis paper 2.0 and 3.0 [138].

3.15. Effects on the Environment

According to WHO estimates of a demand of 89 million masks per month, their global production will continue to increase under the Corona pandemic [139]. Due to the composition of, e.g., disposable surgical masks with polymers such as polypropylene, polyurethane, polyacrylonitrile, polystyrene, polycarbonate, polyethylene and polyester [140], an increasing global challenge, also from an environmental point of view, can be expected, especially outside Europe, in the absence of recycling and disposal strategies [139]. The aforementioned single use polymers have been identified as a significant source of plastic and plastic particles for the pollution of all water cycles up to the marine environment [141].

A significant health hazard factor is contributed by mask waste in the form of microplastics after decomposition into the food chain. Likewise, contaminated macroscopic disposable mask waste—especially before microscopic decay—represents a widespread medium for microbes (protozoa, bacteria, viruses, fungi) in terms of invasive pathogens [86–89,142]. Proper disposal of bio-contaminated everyday mask material is insufficiently regulated even in western countries.

4. Discussion

The potential drastic and undesirable effects found in multidisciplinary areas illustrate the general scope of global decisions on masks in general public in the light of combating the pandemic. According to the literature found, there are clear, scientifically recorded adverse effects for the mask wearer, both on a psychological and on a social and physical level.

Neither higher level institutions such as the WHO or the European Centre for Disease Prevention and Control (ECDC) nor national ones, such as the Centers for Disease Control and Prevention, GA, USA (CDC) or the German RKI, substantiate with sound scientific data a positive effect of masks in the public (in terms of a reduced rate of spread of COVID-19 in the population) [2,4,5].

Contrary to the scientifically established standard of evidence-based medicine, national and international health authorities have issued their theoretical assessments on the masks in public places, even though the compulsory wearing of masks gives a deceptive feeling of safety [5,112,143].

From an infection epidemiological point of view, masks in everyday use offer the risk of self-contamination by the wearer from both inside and outside, including via contaminated hands [5,16,88]. In addition, masks are soaked by exhaled air, which potentially accumulates infectious agents from the nasopharynx and also from the ambient air on the outside and inside of the mask. In particular, serious infection-causing bacteria and fungi should be mentioned here [86,88,89], but also viruses [87]. The unusual increase in the detection of rhinoviruses in the sentinel studies of the German RKI from 2020 [90] could be an indication of this phenomenon. Clarification through further investigations would therefore be desirable.

Masks, when used by the general public, are considered by scientists to pose a risk of infection because the standardized hygiene rules of hospitals cannot be followed by the general public [5]. On top of that, mask wearers (surgical, N95, fabric masks) exhale relatively smaller particles (size 0.3 to 0.5 μm) than mask-less people and the louder speech under masks further amplifies this increased fine aerosol production by the mask wearer (nebulizer effect) [98].

The history of modern times shows that already in the influenza pandemics of 1918–1919, 1957–58, 1968, 2002, in SARS 2004–2005 as well as with the influenza in 2009, masks in everyday use could not achieve the hoped-for success in the fight against viral infection scenarios [67,144]. The experiences led to scientific studies describing as early as 2009 that masks do not show any significant effect with regard to viruses in an everyday scenario [129,145]. Even later, scientists and institutions rated the masks as unsuitable to protect the user safely from viral respiratory infections [137,146,147]. Even in hospital use, surgical masks lack strong evidence of protection against viruses [67].

Originally born out of the useful knowledge of protecting wounds from surgeons' breath and predominantly bacterial droplet contamination [144,148,149], the mask has been visibly misused with largely incorrect popular everyday use, particularly in Asia in recent years [150]. Significantly, the sociologist Beck described the mask as a cosmetic of risk as early as 1992 [151]. Unfortunately, the mask is inherent in a vicious circle: strictly speaking, it only protects symbolically and at the same time represents the fear of infection. This phenomenon is reinforced by the collective fear mongering, which is constantly nurtured by main stream media [137].

Nowadays, the mask represents a kind of psychological support for the general population during the virus pandemic, promising them additional anxiety-reduced freedom of movement. The recommendation to use masks in the sense of "source control" not out of self-protection but out of "altruism" [152] is also very popular with the regulators as well as the population of many countries. The WHO's recommendation of the mask in the current pandemic is not only a purely infectiological approach, but is also clear on the possible advantages for healthy people in the general public. In particular, a reduced potential stigmatization of mask wearers, the feeling of a contribution made to preventing the spread of the virus, as well as the reminder to adhere to other measures are mentioned [2].

It should not go unmentioned that very recent data suggest that the detection of SARS-CoV-2 infection does not seem to be directly related to popular mask use. The groups examined in a retrospective comparative study (infected with SARS-CoV-2 and not infected) did not differ in their habit of using masks: approximately 70% of the subjects in both groups always wore masks and another 14.4% of them frequently [143].

In a Danish prospective study on mask-wearing carried out on about 6000 participants and published in 2020, scientists found no statistically significant difference in the rates of SARS-CoV-2 infection when comparing the group of 3030 mask wearers with the 2994 maskless participants in the study ($p = 0.38$) [132].

Indeed, in the case of viral infections, masks appear to be not only less effective than expected, but also not free of undesirable biological, chemical, physical and psychological side effects [67]. Accordingly, some experts claim that well-intentioned unprofessionalism can be quite dangerous [6].

The dermatological colleagues were the first to describe common adverse effects of mask-wearing in larger collectives. Simple, direct physical, chemical and biological effects of the masks with increases in temperature, humidity and mechanical irritation caused acne in up to 60% of wearers [37,71–73,85]. Other significantly documented consequences were eczema, skin damage and overall impaired skin barrier function [37,72,73].

These direct effects of mask use are an important pointer to further detrimental effects affecting other organ systems.

In our work, we have identified scientifically validated and numerous statistically significant adverse effects of masks in various fields of medicine, especially with regard to a disruptive influence on the highly complex process of breathing and negative effects on the respiratory physiology and gas metabolism of the body (see Figures 2 and 3). The respiratory physiology and gas exchange play a key role in maintaining a health-sustaining balance in the human body [136,153]. According to the studies we found, a dead space volume that is almost doubled by wearing a mask and a more than doubled breathing resistance (Figure 3) [59–61] lead to a rebreathing of carbon dioxide with every breathing cycle [16–18,39,83] with—in healthy people mostly—a subthreshold but, in sick people, a partly pathological increase in the carbon dioxide partial pressure ($PaCO_2$) in the blood [25,34,58]. According to the primary studies found, these changes contribute reflexively to an increase in respiratory frequency and depth [21,23,34,36] with a corresponding increase in the work of the respiratory muscles via physiological feedback mechanisms [31,36]. Thus, it is not, as initially assumed, purely positive training through mask use. This often increases the subliminal drop in oxygen saturation SpO_2 in the blood [23,28–30,32], which is already reduced by increased dead space volume and increased breathing resistance [18,31].

The overall possible resulting measurable drop in oxygen saturation O_2 of the blood on the one hand [18,23,28–30,32] and the increase in carbon dioxide (CO_2) on the other [13,15,19,21–28] contribute to an increased noradrenergic stress response, with heart rate increase [29,30,35] and respiratory rate increase [15,21,23,34], in some cases also to a significant blood pressure increase [25,35].

In panic-prone individuals, stress-inducing noradrenergic sympathetic activation can be partly directly mediated via the carbon dioxide (CO_2) mechanism at the locus coeruleus in the brainstem [39,78,79,153], but also in the usual way via chemo-sensitive neurons of the nucleus solitarius in the medulla [136,154]. The nucleus solitarius [136] is located in the deepest part of the brainstem, a gateway to neuronal respiratory and circulatory control [154]. A decreased oxygen (O_2) blood level there causes the activation of the sympathetic axis via chemoreceptors in the carotids [155,156].

Even subthreshold changes in blood gases such as those provoked when wearing a mask cause reactions in these control centers in the central nervous system. Masks, therefore, trigger direct reactions in important control centers of the affected brain via the slightest changes in oxygen and carbon dioxide in the blood of the wearer [136,154,155].

A link between disturbed breathing and cardiorespiratory diseases such as hypertension, sleep apnea and metabolic syndrome has been scientifically proven [56,57]. Interestingly, decreased oxygen/O_2 blood levels and also increased carbon dioxide/CO_2 blood levels are considered the main triggers for the sympathetic stress response [38,136]. The aforementioned chemo-sensitive neurons of the nucleus solitarius in the medulla are considered to be the main responsible control centers [136,154,155]. Clinical effects of prolonged mask-wearing would, thus, be a conceivable intensification of chronic stress reactions and negative influences on the metabolism leading towards a metabolic syndrome. The mask studies we found show that such disease-relevant respiratory gas changes (O_2 and CO_2) [38,136] are already achieved by wearing a mask [13,15,18,19,21–34].

A connection between hypoxia, sympathetic reactions and leptin release is scientifically known [136].

Additionally important is the connection of breathing with the influence on other bodily functions [56,57], including the psyche with the generation of positive emotions and drive [153]. The latest findings from neuro-psychobiological research indicate that respiration is not only a function regulated by physical variables to control them (feedback mechanism), but rather independently influences higher-level brain centers and, thus, also helps to shape psychological and other bodily functions and reactions [153,157,158]. Since masks impede the wearer's breathing and accelerate it, they work completely against the principles of health-promoting breathing [56,57] used in holistic medicine and yoga. According to recent research, undisturbed breathing is essential for happiness and healthy drive [157,159], but masks work against this.

The result of significant changes in blood gases in the direction of hypoxia (drop in oxygen saturation) and hypercapnia (increase in carbon dioxide concentration) through masks, thus, has the potential to have a clinically relevant influence on the human organism even without exceeding normal limits.

According to the latest scientific findings, blood-gas shifts towards hypoxia and hypercapnia not only have an influence on the described immediate, psychological and physiological reactions on a macroscopic and microscopic level, but additionally on gene expression and metabolism on a molecular cellular level in many different body cells. Through this, the drastic disruptive intervention of masks in the physiology of the body also becomes clear down to the cellular level, e.g., in the activation of hypoxia-induced factor (HIF) through both hypercapnia and hypoxia-like effects [160]. HIF is a transcription factor that regulates cellular oxygen supply and activates signaling pathways relevant to adaptive responses. e.g., HIF inhibits stem cells, promotes tumor cell growth and inflammatory processes [160]. Based on the hypoxia- and hypercapnia-promoting effects of masks, which have been comprehensively described for the first time in our study, potential disruptive influences down to the intracellular level (HIF-a) can be assumed, especially through the prolonged and excessive use of masks. Thus, in addition to the vegetative chronic stress reaction in mask wearers, which is channeled via brain centers, there is also likely to be an adverse influence on metabolism at the cellular level. With the prospect of continued mask use in everyday life, this also opens up an interesting field of research for the future.

The fact that prolonged exposure to latently elevated CO_2 levels and unfavorable breathing air compositions has disease-promoting effects was recognized early on. As early as 1983, the WHO described "Sick Building Syndrome" (SBS) as a condition in which people living indoors experienced acute disease-relevant effects that increased with time of their stay, without specific causes or diseases [161,162]. The syndrome affects people who spend most of their time indoors, often with subliminally elevated CO_2 levels, and are prone to symptoms such as increased heart rate, rise in blood pressure, headaches, fatigue and difficulty concentrating [38,162]. Some of the complaints described in the mask studies we found (Figure 2) are surprisingly similar to those of Sick Building Syndrome [161]. Temperature, carbon dioxide content of the air, headaches, dizziness, drowsiness and itching also play a role in Sick Building Syndrome. On the one hand, masks could themselves be responsible for effects such as those described for Sick Building Syndrome when used for a longer period of time. On the other hand, they could additionally intensify these effects when worn in air-conditioned buildings, especially when masks are mandatory indoors. Nevertheless, there was a tendency towards higher systolic blood pressure values in mask wearers in some studies [21,31,34], but statistical significance was only found in two studies [25,35]. However, we found more relevant and significant evidence of heart rate increase, headache, fatigue and concentration problems associated with mask wearers (Figure 2) indicating the clinical relevance of wearing masks.

According to the scientific results and findings, masks have measurably harmful effects not only on healthy people, but also on sick people and their relevance is likely to increase with the duration of use [69]. Further research is needed here to shed light on the long-term consequences of widespread mask use with subthreshold hypoxia and hypercapnia in the general population, also regarding possible exacerbating effects on cardiorespiratory lifestyle diseases such as hypertension, sleep apnea and metabolic syndrome. The already often elevated blood carbon dioxide (CO_2) levels in overweight people, sleep apnea patients and patients with overlap-COPD could possibly increase even further with everyday masks. Not only a high body mass index (BMI) but also sleep apnea are associated with hypercapnia during the day in these patients (even without masks) [19,163]. For such patients, hypercapnia means an increase in the risk of serious diseases with increased morbidity, which could then be further increased by excessive mask use [18,38].

The hypercapnia-induced effects of sympathetic stress activation are even cycle phase-dependent in women. Controlled by a progesterone mechanism, the sympathetic reaction, measured by increased blood pressure in the luteal phase, is considerably stronger [164]. This may also result in different sensitivities for healthy and sick women to undesirable effects masks have, which are related to an increase in carbon dioxide (CO_2).

In our review, negative physical and psychological changes caused by masks could be objectified even in younger and healthy individuals.

The physical and chemical parameters did not exceed the normal values in most cases but were statistically significantly measurable ($p < 0.05$) tending towards pathological ranges. They were accompanied by physical impairments (see Figure 2). It is well known that subthreshold stimuli are capable of causing pathological changes when exposed to them for a long time: not only a single high dose of a disturbance, but also a chronically persistent, subthreshold exposure to it often leads to illness [38,46–48,50–54]. The scientifically repeatedly measurable physical and chemical mask effects were often accompanied by typical subjective complaints and pathophysiological phenomena. The fact that these frequently occur simultaneously and together indicates a syndrome under masks.

Figure 2 sums up the significant mask-dependent physiological, psychological, somatic and general pathological changes and their frequent occurrence together is striking. Within the framework of the quantitative evaluation of the experimental studies, we were actually able to prove a statistically significant correlation of the observed side effects of fatigue and oxygen depletion under mask use with $p < 0.05$. In addition, we found a frequent, simultaneous and joint occurrence of further undesirable effects in the scientific studies (Figure 2). Statistically significant associations of such co-occurring, adverse effects have already been described in primary studies [21,29]. We detected a combined occurrence of the physical parameter temperature rise under the mask with the symptom respiratory impairment in seven of the nine studies concerned (88%). We found a similar result for the decrease in oxygen saturation under mask and the symptom respiratory impairment with a simultaneous detection in six of the eight studies concerned (67%). We detected a combined occurrence of carbon dioxide rise under N95 mask use in nine of the 11 scientific papers (82%). We found a similar result for oxygen drop under N95 mask use with simultaneous co-occurrence in eight of 11 primary papers (72%). The use of N95 masks was also associated with headache in six of the 10 primary studies concerned (60%). A combined occurrence of the physical parameters temperature rise and humidity under masks was even found 100% within six of the six studies with significant measurements of these parameters (Figure 2).

Since the symptoms were described in combination in mask wearers and were not observed in isolation in the majority of cases, we refer to them as general Mask-Induced Exhaustion Syndrome (MIES) because of the consistent presentation in numerous papers from different disciplines. These include the following, predominantly statistically significantly

($p < 0.05$) proven pathophysiological changes and subjective complaints, which often occur in combination as described above (see also Section 3.1 to Section 3.11, Figures 2–4):

- Increase in dead space volume [22,24,58,59] (Figure 3, Sections 3.1 and 3.2).
- Increase in breathing resistance [31,35,61,118] (Figure 3, Figure 2: Column 8).
- Increase in blood carbon dioxide [13,15,19,21–28] (Figure 2: Column 5).
- Decrease in blood oxygen saturation [18,19,21,23,28–34] (Figure 2: Column 4).
- Increase in heart rate [15,19,23,29,30,35] (Figure 2: Column 12).
- Decrease in cardiopulmonary capacity [31] (Section 3.2).
- Feeling of exhaustion [15,19,21,29,31–35,69] (Figure 2: Column 14).
- Increase in respiratory rate [15,21,23,34] (Figure 2: Column 9).
- Difficulty breathing and shortness of breath [15,19,21,23,25,29,31,34,35,71,85,101,133] (Figure 2: Column 13).
- Headache [19,27,37,66–68,83] (Figure 2: Column 17).
- Dizziness [23,29] (Figure 2: Column 16).
- Feeling of dampness and heat [15,16,22,29,31,35,85,133] (Figure 2: Column 7).
- Drowsiness (qualitative neurological deficits) [19,29,32,36,37] (Figure 2: Column 15).
- Decrease in empathy perception [99] (Figure 2: Column 19).
- Impaired skin barrier function with acne, itching and skin lesions [37,72,73] (Figure 2: Column 20–22).

It can be deduced from the results that the effects described in healthy people are all more pronounced in sick people, since their compensatory mechanisms, depending on the severity of the illness, are reduced or even exhausted. Some existing studies on and with patients with measurable pathological effects of the masks support this assumption [19,23,25,34]. In most scientific studies, the exposure time to masks in the context of the measurements/investigations was significantly less (in relation to the total wearing and duration of use) than is expected of the general public under the current pandemic regulations and ordinances.

The exposure time limits are little observed or knowingly disregarded in many areas today as already mentioned in Section 3.11 on occupational medicine. The above facts allow the conclusion that the described negative effects of masks, especially in some of our patients and the very elderly, may well be more severe and adverse with prolonged use than presented in some mask studies.

From a doctor's viewpoint, it may also be difficult to advise children and adults who, due to social pressure (to wear a mask) and the desire to feel they belong, suppress their own needs and concerns until the effects of masks have a noticeable negative impact on their health [76]. Nevertheless, the use of masks should be stopped immediately at the latest when shortness of breath, dizziness or vertigo occur [23,25]. From this aspect, it seems sensible for decision makers and authorities to provide information, to define instruction obligations and offer appropriate training for employers, teachers and other persons who have a supervisory or caregiving duty. Knowledge about first aid measures could also be refreshed and expanded accordingly in this regard.

Elderly, high-risk patients with lung disease, cardiac patients, pregnant women or stroke patients are advised to consult a physician to discuss the safety of an N95 mask as their lung volume or cardiopulmonary performance may be reduced [23]. A correlation between age and the occurrence of the aforementioned symptoms while wearing a mask has been statistically proven [19]. Patients with reduced cardiopulmonary function are at increased risk of developing serious respiratory failure with mask use according to the referenced literature [34]. Without the possibility of continuous medical monitoring, it can be concluded that they should not wear masks without close monitoring. The American Asthma and Allergy Society has already advised caution in the use of masks with regard to the COVID-19 pandemic for people with moderate and severe lung disease [165]. Since the severely overweight, sleep apnea patients and overlap-COPD sufferers are known to be prone to hypercapnia, they also represent a risk group for serious adverse health effects under extensive mask use [163]. This is because the potential of masks to produce additional

CO_2 retention may not only have a disruptive effect on the blood gases and respiratory physiology of sufferers, but may also lead to further serious adverse health effects in the long term. Interestingly, in an animal experiment an increase in CO_2 with hypercapnia leads to contraction of smooth airway muscles with constriction of bronchi [166]. This effect could explain the observed pulmonary decompensations of patients with lung disease under masks (Section 3.2) [23,34].

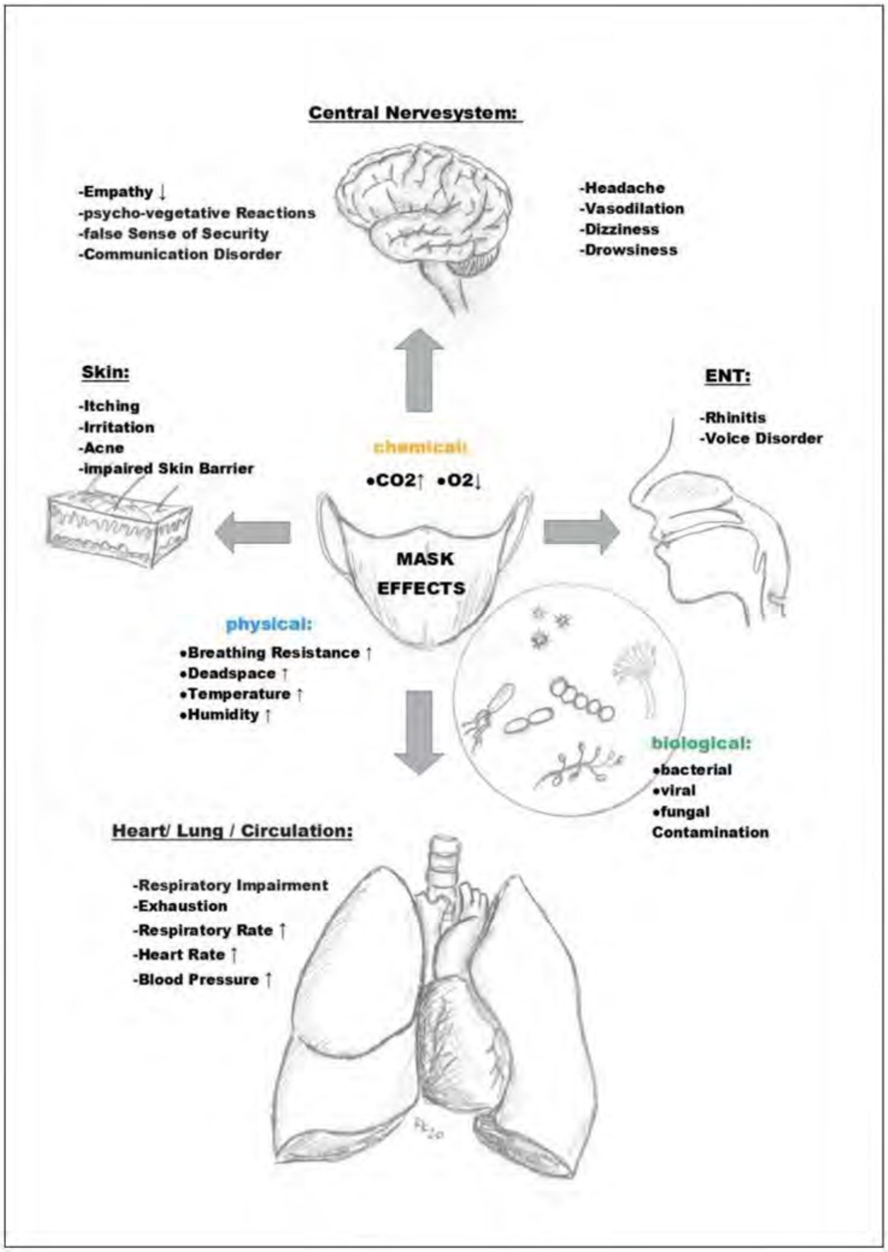

Figure 4. Unfavorable mask effects as components of Mask-Induced Exhaustion Syndrome (MIES). The chemical, physical and biological effects, as well as the organ system consequences mentioned, are all documented with statistically significant results in the scientific literature found (Figure 2). The term drowsiness is used here to summarize any qualitative neurological deficits described in the examined scientific literature.

Patients with renal insufficiency requiring dialysis are, according to the literature available, further candidates for a possible exemption from the mask requirement [34].

According to the criteria of the Centers for Disease Control and Prevention, GA, USA (CDC), sick and helpless people who cannot remove a mask on their own should be exempted from the mask requirement [82].

Since it can be assumed that children react even more sensitively to masks, the literature suggests that masks are a contraindication for children with epilepsies (hyperventilation as a trigger for seizures) [63]. In the field of pediatrics, special attention should also be paid to the mask symptoms described under psychological, psychiatric and sociological effects with possible triggering of panic attacks by CO_2 rebreathing in the case of predisposition and also reinforcement of claustrophobic fears [77–79,167]. The mask-related disturbance of verbal [43,45,71] and non-verbal communication and, thus, of social interaction is particularly serious for children. Masks restrict social interaction and block positive perceptions (smiling and laughing) and emotional mimicry [42]. The proven mask-induced mild to moderate cognitive impairment with impaired thinking, decreased attention and dizziness [19,23,29,32,36,37,39–41,69], as well as the psychological and neurological effects [135], should be additionally taken into account when masks are compulsory at school and in the vicinity of both public and non-public transport, also regarding the possibility of an increased risk of accidents (see also occupational health side effects and hazards) [19,29,32,36,37]. The exclusion criteria mentioned in pediatric studies on masks (see pediatric impairments, Section 3.14) [26,133] should also apply to an exclusion of these children from the general mask obligation in accordance with the scientific findings for the protection of the sick children concerned. The long-term sociological, psychological and educational consequences of a comprehensive masking requirement extended to schools are also unpredictable with regard to the psychological and physical development of healthy children [42,135]. Interestingly, according to the Corona Thesis Paper of the University of Bremen children "are infected less often, they become ill less often, the lethality is close to zero, and they also pass on the infection less often", according to the Thesis Paper 2.0 of the German University of Bremen on page 6 [138]. Studies conducted under real-life conditions with outcome endpoints showing hardly any infections, hardly any morbidity, hardly any mortality and only low contagiousness in children are clearly in the majority, according to Thesis Paper 3.0 of the German University of Bremen [138]. A recent German observational study (5600 reporting pediatricians) also showed a surprisingly low incidence of COVID-19 disease in children [168]. The infection of adults with SARS-CoV-2 by children has been considered in only one suspected case, but could not be proven with certainty, since the parents also had numerous contacts and exposure factors for viral infections due to their occupation. In this case, the circulating headlines in the public media that children contribute more to the incidence of infection are to be regarded as anecdotal.

In pregnant women, the use of masks during exertion or at rest over long periods of time is to be regarded as critical as little research has been done on this [20]. If there is clear scientific evidence of increased dead space ventilation with possible accumulation of CO_2 in the mother's blood, the use of masks by pregnant women for more than 1 h, as well as under physical stress, should be avoided in order to protect the unborn child [20,22]. The hypercapnia-promoting masks could act as a confounder of the fetal/maternal CO_2 gradient in this case (Section 3.6) [20,22,28].

According to the literature cited in the Section 3.5 on psychiatric side effects (personality disorders with anxiety and panic attacks, claustrophobia, dementia and schizophrenia), masking should only be done, if at all, with careful consideration of the advantages and disadvantages. Attention should be paid to possible provocation of the number and severity of panic attacks [77–79].

In patients with headaches, a worsening of symptoms can be expected with prolonged mask use (see also Section 3.3., neurological side effects) [27,66–68]. As a result of the increase in blood carbon dioxide (CO_2) when the mask is used, vasodilatation occurs in the central nervous system and the pulsation of the blood vessels decreases [27]. In this connection, it is also interesting to note radiological experiments that demonstrate an increase in brain volume under subthreshold, but still within normal limits of CO_2 increase in the blood by means of structural MRI. The blood carbon dioxide increase was produced in seven subjects via rebreathing with resulting median carbon dioxide concentration of 42 mmHg and an interquartile range of 39.44 mmHg, corresponding to only a subthreshold increase given the normal values of 32–45 mmHg. In the experiment, there was a significant increase in brain parenchymal volume measurable under increased arterial CO_2 levels ($p < 0.02$), with a concomitant decrease in CSF spaces ($p < 0.04$), entirely in accordance with the Monroe–Kelly doctrine, according to which the total volume within the skull always remains the same. The authors interpreted the increase in brain volume as an expression of an increase in blood volume due to a CO_2 increase-induced dilation of the cerebral vessels [169]. The consequences of such equally subthreshold carbon dioxide (CO_2) increases even under masks [13,15,18,19,22,23,25] are unclear for people with pathological changes inside the skull (aneurysms, tumors, etc.) with associated vascular changes [27] and brain volume shifts [169] especially due to longer exposure while wearing a mask, but could be of great relevance due to the blood gas-related volume shifts that take place.

In view of the increased dead space volume, the long-term and increased accumulation and rebreathing of other respiratory air components apart from CO_2 is also unexplained, both in children and in old and sick people. Exhaled air contains over 250 substances, including irritant or toxic gases such as nitrogen oxides (NO), hydrogen sulfide (H2S), isoprene and acetone [170]. For nitrogen oxides [47] and hydrogen sulfide [46], pathological effects relevant to disease have been described in environmental medicine even at a low but chronic exposure [46–48]. Among the volatile organic compounds in exhaled air, acetone and isoprene dominate in terms of quantity, but allyl methyl sulfide, propionic acid and ethanol (some of bacterial origin) should also be mentioned [171]. Whether such substances also react chemically with each other underneath masks and in the dead space volume created by masks (Figure 3), and with the mask tissue itself, and in what quantities these and possible reaction products are rebreathed, has not yet been clarified. In addition to the blood gas changes described above (O_2 drop and CO_2 rise), these effects could also play a role with regard to undesirable mask effects. Further research is needed here and is of particular interest in the case of prolonged and ubiquitous use of masks.

The WHO sees the integration of individual companies and communities that produce their own fabric masks as a potential social and economic benefit. Due to the global shortage of surgical masks and personal protective equipment, it sees this as a source of income and points out that the reuse of fabric masks can reduce costs and waste and contribute to sustainability [2]. In addition to the question of certification procedures for such fabric masks, it should also be mentioned that due to the extensive mask obligation, textile (artificial) substances in the form of micro- and nanoparticles, some of which cannot be degraded in the body, are chronically absorbed into the body through inhalation to an unusual extent. In the case of medical masks, disposable polymers such as polypropylene, polyurethane, polyacrylonitrile, polystyrene, polycarbonate, polyethylene and polyester should be mentioned [140]. ENT physicians have already been able to detect such particles in the nasal mucosa of mask wearers with mucosal reactions in the sense of a foreign body reaction with rhinitis [96]. In the case of community masks, other substances from the textile industry are likely to be added to those mentioned above. The body will try to absorb these substances through macrophages and scavenger cells in the respiratory tract and alveoli as part of a foreign body reaction, whereby toxin release and corresponding local and generalized reactions may occur in an unsuccessful attempt to break them down [172]. Extensive respiratory protection in permanent long-term use (24/7), at least from a theoretical point of view, also potentially carries the risk of leading to a mask-related pulmonary [47] or even generalized disorder, as is already known from textile workers chronically exposed to organic dusts in the Third World (byssinosis) [172].

For the general public, from a scientific angle, it is necessary to draw on the long-standing knowledge of respiratory protection in occupational medicine in order to protect children in particular from harm caused by uncertified masks and improper use.

The universal undefined and extended mask requirement—without taking into account multiple predispositions and susceptibilities—contradicts the claim of an increasingly important individualized medicine with a focus on the unique characteristics of each individual [173].

A systematic review on the topic of masks is necessary according to the results of our scoping review. The primary studies often showed weaknesses in operationalization, especially in the evaluation of cognitive and neuropsychological parameters. Computerized test procedures will be useful here in the future. Mask research should also set itself the future goal of investigating and defining subgroups for whom respiratory protection use is particularly risky.

5. Limitations

Our approach with a focus on negative effects is in line with Villalonga-Olives and Kawachi [12]. With the help of such selective questioning in the sense of dialectics, new insights can be gained that might otherwise have remained hidden. Our literature search focused on adverse negative effects of masks, in particular to point out risks especially for certain patient groups. Therefore, publications presenting only positive effects of masks were not considered in this review.

For a compilation of studies with harmless results when using masks, reference must, therefore, be made to reviews with a different research objective, whereby attention must be paid to possible conflicts of interest there. Some of the studies excluded by us lacking negative effects have shown methodological weaknesses (small, non-uniform experimental groups, missing control group even without masks due to corona constraints, etc.) [174]. In other words, if no negative concomitant effects were described in publications, it does not necessarily mean that masks have exclusively positive effects. It is quite possible that negative effects were simply not mentioned in the literature and the number of negative effects may well be higher than our review suggests.

We only searched one database, so the number of papers on negative mask effects may be higher than we reported.

In order to be able to describe characteristic effects for each mask type even more extensively, we did not have enough scientific data on the respective special designs of the masks. There is still a great need for research in this area due to the current pandemic situation with extensive mandatory masking.

In addition, the experiments evaluated in this paper do not always have uniform measurement parameters and study variables and, depending on the study, take into account the effect of masks at rest or under stress with subjects having different health conditions. Figure 2, therefore, represents a compromise. The results of the primary studies on mask use partially showed no natural variation in parameters, but often showed such clear correlations between symptoms and physiological changes, so that a statistical correlation analysis was not always necessary. We found a statistically significant correlation of oxygen deprivation and fatigue in 58% of the studies ($p < 0.05$). A statistically significant correlation evidence for other parameters has been previously demonstrated in primary studies [21,29].

The most commonly used personal particulate matter protective equipment in the COVID-19 pandemic is the N95 mask [23]. Due to its characteristics (better filtering function, but greater airway resistance and more dead space volume than other masks), the N95 mask is able to highlight negative effects of such protective equipment more clearly than others (Figure 3). Therefore, a relatively frequent consideration and evaluation of N95 masks within the studies found (30 of the 44 quantitatively evaluated studies, 68%) is even advantageous within the framework of our research question. Nevertheless, it remains to be noted that the community masks sold on the market are increasingly similar to the protective equipment that has been better investigated in scientific studies, such as surgical masks and N95 masks, since numerous manufacturers and users of community masks are striving to approximate the professional standard (surgical mask, N95/FFP2). Recent study results on community masks indicate similar effects for respiratory physiology as described for medical masks: in a recent publication, fabric masks (community masks) also provoked a measurable increase in carbon dioxide $PtcCO_2$ in wearers during exertion and came very close to surgical masks in this effect [21].

Most of the studies cited in our paper included only short observation and application periods (mask-wearing durations investigated ranged from 5 min [26] to 12 h [19]. In only one study, a maximum observation period of an estimated 2-month period was chosen [37]. Therefore, the actual negative effects of masks over a longer application period might be more pronounced than presented in our work.

6. Conclusions

On the one hand, the advocacy of an extended mask requirement remains predominantly theoretical and can only be sustained with individual case reports, plausibility arguments based on model calculations and promising in vitro laboratory tests. Moreover, recent studies on SARS-CoV-2 show both a significantly lower infectivity [175] and a significantly lower case mortality than previously assumed, as it could be calculated that the median corrected infection fatality rate (IFR) was 0.10% in locations with a lower than average global COVID-19 population mortality rate [176]. In early October 2020, the WHO also publicly announced that projections show COVID-19 to be fatal for approximately 0.14% of those who become ill—compared to 0.10% for endemic influenza—again a figure far lower than expected [177].

On the other hand, the side effects of masks are clinically relevant.

In our work, we focused exclusively on the undesirable and negative side effects that can be produced by masks. Valid significant evidence of combined mask-related changes were objectified ($p < 0.05$, $n \geq 50\%$), and we found a clustered and common occurrence of the different adverse effects within the respective studies with significantly measured effects (Figure 2). We were able to demonstrate a statistically significant correlation of the observed adverse effect of hypoxia and the symptom of fatigue with $p < 0.05$ in the quantitative evaluation of the primary studies. Our review of the literature shows that both healthy and sick people can experience Mask-Induced Exhaustion Syndrome (MIES), with typical changes and symptoms that are often observed in combination, such as an increase in breathing dead space volume [22,24,58,59], increase in breathing resistance [31,35,60,61], increase in blood carbon dioxide [13,15,17,19,21–30,35], decrease in blood oxygen saturation [18,19,21,23,28–34], increase in heart rate [23,29,30,35], increase in blood pressure [25,35], decrease in cardiopulmonary capacity [31], increase in respiratory rate [15,21,23,34,36], shortness of breath and difficulty breathing [15,17,19,21,23,25,29,31,34,35,60,71,85,101,133], headache [19,27,29,37,66–68,71,83], dizziness [23,29], feeling hot and clammy [17,22,29,31,35,44,71,85,133], decreased ability to concentrate [29], decreased ability to think [36,37], drowsiness [19,29,32,36,37], decrease in empathy perception [99], impaired skin barrier function [37,72,73] with itching [31,35,67,71–73,91–93], acne, skin lesions and irritation [37,72,73], overall perceived fatigue and exhaustion [15,19,21,29,31,32,34,35,69] (Figures 2–4).

Wearing masks does not consistently cause clinical deviations from the norm of physiological parameters, but according to the scientific literature, a long-term pathological consequence with clinical relevance is to be expected owing to a longer-lasting effect with a subliminal impact and significant shift in the pathological direction. For changes that do not exceed normal values, but are persistently recurring, such as an increase in blood carbon dioxide [38,160], an increase in heart rate [55] or an increase in respiratory rate [56,57], which have been documented while wearing a mask [13,15,17,19,21–30,34,35] (Figure 2), a long-term generation of high blood pressure [25,35], arteriosclerosis and coronary heart disease and of neurological diseases is scientifically obvious [38,55–57,160]. This pathogenetic damage principle with a chronic low-dose exposure with long-term effect, which leads to disease or disease-relevant conditions, has already been extensively studied and described in many areas of environmental medicine [38,46–54]. Extended mask-wearing would have the potential, according to the facts and correlations we have found, to cause a chronic sympathetic stress response induced by blood gas modifications and controlled by brain centers. This in turn induces and triggers immune suppression and metabolic syndrome with cardiovascular and neurological diseases.

We not only found evidence in the reviewed mask literature of potential long-term effects, but also evidence of an increase in direct short-term effects with increased mask-wearing time in terms of cumulative effects for: carbon dioxide retention, drowsiness, headache, feeling of exhaustion, skin irritation (redness, itching) and microbiological contamination (germ colonization) [19,22,37,66,68,69,89,91,92].

Overall, the exact frequency of the described symptom constellation MIES in the mask-using populace remains unclear and cannot be estimated due to insufficient data.

Theoretically, the mask-induced effects of the drop in blood gas oxygen and increase in carbon dioxide extend to the cellular level with induction of the transcription factor HIF (hypoxia-induced factor) and increased inflammatory and cancer-promoting effects [160] and can, thus, also have a negative influence on pre-existing clinical pictures.

In any case, the MIES potentially triggered by masks (Figures 3 and 4) contrasts with the WHO definition of health: "health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity." [178].

All the scientific facts found in our work expand the knowledge base for a differentiated view of the mask debate. This gain can be relevant for decision makers who have to deal with the issue of mandatory mask use during the pandemic under constant review of proportionality as well as for physicians who can advise their patients more appropriately on this basis. For certain diseases, taking into account the literature found in this study, it is also necessary for the attending physician to weigh up the benefits and risks with regard to a mask obligation. With an overall strictly scientific consideration, a recommendation for mask exemption can become justifiable within the framework of a medical appraisal (Figure 5).

Increased risk of adverse effects when using masks:

Internal diseases
COPD
Sleep Apnea Syndrome
advanced renal Failure
Obesity
Cardiopulmonary Dysfunction
Asthma

Psychiatric illness
Claustrophobia
Panic Disorder
Personality Disorders
Dementia
Schizophrenia
helpless Patients
fixed and sedated Patients

Neurological Diseases
Migraines and Headache Sufferers
Patients with intracranial Masses
Epilepsy

Pediatric Diseases
Asthma
Respiratory diseases
Cardiopulmonary Diseases
Neuromuscular Diseases
Epilepsy

ENT Diseases
Vocal Cord Disorders
Rhinitis and obstructive Diseases

Dermatological Diseases
Acne
Atopic

Occupational Health Restrictions
moderate / heavy physical Work

Gynecological restrictions
Pregnant Women

Figure 5. Diseases/predispositions with significant risks, according to the literature found, when using masks. Indications for weighing up medical mask exemption certificates.

In addition to protecting the health of their patients, doctors should also base their actions on the guiding principle of the 1948 Geneva Declaration, as revised in 2017. According to this, every doctor vows to put the health and dignity of his patient first and, even under threat, not to use his medical knowledge to violate human rights and civil liberties [9]. Within the framework of these findings, we, therefore, propagate an explicitly medically judicious, legally compliant action in consideration of scientific factual reality [2,4,5,16,130,132,143,175–177] against a predominantly assumption-led claim to a general effectiveness of masks, always taking into account possible unwanted individual effects for the patient and mask wearer concerned, entirely in accordance with the principles of evidence-based medicine and the ethical guidelines of a physician.

The results of the present literature review could help to include mask-wearing in the differential diagnostic pathophysiological cause consideration of every physician when corresponding symptoms are present (MIES, Figure 4). In this way, the physician can draw on an initial complaints catalogue that may be associated with mask-wearing (Figure 2) and also exclude certain diseases from the general mask requirement (Figure 5).

For scientists, the prospect of continued mask use in everyday life suggests areas for further research. In our view, further research is particularly desirable in the gynecological (fetal and embryonic) and pediatric fields, as children are a vulnerable group that would face the longest and, thus, most profound consequences of a potentially risky mask use. Basic research at the cellular level regarding mask-induced triggering of the transcription factor HIF with potential promotion of immunosuppression and carcinogenicity also appears to be useful under this circumstance. Our scoping review shows the need for a systematic review.

The described mask-related changes in respiratory physiology can have an adverse effect on the wearer's blood gases sub-clinically and in some cases also clinically manifest and, therefore, have a negative effect on the basis of all aerobic life, external and internal respiration, with an influence on a wide variety of organ systems and metabolic processes with physical, psychological and social consequences for the individual human being.

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Plaintiff's Exhibit 90

Nonpharmaceutical Measures for Pandemic Influenza in Nonhealthcare Settings—Personal Protective and Environmental Measures

Jingyi Xiao,[1] Eunice Y. C. Shiu,[1] Huizhi Gao, Jessica Y. Wong, Min W. Fong, Sukhyun Ryu, Benjamin J. Cowling

There were 3 influenza pandemics in the 20th century, and there has been 1 so far in the 21st century. Local, national, and international health authorities regularly update their plans for mitigating the next influenza pandemic in light of the latest available evidence on the effectiveness of various control measures in reducing transmission. Here, we review the evidence base on the effectiveness of nonpharmaceutical personal protective measures and environmental hygiene measures in nonhealthcare settings and discuss their potential inclusion in pandemic plans. Although mechanistic studies support the potential effect of hand hygiene or face masks, evidence from 14 randomized controlled trials of these measures did not support a substantial effect on transmission of laboratory-confirmed influenza. We similarly found limited evidence on the effectiveness of improved hygiene and environmental cleaning. We identified several major knowledge gaps requiring further research, most fundamentally an improved characterization of the modes of person-to-person transmission.

Influenza pandemics occur at irregular intervals when new strains of influenza A virus spread in humans (*1*). Influenza pandemics cause considerable health and social impact that exceeds that of typical seasonal (interpandemic) influenza epidemics. One of the characteristics of influenza pandemics is the high incidence of infections in all age groups because of the lack of population immunity. Although influenza vaccines are the cornerstone of seasonal influenza control, specific vaccines for a novel pandemic strain are not expected to be available for the first 5–6 months of the next pandemic. Antiviral drugs will be available in some locations to treat more severe infections but are unlikely to be available in the quantities that might be required to control transmission in the general community. Thus, efforts to control the next pandemic will rely largely on nonpharmaceutical interventions.

Most influenza virus infections cause mild and self-limiting disease; only a small fraction of case-patients require hospitalization. Therefore, influenza virus infections spread mainly in the community. Influenza virus is believed to be transmitted predominantly by respiratory droplets, but the size distribution of particles responsible for transmission remains unclear, and in particular, there is a lack of consensus on the role of fine particle aerosols in transmission (*2*,*3*). In healthcare settings, droplet precautions are recommended in addition to standard precautions for healthcare personnel when interacting with influenza patients and for all visitors during influenza seasons (*4*). Outside healthcare settings, hand hygiene is recommended in most national pandemic plans (*5*), and medical face masks were a common sight during the influenza pandemic in 2009. Hand hygiene has been proven to prevent many infectious diseases and might be considered a major component in influenza pandemic plans, whether or not it has proven effectiveness against influenza virus transmission, specifically because of its potential to reduce other infections and thereby reduce pressure on healthcare services.

In this article, we review the evidence base for personal protective measures and environmental hygiene measures, and specifically the evidence for the effectiveness of these measures in reducing transmission of laboratory-confirmed influenza in the community. We also discuss the implications of the evidence base for inclusion of these measures in pandemic plans.

Author affiliation: University of Hong Kong, Hong Kong, China

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[1]These first authors contributed equally to this article.

Methods and Results

We conducted systematic reviews to evaluate the effectiveness of personal protective measures on influenza virus transmission, including hand hygiene, respiratory etiquette, and face masks, and a systematic review of surface and object cleaning as an environmental measure (Table 1). We searched 4 databases (Medline, PubMed, EMBASE, and CENTRAL) for literature in all languages. We aimed to identify randomized controlled trials (RCTs) of each measure for laboratory-confirmed influenza outcomes for each of the measures because RCTs provide the highest quality of evidence. For respiratory etiquette and surface and object cleaning, because of a lack of RCTs for laboratory-confirmed influenza, we also searched for RCTs reporting effects of these interventions on influenza-like illness (ILI) and respiratory illness outcomes and then for observational studies on laboratory-confirmed influenza, ILI, and respiratory illness outcomes. For each review, 2 authors (E.Y.C.S. and J.X.) screened titles and abstracts and reviewed full texts independently.

We performed meta-analysis for hand hygiene and face mask interventions and estimated the effect of these measures on laboratory-confirmed influenza prevention by risk ratios (RRs). We used a fixed-effects model to estimate the overall effect in a pooled analysis or subgroup analysis. No overall effect would be generated if there was considerable heterogeneity on the basis of I^2 statistic $\geq$75% (*6*). We performed quality assessment of evidence on hand hygiene and face mask interventions by using the GRADE (Grading of Recommendations Assessment, Development and Evaluation) approach (*7*). We provide additional details of the search strategies, selection of articles, summaries of the selected articles, and quality assessment (Appendix, https://wwwnc.cdc.gov/EID/article/26/5/19-0994-App1.pdf).

Personal Protective Measures

Hand Hygiene

We identified a recent systematic review by Wong et al. on RCTs designed to assess the efficacy of hand hygiene interventions against transmission of laboratory-confirmed influenza (*8*). We used this review as a starting point and then searched for additional literature published after 2013; we found 3 additional eligible articles published during the search period of January 1, 2013–August 13, 2018. In total, we identified 12 articles (*9*–*20*), of which 3 articles were from the updated search and 9 articles from Wong et al. (*8*). Two articles relied on the same underlying dataset (*16*,*19*); therefore, we counted these 2 articles as 1 study, which resulted in 11 RCTs. We further selected 10 studies with >10,000 participants for inclusion in the meta-analysis (Figure 1). We excluded 1 study from the meta-analysis because it provided estimates of infection risks only at the household level, not the individual level (*20*). We did not generate an overall pooled effect of hand hygiene only or of hand hygiene with or without face mask because of high heterogeneity in individual estimates (I^2 87 and 82%, respectively). The effect of hand hygiene combined with face masks on laboratory-confirmed influenza was not statistically significant (RR 0.91, 95% CI 0.73–1.13; I^2 = 35%, p = 0.39). Some studies reported being underpowered because of limited sample size, and low adherence to hand hygiene interventions was observed in some studies.

We further analyzed the effect of hand hygiene by setting because transmission routes might vary

Table 1. Summary of literature searches for systematic review on personal and environmental nonpharmaceutical interventions for pandemic influenza*

Types of interventions	No. studies identified	Study designs included†	Main findings
Hand hygiene	12	RCT	The evidence from RCTs suggested that hand hygiene interventions do not have a substantial effect on influenza transmission.
Respiratory etiquette	0	NA	We did not identify research evaluating the effectiveness of respiratory etiquette on influenza transmission.
Face masks	10	RCT	The evidence from RCTs suggested that the use of face masks either by infected persons or by uninfected persons does not have a substantial effect on influenza transmission.
Surface and object cleaning	3	RCT, observational studies	There was a limited amount of evidence suggesting that surface and object cleaning does not have a substantial effect on influenza transmission.

*NA, not available; RCT randomized controlled trial.
†In these systematic reviews, we prioritized RCTs, and only considered observational studies if there were a small number of RCTs. Our rationale was that with evidence from a larger number of RCTs, additional evidence from observational studies would be unlikely to change overall conclusions.

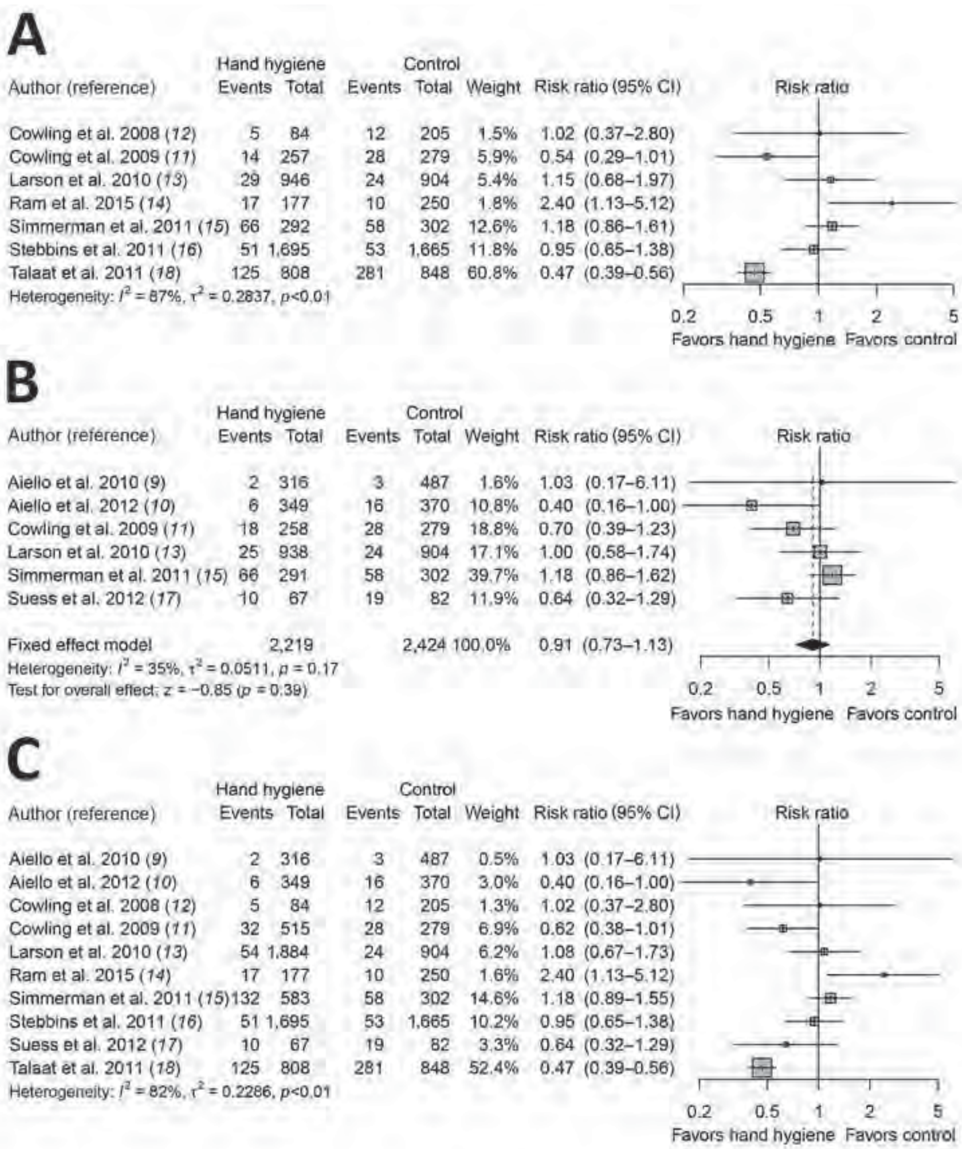

Figure 1. Meta-analysis of risk ratios for the effect of hand hygiene with or without face mask use on laboratory-confirmed influenza from 10 randomized controlled trials with >11,000 participants. A) Hand hygiene alone; B) hand hygiene and face mask; C) hand hygiene with or without face mask. Pooled estimates were not made if there was high heterogeneity ($I^2 \geq$75%). Squares indicate risk ratio for each of the included studies, horizontal line indicates 95% CIs, dashed vertical line indicates pooled estimation of risk ratio, and diamond indicates pooled estimation of risk ratio. Diamond width corresponds to the 95% CI.

in different settings. We found 6 studies in household settings examining the effect of hand hygiene with or without face masks, but the overall pooled effect was not statistically significant (RR 1.05, 95% CI 0.86–1.27; I^2 = 57%, p = 0.65) (Appendix Figure 4) (*11–15*,*17*). The findings of 2 studies in school settings were different (Appendix Figure 5). A study conducted in the United States (*16*) showed no major effect of hand hygiene, whereas a study in Egypt (*18*) reported that hand hygiene reduced the risk for influenza by >50%. A pooled analysis of 2 studies in university residential halls reported a marginally significant protective effect of a combination of hand hygiene plus face masks worn by all residents (RR 0.48, 95% CI 0.21–1.08; I^2 = 0%, p = 0.08) (Appendix Figure 6) (*9*,*10*).

In support of hand hygiene as an effective measure, experimental studies have reported that influenza virus could survive on human hands for a short time and could transmit between hands and contaminated surfaces (*2*,*21*). Some field studies reported that influenza A(H1N1)pdm09 and influenza A(H3N2) virus RNA and viable influenza virus could be detected on the hands of persons with laboratory-confirmed influenza (*22*,*23*), supporting the potential of direct and indirect contact transmission to play a role in the spread of influenza. Other experimental studies also demonstrated that hand hygiene could reduce or remove infectious influenza virus from human hands (*24*,*25*). However, results from our meta-analysis on RCTs did not provide evidence to support a protective effect of hand hygiene against transmission of laboratory-confirmed influenza. One study did report a major effect, but in this trial of hand hygiene in schools in Egypt, running water had to be installed and soap and hand-drying material had to be introduced into the intervention schools as part of the project (*18*). Therefore, the impact of hand hygiene might also be a reflection of the introduction of soap and running water into primary schools in a lower-income setting. If one considers all of the evidence from RCTs together, it is useful to note that some studies might have underestimated the true effect of hand hygiene because of the complexity of implementing these intervention studies. For instance, the control group would not typically have zero knowledge or use of hand hygiene, and the intervention group might not adhere to optimal hand hygiene practices (*11*,*13*,*15*).

Hand hygiene is also effective in preventing other infectious diseases, including diarrheal diseases and some respiratory diseases (*8,26*). The need for hand hygiene in disease prevention is well recognized among most communities. Hand hygiene has been accepted as a personal protective measure in >50% of national preparedness plans for pandemic influenza (*5*). Hand hygiene practice is commonly performed with soap and water, alcohol-based hand rub, or other waterless hand disinfectants, all of which are easily accessible, available, affordable, and well accepted in most communities. However, resource limitations in some areas are a concern when clean running water or alcohol-based hand rub are not available. There are few adverse effects of hand hygiene except for skin irritation caused by some hand hygiene products (*27*). However, because of certain social or religious practices, alcohol-based hand sanitizers might not be permitted in some locations (*28*). Compliance with proper hand hygiene practice tends to be low because habitual behaviors are difficult to change (*29*). Therefore, hand hygiene promotion programs are needed to advocate and encourage proper and effective hand hygiene.

Respiratory Etiquette

Respiratory etiquette is defined as covering the nose and mouth with a tissue or a mask (but not a hand) when coughing or sneezing, followed by proper disposal of used tissues, and proper hand hygiene after contact with respiratory secretions (*30*). Other descriptions of this measure have included turning the head and covering the mouth when coughing and coughing or sneezing into a sleeve or elbow, rather than a hand. The rationale for not coughing into hands is to prevent subsequent contamination of other surfaces or objects (*31*). We conducted a search on November 6, 2018, and identified literature that was available in the databases during 1946–November 5, 2018. We did not identify any published research on the effectiveness of respiratory etiquette in reducing the risk for laboratory-confirmed influenza or ILI. One observational study reported a similar incidence rate of self-reported respiratory illness (defined by >1 symptoms: cough, congestion, sore throat, sneezing, or breathing problems) among US pilgrims with or without practicing respiratory etiquette during the Hajj (*32*). The authors did not specify the type of respiratory etiquette used by participants in the study. A laboratory-based study reported that common respiratory etiquette, including covering the mouth by hands, tissue, or sleeve/arm, was fairly ineffective in blocking the release and dispersion of droplets into the surrounding environment on the basis of measurement of emitted droplets with a laser diffraction system (*31*).

Respiratory etiquette is often listed as a preventive measure for respiratory infections. However, there is a lack of scientific evidence to support this measure. Whether respiratory etiquette is an effective nonpharmaceutical intervention in preventing influenza virus transmission remains questionable, and worthy of further research.

Face Masks

In our systematic review, we identified 10 RCTs that reported estimates of the effectiveness of face masks in reducing laboratory-confirmed influenza virus infections in the community from literature published during 1946–July 27, 2018. In pooled analysis, we found no significant reduction in influenza transmission with the use of face masks (RR 0.78, 95% CI 0.51–1.20; I^2 = 30%, p = 0.25) (Figure 2). One study evaluated the use of masks among pilgrims from Australia during the Hajj pilgrimage and reported no major difference in the risk for laboratory-confirmed influenza virus infection in the control or mask group (*33*). Two studies in university settings assessed the effectiveness of face masks for primary protection by monitoring the incidence of laboratory-confirmed influenza among student hall residents for 5 months (*9*,*10*). The overall reduction in ILI or laboratory-confirmed influenza cases in the face mask group was not significant in either studies (*9*,*10*). Study designs in the 7 household studies were slightly different: 1 study provided face masks and P2 respirators for household contacts only (*34*), another study evaluated face mask use as a source control for infected persons only (*35*), and the remaining studies provided masks for the infected persons as well as their close contacts (*11*–*13*,*15*,*17*). None of the household studies reported a significant reduction in secondary laboratory-confirmed influenza virus infections in the face

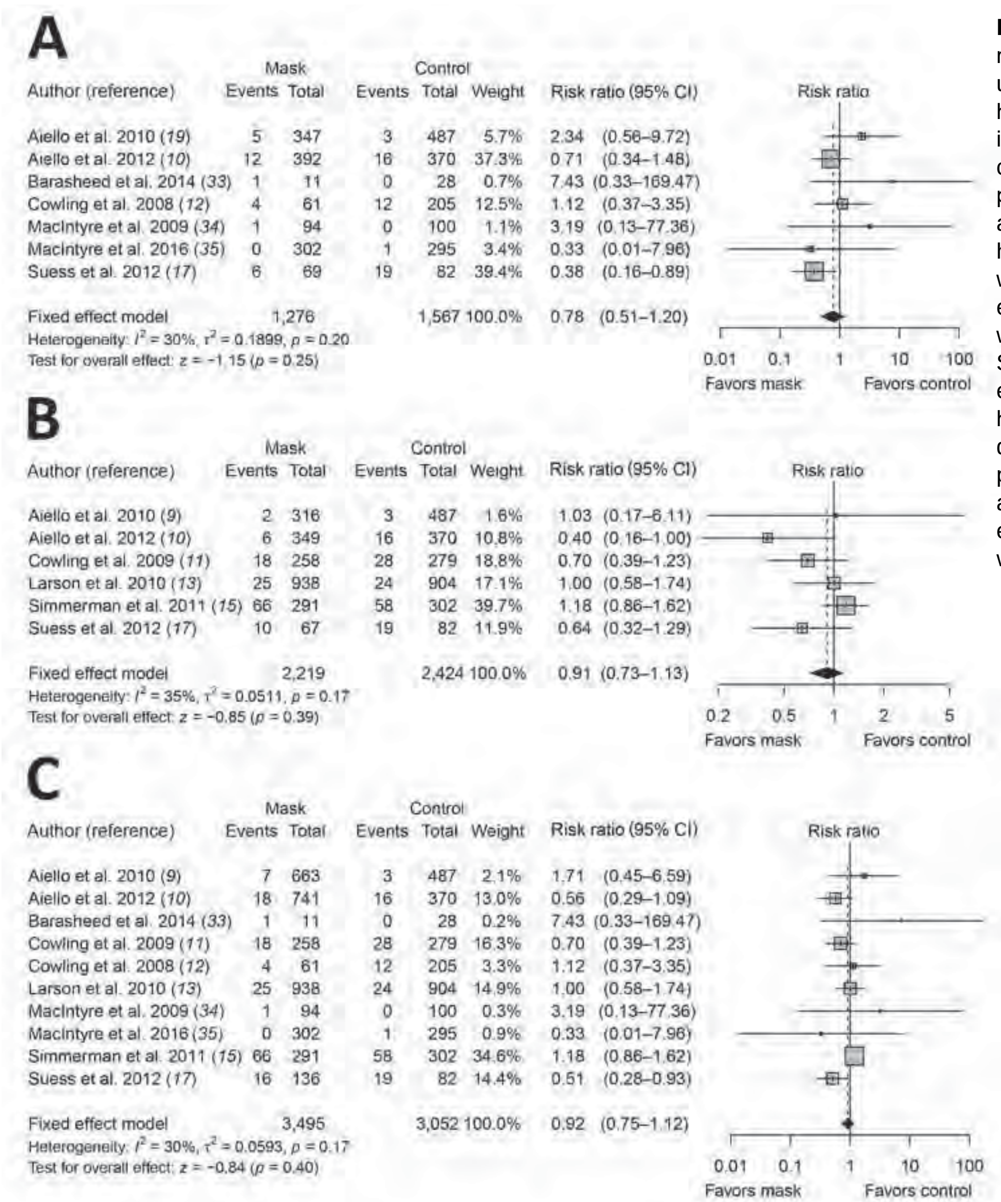

Figure 2. Meta-analysis of risk ratios for the effect of face mask use with or without enhanced hand hygiene on laboratory-confirmed influenza from 10 randomized controlled trials with >6,500 participants. A) Face mask use alone; B) face mask and hand hygiene; C) face mask with or without hand hygiene. Pooled estimates were not made if there was high heterogeneity (I^2 ≥75%). Squares indicate risk ratio for each of the included studies, horizontal lines indicate 95% CIs, dashed vertical lines indicate pooled estimation of risk ratio, and diamonds indicate pooled estimation of risk ratio. Diamond width corresponds to the 95% CI.

mask group (*11–13*,*15*,*17*,*34*,*35*). Most studies were underpowered because of limited sample size, and some studies also reported suboptimal adherence in the face mask group.

Disposable medical masks (also known as surgical masks) are loose-fitting devices that were designed to be worn by medical personnel to protect accidental contamination of patient wounds, and to protect the wearer against splashes or sprays of bodily fluids (*36*). There is limited evidence for their effectiveness in preventing influenza virus transmission either when worn by the infected person for source control or when worn by uninfected persons to reduce exposure. Our systematic review found no significant effect of face masks on transmission of laboratory-confirmed influenza.

We did not consider the use of respirators in the community. Respirators are tight-fitting masks that can protect the wearer from fine particles (*37*) and should provide better protection against influenza virus exposures when properly worn because of higher filtration efficiency. However, respirators, such as N95 and P2 masks, work best when they are fit-tested, and these masks will be in limited supply during the next pandemic. These specialist devices should be reserved for use in healthcare settings or in special subpopulations such as immunocompromised persons in the community, first responders, and those performing other critical community functions, as supplies permit.

In lower-income settings, it is more likely that reusable cloth masks will be used rather than disposable medical masks because of cost and availability (*38*). There are still few uncertainties in the practice of face mask use, such as who should wear the mask and how long it should be used for. In theory, transmission should be reduced the most if both infected members and other contacts wear masks, but compliance in uninfected close contacts could be a problem (*12*,*34*). Proper use of face masks is essential because improper use might increase the risk for transmission (*39*). Thus, education on the proper use and disposal of used face masks, including hand hygiene, is also needed.

Environmental Measures

Surface and Object Cleaning

For the search period from 1946 through October 14, 2018, we identified 2 RCTs and 1 observational study about surface and object cleaning measures for inclusion in our systematic review (*40*–*42*). One RCT conducted in day care nurseries found that biweekly cleaning and disinfection of toys and linen reduced the detection of multiple viruses, including adenovirus, rhinovirus, and respiratory syncytial virus in the environment, but this intervention was not significant in reducing detection of influenza virus, and it had no major protective effect on acute respiratory illness (*41*). Another RCT found that hand hygiene with hand sanitizer together with surface disinfection reduced absenteeism related to gastrointestinal illness in elementary schools, but there was no major reduction in absenteeism related to respiratory illness (*42*). A cross-sectional study found that passive contact with bleach was associated with a major increase in self-reported influenza (*40*).

Given that influenza virus can survive on some surfaces for prolonged periods (*43*), and that cleaning or disinfection procedures can effectively reduce or inactivate influenza virus from surfaces and objects in experimental studies (*44*), there is a theoretical basis to believe that environmental cleaning could reduce influenza transmission. As an illustration of this proposal, a modeling study estimated that cleaning of extensively touched surfaces could reduce influenza A infection by 2% (*45*). However, most studies of influenza virus in the environment are based on detection of virus RNA by PCR, and few studies reported detection of viable virus.

Although we found no evidence that surface and object cleaning could reduce influenza transmission, this measure does have an established impact on prevention of other infectious diseases (*42*). It should be feasible to implement this measure in most settings, subject to the availability of water and cleaning products. Although irritation caused by cleaning products is limited, safety remains a concern because some cleaning products can be toxic or cause allergies (*40*).

Discussion

In this review, we did not find evidence to support a protective effect of personal protective measures or environmental measures in reducing influenza transmission. Although these measures have mechanistic support based on our knowledge of how influenza is transmitted from person to person, randomized trials of hand hygiene and face masks have not demonstrated protection against laboratory-confirmed influenza, with 1 exception (*18*). We identified only 2 RCTs on environmental cleaning and no RCTs on cough etiquette.

Hand hygiene is a widely used intervention and has been shown to effectively reduce the transmission of gastrointestinal infections and respiratory infections (*26*). However, in our systematic review, updating the findings of Wong et al. (*8*), we did not find evidence of a major effect of hand hygiene on laboratory-confirmed influenza virus transmission (Figure 1). Nevertheless, hand hygiene might be included in influenza pandemic plans as part of general hygiene and infection prevention.

We did not find evidence that surgical-type face masks are effective in reducing laboratory-confirmed influenza transmission, either when worn by infected persons (source control) or by persons in the general community to reduce their susceptibility (Figure 2). However, as with hand hygiene, face masks might be able to reduce the transmission of other infections and therefore have value in an influenza pandemic when healthcare resources are stretched.

It is essential to note that the mechanisms of person-to-person transmission in the community have not been fully determined. Controversy remains over the role of transmission through fine-particle aerosols (*3*,*46*). Transmission by indirect contact requires transfer of viable virus from respiratory mucosa onto hands and other surfaces, survival on those surfaces, and successful inoculation into the respiratory mucosa of another person. All of these components of the transmission route have not been studied extensively. The impact of environmental factors, such as temperature and humidity, on influenza transmission is also uncertain (*47*). These uncertainties over basic transmission modes and mechanisms hinder the optimization of control measures.

Table 2. Knowledge gaps for personal protective and environmental nonpharmaceutical interventions for pandemic influenza*

Intervention	Knowledge gaps	Suggested studies
Hand hygiene	There are major gaps in our knowledge of the mechanisms of person-to-person transmission of influenza, including the role of direct and indirect contact, the degree of viral contamination on hands and various types of surfaces in different settings, and the potential for contact transmission to occur in different locations and under different environmental conditions. There is little information on whether greater reductions in transmission could be possible with combinations of personal intervention (e.g., isolation away from family members as much as possible, plus using face masks and enhancing hand hygiene).	Additional high-quality RCTs of efficacy of hand hygiene against laboratory-confirmed influenza in other nonhealthcare settings, except households and university residential halls, would be valuable. In particular, studies in school settings are needed to solve the discrepancy between the two studies from the United States and Egypt.
Respiratory etiquette	There is no evidence about the quantitative effectiveness of respiratory etiquette against influenza virus.	RCTs of interventions to demonstrate the effectiveness of respiratory etiquette in reducing influenza transmission would be valuable.
Face mask	There are major gaps in our knowledge of the mechanisms of person-to-person transmission of influenza, including the importance of transmission through droplets of different sizes including small particle aerosols, and the potential for droplet and aerosol transmission to occur in different locations and with environmental conditions.	Additional high-quality RCTs of efficacy of face masks against laboratory-confirmed influenza would be valuable. Effectiveness of face masks or respirator use to prevent influenza prevention in special subpopulation, such as immunocompromised persons, would be valuable.
Surface and object cleaning	The effectiveness of different cleaning products in preventing influenza transmission–in terms of cleaning frequency, cleaning dosage, cleaning time point, and cleaning targeted surface and object material–remains unknown.	RCTs of interventions to demonstrate the effectiveness of surface and object cleaning in reducing influenza transmission would be valuable. Studies that can demonstrate the reduction of environmental detection of influenza virus through cleaning of surfaces and objects would also be valuable.

*RCT, randomized control trial.

In this review, we focused on 3 personal protective measures and 1 environmental measure. Other potential environmental measures include humidification in dry environments (*48*), increasing ventilation (*49*), and use of upper-room UV light (*50*), but there is limited evidence to support these measures. Further investigations on the effectiveness of respiratory etiquette and surface cleaning through conducting RCTs would be helpful to provide evidence with higher quality; evaluation of the effectiveness of these measures targeting specific population groups, such as immunocompromised persons, would also be beneficial (Table 2). Future cost-effectiveness evaluations could provide more support for the potential use of these measures. Further research on transmission modes and alternative interventions to reduce influenza transmission would be valuable in improving pandemic preparedness. Finally, although our review focused on nonpharmaceutical measures to be taken during influenza pandemics, the findings could also apply to severe seasonal influenza epidemics. Evidence from RCTs of hand hygiene or face masks did not support a substantial effect on transmission of laboratory-confirmed influenza, and limited evidence was available on other environmental measures.

This study was conducted in preparation for the development of guidelines by the World Health Organization on the use of nonpharmaceutical interventions for pandemic influenza in nonmedical settings.

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About the Author

Ms. Xiao is a postgraduate student at the School of Public Health, University of Hong Kong, Hong Kong, China. Her primary research interests are influenza epidemiology and the dynamics of person-to-person transmission.

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Address for correspondence: Benjamin J. Cowling, World Health Organization Collaborating Centre for Infectious Disease Epidemiology and Control, School of Public Health, Li Ka Shing Faculty of Medicine, University of Hong Kong, 1/F Patrick Manson Bldg (North Wing), 7 Sassoon Rd, Hong Kong, China; email: bcowling@hku.hk

Plaintiff's Exhibit 91

The Potential for Cloth Masks to Protect Health Care Clinicians From SARS-CoV-2: A Rapid Review

Ariel Kiyomi Daoud
Jessica Kole Hall
Haylie Petrick
Anne Strong
Cleveland Piggott, MD, MPH

Department of Family Medicine, University of Colorado School of Medicine, Aurora, Colorado

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ABSTRACT

PURPOSE The coronavirus disease 2019 (COVID-19) pandemic has led at times to a scarcity of personal protective equipment, including medical masks, for health care clinicians, especially in primary care settings. The objective of this review was to summarize current evidence regarding the use of cloth masks to prevent respiratory viral infections, such as severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), among health care clinicians.

METHODS We searched 5 databases, the Centers for Disease Control and Prevention website, and the reference lists of identified articles on April 3, 2020. All identified publications were independently screened by 2 reviewers. Two authors independently extracted data and graded the studies. Randomized control trials (RCTs) were graded using the Consolidated Standards of Reporting Trials (CONSORT) checklist, and observational and nonhuman subject studies were graded using 11 domains common across frequently used critical appraisal tools. All discrepancies were resolved by consensus.

RESULTS Our search identified 136 original publications. Nine studies met inclusion criteria. We performed a qualitative synthesis of the data from these studies. Four nonrandomized trials, 3 laboratory studies, 1 single-case experiment, and 1 RCT were identified. The laboratory studies found that cloth materials provided measurable levels of particle filtration but were less efficacious at blocking biologic material than medical masks. The RCT found that cloth masks were associated with significantly more viral infections than medical masks.

CONCLUSIONS The current literature suggests that cloth materials are somewhat efficacious in filtering particulate matter and aerosols but provide a worse fit and inferior protection compared to medical masks in clinical environments. The quality and quantity of literature addressing this question are lacking. Cloth masks lack evidence for adequate protection of health care clinicians against respiratory viral infections.

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INTRODUCTION

In December 2019, the novel coronavirus, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), emerged in Wuhan, China and quickly became a global pandemic as the coronavirus disease 2019 (COVID-19) respiratory syndrome. At the time of this article's writing, more than 68 million cases were reported worldwide, with more than 1,500,000 deaths.[1] In the United States, health care clinicians have been faced with a scarcity of personal protective equipment (PPE) including N95 respirators and disposable medical masks.[2] As the United States has focused primarily on supporting large urban hospitals to care for the surge of severely ill patients, primary care offices have experienced severe PPE shortages.[3] During the week of this article's writing in April 2020, 58% of primary care clinicians reported in a national survey to have resorted to the use of homemade and/or used PPE. Seven months later, 32% reported that they were either lacking PPE or felt that their required level of PPE reuse was unsafe.[4]

Conflicts of interest: authors report none.

CORRESPONDING AUTHOR

Cleveland Piggott
Department of Family Medicine
University of Colorado School of Medicine
13001 E 17th Pl
Aurora, CO 80045
Cleveland.Piggott@cuanschutz.edu

Hospitals, health care systems, and the National Strategic Stockpile have insufficient supply to provide adequate PPE for health care clinicians. This leaves primary care practices and other resource-limited organizations, such as rural hospitals, to determine how to protect their clinicians. Conflicting information from the popular media, messaging from various health care systems, and constantly changing societal guidelines complicate decisions regarding appropriate mask usage in clinical settings during times of scarcity. Creative solutions include rationing supplies, extending the use of PPE, recycling masks, and devising alternative face protection.[2] The US Centers for Disease Control and Prevention (CDC) states that health care clinicians may used cloth masks as a last resort.[5] The CDC notes that cloth masks are not considered PPE and that their capability to protect health care clinicians is not currently known. The CDC does not offer information regarding the degree of protection a cloth mask might provide compared to a medical mask. In addition, there is no recommendation for what the best design of a cloth mask might be in the face of a shortage of PPE. This rapid review summarizes current evidence on the efficacy and effectiveness of cloth masks compared with medical masks to prevent respiratory viral infections among health care clinicians.

METHODS

Criteria for Study Consideration

We followed Cochrane rapid review methods for this review.[6] We included all studies examining the efficacy and/or effectiveness of cloth masks in filtering biologic materials or comparing a cloth mask to an industrial medical or surgical mask. Efficacy refers to the performance of mask materials in a laboratory setting (ie, filtration, fit factor, pressure gradient), whereas effectiveness considers the performance of masks when used by human subjects in clinical environments (ie, infection rate). Biologic materials were defined as bacteria or viruses. The term cloth was applied broadly and included any type of woven nonsynthetic material or woven polyester fabric that might be used to create a homemade cloth mask. Studies examining filtering ability of cloth masks against environmental exposures, such as diesel particles, foundry exposure, welding fumes, or pollution, were excluded. Reviews, opinion pieces, letters to the editor, commentaries, research briefs, and anecdotes were also excluded.

Main Outcome Measures

Inclusion in this review required at least 1 of the following outcome measures:

- Efficacy or effectiveness of cloth masks
- Respiratory illness/infection rate of health care clinicians wearing cloth masks
- Filtration efficiency of cloth masks compared to medical or surgical masks
- Percentage aerosol penetration of cloth masks compared to medical or surgical masks
- Comparison of mask fit between cloth and medical or surgical masks

Search Methods

We performed a search of MEDLINE, the Cochrane Library, Embase, the Cumulative Index to Nursing and Allied Health Literature (CINAHL), and the Web of Science databases on April 3, 2020, to identify relevant studies for this review. Gray literature was searched briefly via the CDC's website. Reference lists of identified studies were consulted for additional publications. Publication dates before 1970 were not considered. No exclusion criteria were applied on the basis of study quality grade or language. A health science librarian was consulted for the identification of appropriate databases and assistance with search term definitions. See Supplemental Table 1, https://www.AnnFamMed.org/content/19/1/55/suppl/DC1/, for search strategies.

Data Collection and Analysis

Study Selection

All studies retrieved via database searches were downloaded to citation manager software. Duplicates were removed. Two authors (JKH and AS) independently screened identified studies via title and abstract content and then independently reviewed full-text publications of the screened studies. Any discrepancies in eligibility were resolved via discussion and consensus between the independent reviewers and additional authors as needed.

Data Extraction and Management

Two authors (HP and AKD) independently extracted data from the final list of eligible studies to separate spreadsheets. Data were compared and discrepancies resolved via discussion and consensus, including additional author(s) as necessary. They then independently appraised each study and resolved discrepancies via discussion and consensus. Study appraisal was implemented to identify flaws in methodology and assess bias. Randomized control trials (RCTs) were appraised using the Consolidated Standards of Reporting Trials (CONSORT) checklist.[7] The diversity of study type included prevented implementation of a single critical appraisal tool. Reviewers considered observational and nonhuman subjects studies using 11 domains common across frequently used critical appraisal tools.[8]

RESULTS

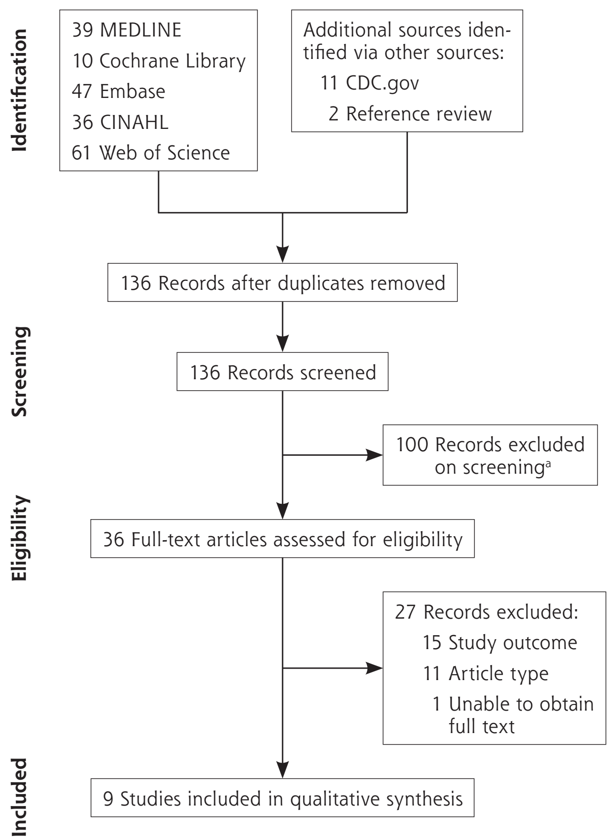
Publication Identification

Our search of 5 databases and gray literature yielded 136 nonduplicate original publications (Figure 1). Ten of the publications required title or available abstract translation from non-English languages; all were irrelevant to our study question and were excluded. Thirty-six articles were identified for full-text evaluation, and 27 were excluded (Supplemental Table 2, https://www.AnnFamMed.org/content/19/1/55/suppl/DC1/). Nine studies were included for analysis after screening and selection. Four nonrandomized trials, 3 laboratory efficacy studies, 1 single-case experiment, and 1 RCT were included.[9-17] We excluded several studies that investigated cloth mask protection against air pollution or industrial debris. Although those studies might provide insight regarding physical characteristics of cloth materials, we chose to include only studies that explicitly considered mask use to prevent disease or measured particles of biologic significance such as bacteria, viruses, or particles intended to be of similar size to respiratory droplets or aerosols.

Overall quality assessment and appraisal details of the observational and nonhuman subject studies are summarized in Table 1. The 11 domains[8] for which each study was considered were not equally weighted for determination of overall study quality. The low-quality studies[15,16] had small trial numbers, did not report statistical significance, failed to address potential sources of bias, and did not report funding sources. The moderate-quality studies[13,14] had higher-quality methods but did not fully discuss limitations. The most-commonly neglected criterion among the high-quality studies[9-12] was lack of a no-mask control for comparison with cloth masks. We considered these appraisal findings when reporting results and drawing conclusions from each publication.

The 9 studies that met inclusion for analysis were then appraised (Table 2).[9-17] The RCT by MacIntyre et al[17] closely followed CONSORT guidelines but notably did not include a control group without masks, owing to the clinical setting. In addition, the authors disclosed a former relationship with 3M, which produces commercial masks. Although they reported that 3M was not involved in their RCT, it remains a source of potential bias.

Figure 1. Study flowchart for selection of articles.



CDC = Centers for Disease Control and Prevention; CINAHL = Cumulative Index to Nursing and Allied Health Literature.

[a] Ten studies were non-English and did not answer identified outcome measures.

Filtration

Seven publications addressed the filtration efficacy of commercial cloth masks or materials used to create homemade masks, such as polyester, cotton, tea towel, and scarves, in a laboratory setting.[9-11,13-15,17] These studies used various experimental techniques to investigate filtration of aerosolized virus,[9,14] aerosolized particles,[11,17] or bacteria.[9,10,13,15] Of the studies that evaluated pathogen penetration, 4 detected viable pathogens via colony formation,[9,10,13,15] and 1 detected postfiltration virus via polymerase chain reaction (PCR).[14] Regardless of the filtered substance or detection method, all concluded that cloth materials prevent some level of penetration but generally had lesser filtration efficiency and greater variability than medical masks. These findings suggest some, though highly variable, filtration by cloth mask materials.

Two of the identified studies investigated the effect of multiple layers of material on viral filtration.[9,14] Both reported that use of multiple layers increased the viral filtration efficacy of cloth mask material. Ma et al also specifically selected experimental material for physical similarity to SARS-CoV-2.[14] That study concluded that 1 layer of polyester combined with 4 layers of paper towel was similarly efficacious to a medical mask.[14] Both types of mask, polyester alone and combined with paper

Table 1. Observational and Nonhuman Subjects Study Appraisal Results

Publication	Study Type	Overall Study Assessment[a]	Appropriate Study Design	Prospective Calculation of Study Size	Blinding of Patients and Personnel	Patient Selection/ Inclusion Criteria
Davies et al[9]	Nonrandomized trial	High	Yes	No	No	Yes
Liu et al[10]	Nonrandomized trial	High	Yes	No	No	No
Rengasamy et al[11]	Laboratory efficacy study	High	Yes	No	No	...
van der Sande et al[12]	Nonrandomized trial	High	Yes	No	No	No
Furuhashi[13]	Laboratory efficacy study	Moderate	Yes	No	No	...
Ma et al[14]	Laboratory efficacy study	Moderate	Yes	No	No	...
Quesnel[15]	Single-case experiment	Low	Yes	No	No	No
Sellers et al[16]	Nonrandomized trial	Low	Yes	No	No	Yes

[a] Determined by review of 11 appraisal domains in context of study strengths and weaknesses.

towel, blocked ~95% of viral particles similar in size to SARS-CoV-2, as detected by PCR. However, the authors of the study considered this insufficient protection for health care clinicians and suggested use of N95 respirators.[14]

Fit and Airflow

Four studies investigated fit, particle leakage, or airflow of cloth masks in human volunteers.[9,10,12,16] One study used a commercial fit-testing system for cloth masks that were constructed and worn by volunteers,[9] and

Table 2. Summary of Included Studies

	Characteristics			Outcomes			
				Efficacy[a]			Effectiveness[b]
Publication	Study Type	Population	Pathogen/Particle	Filtration	Fit	Airflow	Infection
MacIntyre et al[17]	Randomized trial	Health care clinicians in high-risk wards in Viet-nam (N = 1,607)	Viral respiratory infection,[c] aerosolized particles	Cloth < medical	...	...	Cloth < medical (↑ infection in cloth)
Davies et al[9]	Nonrandomized trial	Volunteers, general population (N = 21)	Aerosolized virus,[d] aerosolized bacteria[d]	Cloth < medical	Cloth < medical	Cloth < medical	...
Liu et al[10]	Nonrandomized trial	Surgeons (N = 50)	Bacteria[d]	Cloth < medical	...	Cloth < medical	...
Sellers et al[16]	Nonrandomized trial	Human subjects exposed to hand-and-foot virus (N = 8)	Picornavirus[e]	...	...	...	Cloth = medical (↑ infection in both)
van der Sande et al[12]	Nonrandomized trial	Volunteers, general population (N = 39)	Particles (0.02-1 μm)	...	Cloth < medical	...	...
Furuhashi[13]	Laboratory efficacy study	...	Bacteria[d]	Cloth < medical	...	Cloth < medical	...
Ma et al[14]	Laboratory efficacy study	...	Aerosolized virus[f]	Cloth = medical	...	...	...
Rengasamy et al[11]	Laboratory efficacy study	...	Aerosolized particles (20-1,000 nm)	Cloth < N95	...	...	...
Quesnel[15]	Single-case experiment	Single human test subject, general population	Bacteria[d]	Cloth = medical	...	...	...

hMPV = *human metapneumovirus*; PCR = polymerase chain reaction.

Note: < indicates less effective or efficacious; = indicates no difference in effectiveness or efficacy; ↑ indicates increased incidence.

[a] Efficacy refers to the performance of mask materials in a laboratory setting.
[b] Effectiveness refers to the performance of masks when used by human subjects in clinical environments.
[c] Influenza-like illness and/or pharyngeal swab multiplex PCR-confirmed infection (rhinovirus, hMPV, influenza, etc).
[d] Viable pathogen detected via postfiltration colony formation.
[e] Viral colony formation from nasal swab.
[f] Virus detected via postfiltration PCR.

Subject Comparability	Appropriate Endpoints	Assessment of Outcomes/ Exposure	Follow-Up/ Handling of Missing Data	Reporting	Confounding	Appropriate Statistical Analysis
Yes	Yes	Yes	Yes	Yes	Yes	Yes
Yes	Yes	Yes	Yes	Yes	Yes	Yes
...	Yes	Yes	...	Yes	Yes	Yes
Yes	Yes	Yes	Yes	Yes	Yes	Yes
...	Yes	Yes	...	Yes	Yes	Yes
...	Yes	Yes	...	Yes	Yes	Yes
Yes	Yes	Yes	Yes	Yes	Yes	No
No	Yes	Yes	No	No	No	Yes

another quantified fit by measuring inward particle leakage by homemade tea towel masks compared to medical masks.[12] These investigations concluded that cloth masks provide a measurable barrier but have worse fit and a greater level of particle leakage compared to medical masks.[9,12]

Limited airflow through cloth materials can contribute to breathing difficulties and particle leakage. Thus, airflow is an important consideration in cloth mask design. Airflow was assessed in 2 studies with human subjects.[9,10] The materials with the greatest filtration efficacy (vacuum bag and tea towel) were countered by very low airflow, which made breathing difficult and limits use of these materials.[9,10]

Infection Risk

Two studies evaluated cloth mask effectiveness outside of laboratory conditions.[16,17] The only RCT published to date reported the differences in infectious outcomes with standardized use of cloth masks, medical masks, and usual practice and called into question their effectiveness in clinical environments.[17] Usual practice in that study included variable cloth mask use. Participants in that study arm were permitted to choose the type and duration of mask use throughout the study; therefore, there was no true unmasked control arm. Both intention-to-treat and post hoc analyses adjusting for compliance and confounders found greater rates of influenza-like illness (ILI) in the cloth mask arm compared to the medical mask arm. Of note, the relative risk of ILI was 13.25, and the 95% CI ranged broadly, from 1.74 to 100.97. Comparing participants from all arms who exclusively wore medical masks to those who only wore cloth masks, the incidences of ILI and laboratory-confirmed virus were significantly greater among health care clinicians who used cloth masks. The RCT's authors could not definitively determine whether these results reflected superior protection from medical masks or a harmful effect of cloth masks. Considering their prior findings of negligible effect of medical masks against viral infection compared to N95 respirators,[18,19] and that the medical mask used had particularly poor filtration, they concluded that the increased incidence of ILI in cloth mask users might be due to a detrimental effect of cloth masks.

Sellers et al evaluated cloth mask effectiveness against the transmission of foot-and-mouth virus.[16] That study compared viral transmission of foot-and-mouth virus in exposed subjects wearing industrial gauze and cotton masks, cloth surgical masks, or paper masks. They concluded that the industrial and cloth masks minimally decreased total virus inhalation, and paper masks had no effect.

DISCUSSION

The current COVID-19 pandemic has at times caused a shortage of PPE worldwide. Communities across the United States have mobilized efforts to provide health care clinicians with homemade cloth masks[20] as a reusable and accessible last-resort face covering. Primary care clinicians must decide how to protect themselves and their colleagues when adequate numbers of medical masks are not available. Several reports published during this pandemic addressed the effectiveness of cloth mask use in the community to prevent viral spread[21-25]; however, the use of cloth masks for protection of health care clinicians has not been thoroughly explored. This rapid review identified the relevant literature and brings together the disparate variables of filtration, fit and airflow, and clinical effectiveness to evaluate the potential for cloth masks to protect health care clinicians.

Filtration

Our qualitative synthesis suggested that cloth materials provide a measurable level of particle filtration. On this basis alone, cloth masks are superior to complete lack of face protection. However, this cannot serve as reassurance of sufficient protection for health care clinicians. The level of filtration provided is highly variable and consistently inferior to standard medical masks.[9-11,13-15] Studies included in this review that considered protection for the wearer suggested that the filtration capabilities of cloth masks would not adequately protect health care clinicians against viral infection.[12,14,17] For clinicians treating patients with COVID-19, it is notable that none of the studies in this review specifically tested SARS-CoV-2 transmission, and only 1 study selected experimental bioaerosols for physical similarity to SARS-CoV-2.[14] In addition, conclusions regarding filtration were based on investigations of aerosolized particles including noncoronaviruses,[9,11,14,16] bacteria,[8,13,17] and simulated biologic particles.[12,15] According to the World Health Organization, contact and respiratory droplets are the primary method of SARS-CoV-2 spread,[26] and aerosols are thought to play a smaller role.[22] The majority of efficacy studies examined here investigate filtration of aerosolized particles or virus rather than droplet or contact protections. Thus, we must interpret these results with caution in the context of COVID-19.

Fit and Airflow

When considering a cloth mask as opposed to medical masks or a bandana or scarf, fit and airflow are essential elements to consider. These are also elements that distinguish medical masks from N95 respirators. Poor fit decreases protection because particles can pass through gaps between the wearer's face and the mask, while poor airflow causes breathing difficulty, causing compliance issues.[9,14] No current studies compared variable designs of cloth masks for fit or airflow, but multiple studies showed inferior fit of cloth masks compared to medical masks. Two studies found that the studied designs and materials of cloth masks limit both proper fit and airflow, leading to decreased protection and breathing difficulties.[8,14] This poses a significant challenge to cloth mask use and presents an opportunity for future research and development.

Clinical Effectiveness

Although multiple studies indicated that cloth masks might be somewhat efficacious, the single clinical investigation suggests that they provide inferior protection in clinical settings and might even increase risk to health care clinicians. Whereas that work suggested that clinicians should exercise caution when choosing to use cloth masks, there are no similar real-world studies to support or refute this conclusion and no investigations as to why cloth masks might have increased risk of viral infection. Although they considered poor filtration, moisture retention, ineffective cleaning, and reuse of cloth masks as possible contributors, the authors did not detail how health care clinicians used their 5 provided cloth masks over their 8-hour shifts. This prevents conclusions regarding length of use and moisture retention. The authors noted that 80% of cloth mask wearers washed their masks at home with soap and water rather than in hospital-grade laundry.[17] In addition, the RCT isolated *human metapneumovirus*, rhinoviruses, and influenza B virus, which differ in transmission and pathogenic properties from SARS-CoV-2.[21]

Strengths and Limitations

To our knowledge, this is the only contemporary rapid review of cloth face masks specifically for health care clinician protection. Strengths of this rapid review include a comprehensive search of high-yield databases, in consultation with a health sciences librarian. Owing to the limited number of eligible articles, studies of all grade scores were included. This review excluded studies considering environmental contaminants such as diesel particles. The body of literature on environmental contaminants might provide additional insight regarding the protective qualities of cloth masks that were not addressed by this review. Other considerations, including virus viability on masks or mask materials and behavior change associated with mask use, lack definitive understanding.[27] Given the lack of quantity and quality of literature available, this review cannot remark definitively on protection for health care clinicians from COVID-19 by cloth masks.

Recommendations

Current CDC guidelines recommend use of an N95 respirator for care of patients with COVID-19 because medical masks cannot provide the same level of protection against aerosolized particles.[28] Whereas there is some evidence for SARS-CoV-2 aerosol transmission,[22,26] protective measures against droplet transmission should also be considered. For a primary care clinician without access to medical masks, our qualitative synthesis of the literature suggests that it is better to wear a cloth mask than no mask but not without careful consideration of harm reduction. The psychologic theory of risk compensation refers to the concept that humans might behave less conservatively when they believe their risk to be decreased.[27] This is essential to consider when creating policies regarding the use of cloth masks and messaging to health care clinicians regarding their risks when wearing cloth masks.

We emphasize the CDC's recommendation of pairing cloth masks with a plastic face shield.[5] Considering the findings of MacIntyre et al,[17] it is important to address the potential for increased risk of viral infection to the wearer. We recommend frequent cloth mask changes to reduce the risk of moisture retention and washing according to hospital laundry standards to decrease the risk of ineffective cleaning. The rapidly evolving nature of research and literature regarding protective face coverings during the COVID-19 pandemic presents a challenge for those trying to stay up to date. The CDC has published a running list of studies on masks that might provide additional guidance for health care clinicians considering cloth masks.[29]

CONCLUSIONS

Review of the current literature suggests that cloth materials are somewhat effective in filtering particles and aerosols, but cloth masks provide inferior protection, with poorer fit and airflow, compared to medical masks. Some data also suggest a potential harm to health care clinicians using cloth masks for extended periods in the clinical setting. Cloth masks should not be considered equivalent to medical masks, and if clinicians choose to use them, level of fit, type of material, and number of layers should be considered. Overall, we conclude that cloth masks lack evidence for adequate protection of health care clinicians against viral respiratory infections, and health care clinicians should use caution when deciding whether to use cloth masks for extended clinical work.

Additional research is needed to provide a complete understanding of cloth mask effectiveness in health care environments. Future work should include systematic comparison of different cloth mask designs and cloth types against standard surgical masks and N95 respirators in a controlled laboratory setting to optimize fit and material properties. Additional RCTs are required to assess the realities of cloth mask use by health care clinicians.

To read or post commentaries in response to this article, see it online at https://www.AnnFamMed.org/content/19/1/55.

Key words: COVID-19; personal protective equipment; PPE; pandemic

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nomaskers.org

What is the science behind your mask mandate?

13-16 minutes

Posted By: **Fielden Nolan (nolanf)**

Post Date: **02/18/2021**

Is the wearing of masks to reduce the spread of the COVID-19 virus "settled science?" Countless articles in the mainstream media simply label critical thinkers as "conspiracy theorists" or "vaccine deniers" without consideration of the facts.

Everybody loves "fact checks." Let's "fact check" the "settled science." Here is an example of the kind of "settled science" you will find in the mainstream narrative:

Both the Centers for Disease Control and Prevention (CDC) and the World Health Organization now recommend cloth masks for the general public... (UC San Francisco)

FACT CHECK: The UCSF Medical Center, which is educating a host of young, enthusiastic medical students, is wrong in the claim that the CDC and the WHO recommend cloth masks:

More research on cloth masks is needed to inform their use as an alternative to surgical masks/respirators in the event of shortage or high-demand situations. To our knowledge, only 1 randomized controlled trial has been conducted to examine the efficacy of cloth masks in healthcare settings, and the results do not favor use of cloth masks.

More randomized controlled trials should be conducted in community settings to test the efficacy of cloth masks against respiratory infections. (CDC, October 2020, Source)

In fact, that same month, in a report in Emerging Infectious Diseases, the CDC revealed:

...more than 70 percent of COVID-positive patients contracted the virus in spite of faithful mask wearing while in public. Moreover, 14 percent of the patients who said they "often" wore masks were also infected. Meanwhile, just four percent of the COVID-positive patients said they "never" wore masks in the 14 days before the onset of their illness. (Source)

It gets worse. In the same study, the CDC stated:

“This finding suggest that risk for infection was higher for those wearing cloth masks.”

The CDC does not recommend cloth masks in protecting yourself and others from the virus. Don’t believe me. One needs only to take the time to look at their published position.

As of late March, 2020, the efficacy of any face mask in reducing the spread of COVID-19 was generally questioned. In April 2020, the World Health Organization stated that healthy people don't need to wear face masks to prevent coronavirus spread. Masks, they said, should be for the sick, their caretakers, and healthcare workers. At the very end of 2020, the WHO updated their guidelines, noting that any kind of mask was ineffective if the wearer come into close contact with someone for 15 minutes or more. By the end of the year, the WHO was equivocating; they admitted there was no real evidence to support the wearing of ANY mask, but nevertheless recommended them. Their “interim guidance” for the wearing of ANY face masks now contains this:

The World Health Organization (WHO) advises the use of masks as part of a comprehensive package of prevention and control measures to limit the spread of SARS-CoV-2, the virus that causes COVID-19. ***A mask alone, even when it is used correctly, is insufficient to provide adequate protection or source control.***

The European Centre for Disease Prevention and Control reached a similar conclusion:

“It is not known how much the use of masks in the community can contribute to a decrease in transmission in addition to the other countermeasures” (Source)

It can be safely concluded that the World Health Organization or CDC have NEVER explicitly supported the wearing of cloth masks. It’s clear that both organizations are reluctant to endorse the effectiveness of cloth face masks in reducing the spread of the COVID-19 virus. FACT CHECK: FALSE

If upon actual investigation the oft-quoted WHO and CDC will not commit themselves to the wearing of masks as being effective in reducing the spread of the COVID-19 virus, how can their effectiveness be “settled science?”

Once again: it gets worse.

In September of 2020, the CDC reported that 85% of COVID-19 cases in July were people who often or always wear masks. (Source)

Briefly, let’s do some simple math. According to a 2015 randomized clinical trial conducted by the University of South Wales, in testing the effectiveness of cloth masks among health care workers in Hanoi against bacterial infections among schoolchildren, cloth masks were found to be wholly ineffective.

Remember streptococcus cells are between 0.5 and 2 microns, roughly 5-20 times larger than SARS-CoV-2 virions (which are about 0.06-0.14 microns), yet the masks still failed to protect against them and perhaps contributed to the spread of the bacteria. (Source)

Unless you can establish that a BB cannot easily get through a fish net, or that a chain-link fence can stop a sandstorm, you cannot establish that ANY mask (let alone a cloth one) is effective in any sense against the spread of the COVID-19 virus. It really is that simple.

The size of the virus based on electron micrographs show that the virus varies from 60 to 140 nanometers in diameter (.06 to .14 microns). N95 filters provide filtration down to .3 microns. On this basis alone, they should not be relied on for protection from small virus particles such as those of SARS-CoV-2. (Source)

..the pores in surgical masks are about 30 times larger than the average size of SARS-CoV-2 virions, and some of the cheap (but more comfortable) cotton masks that are commonly worn have pores hundreds of times larger than the virus particles. (Source)

At .1 micrometers, the size of the COVID-19 virus is about 1000X smaller than the width of a human hair! Until the invention of the electron microscope in the 1930's, a pathogen this tiny could not be seen – even with the best optics. Yet here is another study offered as "evidence" by UCSF Medical Center that that wearing a mask is effective in preventing COVID-19:

*An experiment using high-speed video found that hundreds of droplets ranging **from 20 to 500 micrometers** were generated when saying a simple phrase, but that nearly all these droplets were blocked when the mouth was covered by a damp washcloth. (NEJM: Visualizing Speech-Generated Oral Fluid Droplets with Laser Light Scattering)*

Of course, attempting to prove that a wet washcloth can inhibit the spread of droplets which are thousands of times greater in size than the COVID-19 virus is of course silly and makes no sense. Moreover, within this simple mechanistic study, the authors stated:

We did not assess the relative roles of droplets generated during speech, droplet nuclei, and aerosols in the transmission of viruses.

There you have it. The assumption driving the test was the validity of the still-unsubstantiated "droplet theory" promoted by the CDC, as well as their well-documented avoidance of the possibility of aerosol involvement in in viral spread. Your taxpayer money probably funded this study. Preschoolers with a box of crayons could have been as persuasive as this one.

How many times have you seen a person wearing a mask below their nose, are constantly adjusting it, or are not changing their mask frequently? According to the World Health Organization (WHO) these are practices which can actually increase the likelihood of COVID-19 transmission!

The following from WHO is listed as behavior that can increase transmission:

- *Touching mouth and nose*
- *Touching a mask in use*
- *Touching a clean mask with unwashed hands*
- *Not washing hands every time after touching a dirty mask*
- *Wearing a mask that is not new and clean*
- *Continuing to wear a mask after it has become damp*
- *Re-using a single-use mask*

- *Not discarding a single-use mask immediately upon removal, as opposed to leaving it in the immediate environment*

  (Source: Alan Stevo)

  What do you actually know about masks? A properly-fitted N95 mask is designed for use in a contaminated environment, and can be effective, for instance, in dealing with chemical spills, or working in a fabrication shop, but not in dealing with viruses. If you purchase a domestically-produced N95 mask, read the CDC statement on the box:

  The Centers for Disease Control and Prevention (CDC) does not recommend that the general public wear N95 respirator masks to protect themselves from respiratory diseases, including coronavirus (COVID-19) (Source)

  The CDC continues:

  '*Cloth masks actually risk your health rather than protect it. The moisture caught in these masks will become mildew-ridden in thirty minutes. Dry coughing, enhanced allergies, sore throat are all symptoms of a micro-mold in your mask'*

  So far, we've been mostly focused only on the combined, dubious wisdom of the CDC and the WHO. There isn't enough room and time to cover all the studies, going back decades, which all call into question the use of masks (particularly cloth masks) in reducing the spread of the COVID-19 virus. Nomaskers.org is full of resources so you can do your own research. Studies from the Annals of Internal Medicine, Association of American Physicians and Surgeons, World Health Organization, U.S. Navy and more can be found from the Resources menu.

  But, again, it gets worse.

  The wearing of masks can harm your health. Masks can come from anywhere, and often contain all kinds of toxic substances and material used in their manufacture. Here is an excerpt from a study which contains a long list of them:

  Disposable surgical face masks are made of synthetic fibers, including polymers such as polypropylene, polyurethane, polyacrylonitrile, polystyrene, polycarbonate, polyethylene or polyester. There is an inner layer of soft fibers and a middle layer, which is a melt-blown filter, as well as a water-resistant outer layer of nonwoven fibers.9 This study shows FT-IR spectra of the degrading fibers of disposable masks. It found that disposable face masks "could be emerging as a new source of microplastic fibers, as they can degrade/fragment or break down into smaller size/pieces . . . .

  Research on synthetic fibers has shown a correlation between the inhalation of synthetic fibers and various bronchopulmonary diseases, such as asthma, alveolitis, chronic bronchitis, bronchiectasis, fibrosis, spontaneous pneumothorax and chronic pneumonia. Cellular proliferation made up of histiocytes and fibroblasts were found in the lungs of those exposed to synthetic fibers in ambient air. Focal lesions in the lungs showed granulomas and collagen fibers containing both fine dust and long fibers. Some of the lung illnesses from this exposure could be reversed, while others had already proceeded to pulmonary fibrosis. (Source)

Scores of dermatologists, dentists, immunologists, virologists, pediatricians all over the world have been sounding the alarm for months over the continued use of face masks. They consistently try communicate to anyone who will listen that patients generally have no training or real understanding of how masks work.

... untrained members of the public are wearing medical masks, repeatedly… in a non-sterile fashion… They're becoming contaminated. They're pulling them off of their car seat, off the rearview mirror, out of their pocket, from their countertop, and they're reapplying a mask that should be worn fresh and sterile every single time. (Dr. James Meehan, MD)

Prolonged wearing of face masks has been tied to advanced stage lung cancer. It should be noted here that would-be debunkers like USA Today have attempted to dispute this finding by deceptively tying its source to a Facebook post, rather than a reputable medical journal. Ethylene Oxide, a carcinogen which is found in Teflon, is often used in the sterilizing process of cheap surgical masks. Even though the Occupational Health & Safety Agency (OSHA) has recommended them only for short-term use, our executive figures, the major media, Big Tech, fake science proponents support a mandate that you wear them for many hours you spend at work. In some states, you were even required to wear them in your home! OSHA has also concluded that surgical masks do not reliably provide protection against "smaller airborne particles." Of course, 100 nanometers is about as small as an airborne particulate can get.

Active duty and defense support personnel know the drill. Handlers in pharmaceutical products production know the drill. So do EMTs and medical professionals. They've all had formal training regarding the selection and fitment of PPE (Personal Protective Equipment). I suspect that all these people should all have spotted by now the many problems with mask mandates.

Face masks for use in limiting the spread of pathogens are classified as Class 1 medical devices by the FDA. Your governors, mayors, grocer, neighbors or evening news announcers are not qualified to prescribe medical devices to you, regardless of how convincing they appear. The use of medical devices require informed consent by the patient. Like many other medical devices, face masks can save your life, but they can also harm you. Know the science about masks, and don't believe everything you hear. *After you have become informed, and you do not agree you should wear a mask, simply do not consent.*

Mask mandates are useless and potentially harmful. There is no "science" behind them. For every resource the major media presents to you in building the case supporting mask efficacy, you can easily respond with ten resources endorsing the opposite position. Truly, their mask "science" is not settled.

-

Plaintiff's Exhibit 93

principia-scientific.com

WHO: You Do NOT Need to Wear a Mask | Principia Scientific Intl.

4-5 minutes

Published on January 25, 2021

Written by John O'Sullivan

The World Health Organization admits there is no scientific medical reason for any healthy person to wear a mask outside of a hospital. Sadly, our corrupt politicians and mainstream media only relate the bad news.

If you do not have any respiratory symptoms, such as fever, cough, or runny nose, you do not need to wear a medical mask. When used alone, masks can give you a false feeling of protection and can even be a source of infection when not used correctly.

The most recent press announcement is at www.who.int

Update & Correction (January 26, 2021): Our apologies for omitting a

reference for the above. The following is added as evidence on current WHO advice:

Last month (December, 2020) WHO issued the following advice that masks are only of some benefit if used in conjunction with a range of other measures and of limited value.

WHO tells us that:

> **"…the use of a mask alone, even when correctly used (see below), is insufficient to provide an adequate level of protection for an uninfected individual or prevent onward transmission from an infected individual**." [1]

As Dr Joseph Mercola, who analysed the WHO advice pointed out in *WHO Admits: Not Clear Masks Prevent Viral Infection'*

> "….the literature rather strongly suggests the usefulness of masks depends on a significant number of factors — type, fit, length of use, purpose and circumstances — which are effectively impossible to account for in public universal-masking policies.
>
> The science, contrary to the ignorant platitudes we are bombarded with, has NOT proven that universal masking is effective for viral containment, and has instead provided substantial grounds for skepticism of such a policy."

[1] 'Mask use in the context of COVID-19 Interim guidance', December 01, 2020, https://apps.who.int/iris/bitstream/handle/10665/337199/WHO-2019-nCov-IPC_Masks-2020.5-eng.pdf?sequence=1&isAllowed=y

Update January 30, 2021:

So angered that our original link to the latest WHO press announcement did not contain a specific suggestion for people not to wear masks USATODAY and other haters have been on our case saying we 'lied' and WHO did not say you did not need to wear a mask.

Well, to all you misinformed haters, you are clearly not good at checking your facts because in December 2020 WHO stated that:

"…the use of a mask alone, even when correctly used (see below), is insufficient to provide an adequate level of protection for an uninfected individual or prevent onward transmission from an infected individual."

Moreover, Dr. Mike Ryan, an epidemiologist who specializes in infectious diseases and public health and who is the executive director of the WHO health emergencies program is on record stating that:

"WHO stands by recommendation to not wear masks if you are not sick or not caring for someone who is sick. There is no specific evidence to suggest that the wearing of masks by the mass population has any potential benefit. In fact, there's some evidence to suggest the opposite in the misuse of wearing a mask properly or fitting it properly" (source).

USATODAY have written to us saying they are going to do a 'fact check' hit piece on us. We gladly welcome them addressing this important topic and will be delighted to offer further scientific evidence that mask wearing is nothing more than a 'talisman' and will likely do more harm than good for healthy, uninfected wearers.

If you doubt that, simply check out the photo below:

Plaintiff's Exhibit 94

Standard Interpretations / Voluntary use of surgical masks

- **Standard Number:** 1910.134

OSHA requirements are set by statute, standards and regulations. Our interpretation letters explain these requirements and how they apply to particular circumstances, but they cannot create additional employer obligations. This letter constitutes OSHA's interpretation of the requirements discussed. Note that our enforcement guidance may be affected by changes to OSHA rules. Also, from time to time we update our guidance in response to new information. To keep apprised of such developments, you can consult OSHA's website at https://www.osha.gov.

December 20, 2017

Mr. John Boren
3633 Wareham Drive
Thompsons Station, TN 37179

Dear Mr. Boren:

Thank you for your letter to the Occupational Safety and Health Administration (OSHA). Your letter has been referred to the Directorate of Enforcement Programs for an answer to your question. Your letter requested clarification of OSHA's Respiratory Protection Standard, 29 CFR 1910.134, pertaining to the voluntary use of surgical masks. This letter constitutes OSHA's interpretation only of the requirements discussed herein, and may not be applicable to any questions not delineated within your original correspondence. Your paraphrased question and our response are below.

Question: Is it permissible to allow surgical masks to be worn on a voluntary basis when respiratory protection is not required to meet any OSHA standards? And if so, is it permissible for employers to provide surgical masks for voluntary use?

Response: Yes. The employer may allow the voluntary use of surgical masks even where an exposure assessment shows respirator use is not required and the employer may provide surgical masks for voluntary use. However, surgical masks may not be used in lieu of required respiratory protection. Surgical masks are not considered respirators by OSHA and, as such, are not covered by 29 CFR 1910.134. They are fluid resistant, disposable, and loose-fitting protection that create a physical barrier between the mouth and nose of the wearer and potential contaminants in the immediate environment. They are commonly used in health care settings for the protection of the patient and they are also often used to prevent splashes from contacting the face of the wearer. However, surgical masks do not seal tightly to the wearer's face, nor do they provide a reliable level of protection from inhaling smaller airborne particles.

If the hazard to which your employees are exposed to is a combination of splashes and respirable contaminants, your company may want to consider NIOSH approved surgical N95 respirators which also are cleared by the Food and Drug Administration (FDA) for use as a surgical mask. Surgical N95s are filtering facepiece respirators equipped with spray- or splash-resistant facemask material on the outside to protect the wearer from splashes. Regardless of which type is used, the employees should be informed on the different varieties and their unique set of cautions, limitations, and restrictions of use. This information will facilitate employee involvement in the respirator program and/or the overall safety and health program.

For more information on surgical masks and surgical respirators, please review the *Hospital Respiratory Protection Program Toolkit* at https://www.osha.gov/Publications/OSHA3767.pdf. OSHA also has a fact sheet that compares respirators and surgical masks titled Respiratory Infection Control: Respirators Versus Surgical Masks that is available at https://www.osha.gov/Publications/respirators-vs-surgicalmasks-factsheet.html.

Please be aware that the Tennessee Department of Labor and Workforce Development operates its own occupational safety and health program under an OSHA-approved State Plan. The Tennessee Occupational Safety and Health Administration (TOSHA) adopts and enforces standards and investigates safety and health concerns in workplaces throughout the state. State Plans are required to have standards and an enforcement program that are "at least as effective" as OSHA's, but may have different or additional requirements. Please contact TOSHA directly at the address below, for further information and to discuss your specific compliance issue:

Tennessee Department of Labor and Workforce Development

220 French Landing Drive
Nashville, Tennessee
Telephone: (615) 741-2793
https://www.tn.gov/workforce/employees/safety-health/tosha.html

Thank you for your interest in occupational safety and health. We hope you find this information helpful. OSHA's requirements are set by statute, standards, and regulations. Our letters of interpretation do not create new or additional requirements but rather explain these requirements and how they apply to particular circumstances. This letter constitutes OSHA's interpretation of the requirements discussed. From time to time, letters are affected when the agency updates a standard, a legal decision impacts a standard, or changes in technology affect the interpretation. To assure that you are using the correct information and guidance, please consult OSHA's website at http://www.osha.gov. If you have further questions, please feel free to contact the Office of Health Enforcement at (202) 693-2190.

Sincerely,

Thomas Galassi, Director
Directorate of Enforcement Programs

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welovetrump.com

WATCH: CNN Admits Cloth Masks Are Useless

by daniel_g

12-28-21

4-5 minutes

The entire Covid-19 narrative is collapsing.

Biden recently gave up the fight on Covid-19, The CDC has halved the quarantine period, and now CNN is saying that masks are basically useless despite what they said last week…

I am not sure if this is because we have beaten back their claims outright, or if they are trying to make Democrats look good in the upcoming primaries by saying that the pandemic is over.

I have said time and time again that if left unchecked this situation will lead to a civil war.

Now I believe that no matter what happens going forward this will *never* be forgotten—in short it will definitely lead to a civil war or the complete breakdown in the state eventually because people *aren't* going to forget this.

It represents a crack in the pillars—a rot that will eat away at the very core of the country until nothing is left, kind of like an unfaithful spouse. Some things can be forgiven in a marriage, other things destroy the sanctity of that marriage.

How can we forget that our neighbors, teachers, and friends essentially lost their minds and gave into tyranny? Where do we go from here?

We cannot just go back to our normal lives now—not after the events of the last 2 years.

Some things can be forgiven, but enforcing the will of the state? Trying to force involuntary vaccinations on people? Ignoring data which is contrary to that of government authorities and large pharmaceutical conglomerates?

Trying to cost your neighbor their job because they refuse to take an unnecessary drug forced on them for profit?

These things cannot be forgotten. The fear, the tyranny, the incessant paranoia —these are wounds which will not heal ever.

So to the people who willingly went along with the government and the establishment congratulations….you're going to have an *extremely* tough road ahead of you.

Here's more. on the story:

> This new CNN declaration that masks "are not appropriate in this pandemic" is an Orwellian escalation. Can the media produce amnesia on demand? And will the people cooperate by wiping their own memories?
>
> Completely intentional. The ultimate power move
>
> pic.twitter.com/RVtN0BZlLf
>
> — Walter Kirn (@walterkirn) December 28, 2021

> "There's no place for them in light of Omicron," Dr. Leana Wen told CNN's Victor Blackwell, but there wasn't any place for them in light of Delta, Beta, or any other variant either.
>
> CNN expert: Cloth masks are useless "face decorations" at this pointhttps://t.co/hOQb5tpzsd
>
> — Ed Morrissey (@EdMorrissey) December 21, 2021

Reason took note of CNN's recent comments:

> *Wen is a supporter of mandates, so perhaps she thinks the higher quality masks should be required in some settings. Yet if she's right, it means the masks that the overwhelming majority of people are wearing in order to comply with mandates—in public schools, on public transportation, in many workplaces, gyms, and even social settings—aren't doing any good.*
>
> *They represent another element of pandemic hygiene theater: a public health requirement that makes people feel safer without offering them much actual protection.*

> Also, can we burn our masks? CNN chick declared (inadvertently) that they were useless, so now that the corrupt media has said out loud what sensible people have been saying for many months, can we do away with this idiocy?
>
> — Admiral Trish (@TrishStuth) December 27, 2021

> Masks worn like that are useless, masks over the nose provide some protection, but not as much as N95s. I got none of this info from CNN

> — Mordicai A.V.A O'Shea (@mordicaioshea) December 27, 2021

Town Hall had this to say:

> *As Katie covered back in August, another CNN guest — former Biden advisor and University of Minnesota Center for Infectious Disease Research and Policy Director Michael Osterholm — similarly said that "many of the face cloth wearings people wear today are not very effective in reducing any of the virus movement in or out." But the White House, via Press Secretary Jen Psaki, rejected Osterholm's conclusion.*

Plaintiff's Exhibit 96

beckernews.com

Dr. Scott Gottlieb Gives Unbelievable Confession: 'A Cloth Mask is Not Going to Protect You' from an Airborne Virus

Written by Kyle Becker

7-8 minutes 1-2-22

Dr. Scott Gottlieb, the former FDA chief who quickly transitioned after leaving office to become a Pfizer board member, has made an admission about cloth masks that should make Americans question the "science" they have been told was unquestionable all along.

Gottlieb appeared on CBS's "Face the Nation" with host Margaret Brennan and punctured the widespread belief that cloth masks provide any significant protection from airborne respiratory viruses, such as Covid-19.

"I have been looking at pediatric hospitalizations at this record high," Brennan claimed. "And concerned about sending my son back into a pre-school even with a mask on."

"What do you tell parents?" she asked breathlessly. "Are cloth masks just not good enough anymore?"

"Cloth masks aren't going to provide a lot of protection, that's the bottom line," he said. "This is an airborne illness. We now understand that. And a cloth mask is not going to protect you from a virus that spreads through airborne transmission. It could protect better through droplet transmission, something like the flu, but not this coronavirus."

Dr. Gottlieb goes on to make wild claims about the severity of Covid-19 among the pediatric population, claiming that more than 600 pediatric deaths (95% of them with underlying health conditions) among a population of 73 million under age 18 is a cause for masking children and mandating they be immunized despite the vaccines failing to significantly stop the spread. Covid-related mortality is approximately *one percent* of all pediatric deaths in the past two years.

Margaret Brennan, for her part, also fed the hysteria of the risk in Covid to children by making a misleading claim about child hospitalizations. Dr. Anthony Fauci recently disabused parents of this notion.

> Fauci: "If you look at the children that are hospitalized, many of them are hospitalized with Covid, as opposed to because of Covid." pic.twitter.com/57Rdx8gPg3
>
> — The Post Millennial (@TPostMillennial) December 31, 2021

"And what we mean by that: If a child goes into the hospital, they automatically get tested for COVID and they get counted as a COVID-hospitalized individual, when, in fact, they may go in for a broken leg or appendicitis or something like that. So it's over counting the number of children who are, quote, hospitalized with COVID as opposed to because of COVID," Fauci said.

Fauci had once shared a similarly candid assessment as Gottlieb's on the efficacy of masks in a February 2020 email to an HHS official.

"Masks are really for infected people to prevent them from spreading infection to people who are not infected rather than protecting uninfected people from acquiring infection," he wrote in the email.

"The typical mask you buy in the drug store is not really effective in keeping out virus, which is small enough to pass through material," he said. "It might, however, provide some slight benefit in keep out gross droplets if someone coughs or sneezes on you."

That was *two years* ago.

Dr. Leanna Wen, who is a regular Covid doomer on CNN, also shared a rare moment of honesty on the network.

> .@DrLeanaWen: "Don't wear a cloth mask. Cloth masks are little more than facial decorations. There's no place for them in light of Omicron." pic.twitter.com/Kpoj18sxdi
>
> — Townhall.com (@townhallcom) December 21, 2021

"Don't wear a cloth mask," she said. "Cloth masks are little more than facial decorations. There's no place for them in light of Omicron."

Now, let's be perfectly clear: The reason that public health officials are backing off the narrative now is because it has crumbled completely. Despite more than 99% mask compliance in countries like South Korea, there is still an explosion of infections no different than in countries that have much lower mask usage rates. This is called "no significant difference."

Ironically, Margaret Brennan recently addressed the mental health crisis among schoolchildren that has been exacerbated by ineffective and aggravating Covid policies.

> "They will be paying for our generation's decisions the rest of their lives": @JanCBS explains why she thinks 2021's biggest underreported story was the devastating impact of COVID policies on children pic.twitter.com/AUU1f6AFNi
>
> — Face The Nation (@FaceTheNation) December 26, 2021

"They will be paying for our generation's decisions the rest of their lives," she said.

The nation's largest teacher's unions don't seem to appreciate the significance of policies like school masking and remote learning on children's psychosocial development. In May, the CDC was going to issue guidance lifting school mask guidance, but the nation's largest teacher's union, the NEA, raised enough of a fuss to get the "science" changed.

Masking in schools has been one of the most contentious aspects of Covid policies throughout the pandemic. The Atlantic recently called out CDC Director Walensky for misleading the public about a school mask study.

"Seen in this context, the CDC has taken an especially aggressive stance, recommending that all kids 2 and older should be masked in school," the article notes. "The agency has argued for this policy amid an atmosphere of persistent backlash and skepticism, but on September 26, its director, Rochelle Walensky, marched out a stunning new statistic: Speaking as a guest on CBS's *Face the Nation*, she cited a study published two days earlier, which looked at data from about 1,000 public schools in Arizona. The ones that didn't have mask mandates, she said, were *3.5 times* as likely to experience COVID outbreaks as the ones that did."

Of course, this is patently false, and The Atlantic article usefully explains why.

As OSHA has stated, neither cloth masks nor surgical masks are designed to protect wearers from airborne pathogens, particularly respiratory viruses. The confidence intervals for the efficacy of cloth masks and surgical masks to slow the spread of respiratory viruses are poor. N95 masks, which are not designed to be worn by the general public for 6 to 8 hours a day, fare only slightly better. These are the facts, regardless of the spin by authoritarian Covid policy advocates.

In January, CDC Director Walensky explained why the general public should not wear N95 masks for long hours over the course of a day.

"They're very hard to breathe in when you wear them properly," Walensky said. "They're very hard to tolerate when you wear them for long periods of time."

The good news is that Omicron is a small fraction as harmful as earlier Covid variants, and new research shows it has a transfer of natural immunity to other variants, such as Delta.

NOW READ:

OPINION: This article contains commentary which reflects the author's opinion.

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ashmedai.substack.com

Facemasks Are Not an 'Inconvenience', Facemasks Are Not Trivial: A List of Some of the Underappreciated and Hard-to-Articulate Reasons Forced Masking is so Distressing

Ashmedai

12-25-21

21-26 minutes

> "Experience has shown that communities faced with epidemics or other adverse events respond best and with the least anxiety when the normal social functioning of the community is least disrupted"

- DA Henderson, Disease Mitigation Measures in the Control of Pandemic Influenza, 2006

One of the most trenchant arguments made by proponents of forced masking is some variation of "it's just an inconvenience", so/and/or "why do you have to make such a big deal about it". (To be clear, this is not a legitimate scientific or factual argument for the adoption of any policy, but that is not what this article is about.) I am largely going to avoid the issues unique to masking children - what is plainly institutionalized child abuse - and for people with disabilities or past trauma, as many of the harms inflicted by masks are readily apparent and easily articulable.

On the surface, this contention seems like a morally and factually compelling argument. After all, if masks had any meaningful efficacy, wouldn't it be a worthwhile tradeoff to endure a little discomfort to reduce the far worse suffering and death that would otherwise be inflicted by covid?

Yet this argument - "what's the big deal" - does not square with how many people experience masks and mask mandates, including practically everyone who disagrees with masking as a policy. It is undeniable that millions of people are considerably more tormented by facemasks than what we would expect is reasonable or even possible for something that is indeed merely an "inconvenience". People generally do not profoundly suffer from trivialities.

In other words, clearly facemasks are a considerably greater burden for many people than how they superficially appear; and yet few people are able to work out for themselves what about them is so abusive or terrible. The goal of this article is to enumerate some of the myriad harms and emotional abuses inflicted by forced masking, specifically those that are difficult to articulate or identify the connection to masking.

So what exactly is the big deal about wearing masks?

In a nutshell - as was just stated - mask wearing is to many people something that is enormously stressful, and something that evokes inordinately powerful negative emotions. This is simply the reality, irrespective of whether such feelings “make sense”.

Now, as a general rule, if someone feels powerfully about something, there’s a reason; or in other words, there is something that is provoking the strong emotions. And the source of these feelings does not have to be the thing that the feelings attach to. The only thing that matters is that the feelings exist, however misguided they may be.

This is not to say that the reality of feelings should be the dominant consideration above everything else. The current radical ‘social justice’ movement that has elevated one’s subjective “identity” as the defining characteristic of a person is the Reductio ad Absurdum of enshrining subjective feelings in place of objective reality itself.

What is true however is that the emotional distress and suffering of people is quite real. So even if you happen to be in favor of mask mandates and not at all bothered by mask wearing, that does not make the profoundly distressing experience of someone else any less real of an experience.

The following list is not exhaustive, just a collection of some of the factors that make mask wearing, especially forced masking, so distressing to many people.

A few important things to keep in mind:

1. Not every listed issue is true for every person who finds masks distressing.
2. Each issue amplifies the other ones, so that the cumulative distress is far greater than the sum of its parts. It’s like the difference between 1+2+3+…10 and 1x2x3x…10 (55 vs 3,628,800).
3. This list is not exhaustive.
4. The short explanations are intended to give a bit more insight into how people might typically experience that particular stress. They are not intended to comprehensively define the issue.

Emotional Stresses of Mask Mandates

Deprivation of Personal Autonomy

Depriving someone of their personal autonomy is stressful and demeaning. This is amplified when it is about something that is emotionally fraught, subject to strong opinions and feelings, relates to morality/values, and/or is something that has an implication that you lack the capacity to look out for your own interest. Free will is a defining trait of being human, and the abrogation thereof is experienced as an assault on ones individuality.

A Sense of Helplessness

Being at the mercy of the arbitrary and capricious whims of others makes you feel a sense of helplessness, which is extremely stressful and grueling, and can eventually break a person mentally and emotionally, and is therefore a favored tactic used by tyrants to break the will of the population so that they are too broken to revolt (see Stalin’s reign of terror).

Invalidating Your Personal Identity

Masking is now - regardless of the factual merits - a political symbol in society. Being forced to mask is by definition being forced to yield in ones own actions - and worse, in ones public appearance - to your ideological and/or political opposition. Imagine if the government decided to make wearing a religious skullcap mandatory for everyone - you can make the same argument that is being made for masking - what's the big deal, you barely notice it, etc - I am quite confident that atheists for instance would would feel very keenly the assault on their personal identity.

Assaulting Your Sense of Morality / Making You Feel Like You're Immoral and Selfish

Mask mandates force people opposed to internalize that they are acting immorally and selfishly for two reasons. The first is that society is enshrining into law that how you act is immoral and selfish, which is a public declaration to the world that you are immoral and selfish. The second is that how you act outwardly always exerts influence in how you fell and identify internally, so constantly wearing a mask eats away at your internal convictions - even if you can withstand this, it creates some degree of cognitive dissonance internally. No one likes to feel like they are evil or selfish.

Deprives / Ruins Human Interactions

The quality and nature of social interactions is greatly reduced. Every interaction behind masks is fundamentally different. Interacting in this way can feel sad, despondent, isolating, cold, and/or cruel, among other things.

Over Time Changes Your Personality

Facemasks are a radical and unnatural impingement on normal mental and emotional functioning. Over time, this can change your personality - such as making you less social, less outgoing, more suspicious, decreased tendency or desire to be kind and so on.

Turns Other People Into Abusive Tyrants

This is meant to capture the phenomenon of a subset of people who have turned into cruel and vicious individuals, and abuse people whom they have power over.

A General Feeling of Being Trapped in a Nightmare

Many people feel a clear and distinct sense of being trapped in some sort of perverse nightmare as a result of covid policies, which is an extremely distressing experience, especially when there feels like there is no end in sight.

Elementary Lack of Fairness

People are very sensitive to fairness, and can feel enormous stress and distress when treated unfairly, especially when the unfair treatment is egregious. Mask policies are literally imposing on some people so other people can feel safer - a grotesquely unequal treatment, that in order to help the emotional health of the scared-to-death-of-covid pro-maskers, everyone else's mental & emotional health will be trampled on by forced masking. Moreover, mask mandates preferentially enshrines the political, moral, and ideological views and sensibilities of one segment of society without any justification.

Repeated Experience of "Losing" in Public Policy Decisions

The experience of losing again, and again, and again in substantial, significant public policy decisions is itself very distressing. This happens to be one of the more prominent animating forces that drove Trump's voter base - that they felt they always lost again and again and again and again. Covid policy for a substantial portion of the population has been a series of devastating losses as practically every policy choice cuts against them.

Feeling That Other People Matter While I Don't

This is a distinct distress in addition to the lack of fairness - that "I don't matter"; this is amplified considerably when "other people matter". This is what people who are systematically disregarded tend to feel, and it is very painful.

And this is especially pronounced in racial minorities who already feel this way from previous history -- mostly white liberal elites are forcing their preferences on blacks and other minorities.

The Stress of Difficulty Communicating

The frustration that comes from difficulty communicating is underappreciated, and tends to leave people feeling annoyed, frustrated and stressed.

The Damage From Failed Communication

This particular harm also has another, more tangible dimension - often, people having a hard time communicating simply give up, and giving up is itself an added stress factor that leaves people frazzled. If you're talking to your doctor and you "give up" instead of making sure you understood what he was trying to tell you - especially older people who psychologically tend to both give up faster and have more innate difficulty physically hearing to begin with - that could be a big problem.

The Distress of Constant Harassment

Mask mandates are a constant intrusion into people's personal lives that leaves people feeling exasperated - "just leave me alone already" / "just let me live in peace". It is a basic human need to not be constantly harassed by others.

Living In Constant State of Worry, Fear, and Anger

Knowing that you have to submit to the mask mandates in many places where you need to go leaves you always feeling a variety of negative and unhealthy emotions about it.

Saps the Joy From Many Different Activities

Take shopping, for instance. For many people, shopping is a leisure activity that can be an effective emotional detox from life stresses… but not when you have to wear a mask to do it.

Living In Perpetual Stress From Social Enforcers

Inevitably, people opposed to mask mandates will not be particularly zealous about following them to a “T”, whether it be letting the mask slide down your face, taking it off for a few minutes here and there, or just munching on a bag of peanuts for 3 hours. There is always a baseline stress of constantly having to be alert for the “mask police” (whether they are actual police or just really annoying Karens).

Public Humiliation

The aforementioned “mask police” are often extremely zealous - unhinged, really - a non-masking-compliant person getting dressed down in public is a common occurrence. Public humiliation can be a traumatic experience.

Emotional Abuse

Mask mandates leave many people feeling emotionally abused. This is both from the masking being forced upon people despite all the mental and emotional distress it causes - in other words, abuse - and from the constant manipulation that is characteristic of abusers that is part and parcel of mask mandates.

Bullying Plain & Simple

Mask mandates are forced coercion jammed down the throats of those who strongly resent them. This is vicious bullying. No one enjoys feeling bullied, or having someone else’s will imposed on them against their own will.

The Distress of Being Under the Control of Someone You Loathe

Think of it this way: Imagine two ppl vying for the same promotion who hate each others guts, and then the winner is made the boss of the loser. This is an added, separate affront to the loser. Same idea here - the anti- mask people are being specifically dictated to by the very opponents they despise, and on the very issue that they’re fighting over. This isn’t just at a national level - this is more true about local county or school board fights, and this is a reliable recipe for bad blood and lasting enmity to boot.

The “Tax” of Buying Masks that are Less Unpleasant

Many people choose to buy fancier masks than the nasty surgical masks widely available everywhere, because they are far less unpleasant (and far more sanitary and subject to manufacturing standards and quality control). This itself is a further indignity - if the government wants to impose a draconian mandate on us, the least the government can do is to make comfortable masks available, especially considering the government is throwing cash everywhere because of covid - it’s an added insult and disrespecting of the people being imposed upon, in the sense that it’s just plain coldhearted to act this way to someone else, at least have a little sensitivity and try to make your own mandates as tolerable as possible on the people you’re imposing on.

Irrational Government Actions Breed A Sense of Fear and Instability

Watching the government act in such a factually irrational manner is itself very stressful to many people, as is living under an irrational regime. One's sense of stability and trust in the world is rooted by necessity in the belief that rationality is a limiting principle at some point upon what government and people/institutions with power in society are able and willing to do.

Makes People Doubt Their Sense of Reality

The very fact of making a crazy policy is itself deeply destructive to people's sense of reality. In other words, there is tremendous cognitive dissonance of on the one hand knowing that masking is nuts, but on the other hand, watching the government make mask mandates - it is very hard to have a genuine emotional conviction that essentially the entire medical community and all of society's institutions have gone stark raving mad. Such cognitive dissonance is very damaging psychologically to your sense of self and your sense of reality, and is also mentally and emotionally exhausting.

Destroys People's Sense of Trust & Stability

Being forced to do irrational and insane things erodes a person's sense of confidence that there is a baseline rationality in society -- something that provides people with a sense of stability and security in life generally. It is distressing to feel like there is absolutely no rational limiting principle on government actions or policies, since this by definition means that there is nothing that you can trust is sacred and beyond government (or someone else) coming and destroying. (This also actively erodes the social fabric that relies upon people being rational.)

Destructive of People's Humanity and Dignity

Being forced to act irrationally causes you to lose your sense of dignity as a human being with an intellectual faculty that distinguishes man from animals. In other words, the more you are suppressed from acting in accordance with intelligence, the less you feel the unique transcendence of being a human being - treating people like animals makes them feel like animals.

Dehumanization Through Forced Anonymity

The face is the most visibly manifest characteristic that sets you apart as a unique individual. Masks, by covering your face, strip you to some degree of your sense of being a unique individual and instead makes you feel more like a number than a person. It also distorts your sense of the humanity of others, as you inevitably become trained to perceive other people as lacking human-ness.

They're so Darn Uncomfortable

Masks can be extremely uncomfortable to wear, especially for long stretches at a time. They can also be quite gross to wear - if you sneeze into the mask, well……

Pragmatic Harms of Mask Mandates

Promotes Authoritarianism and Fascism

This is true as written - the ascendance of authoritarian and tyrannical governance has been as shocking as it was swift. Mask mandates - which are objectively draconian and authoritarian regardless of whether they are scientifically warranted - internalize in people that authoritarian governance is normal, acceptable, and not evil. This is a problem. Every genocidal regime started this way. This by itself is sufficient justification to fight mask mandates "to the death".

On a more relatable level, mask mandates accustom government officials to acting like tyrants, and enjoying their newfound dictatorial powers, a 'perk' they are very unlikely to part with willingly.

Promotes Religious Cultism

Masks have become a religious symbol of virtuosity of a fanatical cult of irrational beliefs that has completely forsaken thinking for the cult members (like lone drivers wearing masks in their cars). Cults have committed some of the most horrific and bizarre atrocities over the past century.

Socially Conditions the Citizenry to Be Docile and Unthinking

Authoritarian mandates that are based only upon the word of people (the "experts"), especially in stark contradiction to facts and common sense, conditions people to be docile, and to not think about anything (as their intellects and opinions are scorned and said to be of too poor quality to be legitimate sources of knowledge for anyone, including themselves). This destroys the vibrancy and energy of the society, and conditions people to not think of themselves as individually capable beings who have the potential to achieve greatness, a critical driving force necessary to impel people to make something of themselves.

Balkanizes Society

Mask mandates help to further sow division and enmity between the factions of society by oppressing one faction while also giving the other faction the moral grounds to claim that the anti-mask faction by not going along with the mandate policies are in violation of the law, and are acting immorally as defined by societal approbation of mask mandates as a crucial health measure.

All-Encompassing Harms of Mask Mandates

Stress

The most obvious general harm of mask mandates is stress. Stress is known to be aggressively destructive to your health, and something that significantly exacerbates every known medical condition. Everything listed above causes the people afflicted to be stressed.

Breach of the Social Compact

When part of society is so wantonly destructive towards another part of society, the society loses its legitimacy in the eyes of the oppressed, and the rule of law is incorrigibly eroded, since one side simply inflicts their will upon the other side regardless of the laws, conventions, and norms of society; and without any limiting principle. "Rule of law for thee but not for me" is not rule of law, and has no moral legitimacy for the "thee" to respect or comply.

Indefinite Nature of the Suffering

The indefinite-ness of the situation is itself a source of considerable suffering, or a powerful amplification of the suffering one is already experiencing. It is infinitely easier and more bearable to handle suffering that you can see its end, when it will pass, versus suffering that seems inescapable and endless. (The feeling that the suffering is inescapable is a ubiquitous factor that leads people to commit suicide.)

C'mon, most of these are silly?

The ultimate refuge of someone trapped by the facts is scorn and mockery. Human nature drives a person to feel and act derisive about something that requires depth to grasp. Human nature also strongly tends towards not just denying but mocking anything that challenges the morality and prudence of your opinions and actions. Thus people are told that their experiences and suffering from mask mandates is not real and makes no sense - one of the most insidious and abhorrent forms of abusive manipulation.

It is very difficult to gain an appreciation and understanding of most of the things on this list. On the other hand, it is far easier to destroy any sense of comprehension and emotional awareness of these - all that is necessary is one pithy line scorning this whole notion as delusional. Such is the power of mockery, that one witty zinger can completely vanquish the awareness gained from many hours of thoughtfulness and introspection.

So no, these are not silly, and feeling these does not make you a baby. This accusation is nothing more than the panicked derision that is the last defense of someone who can't debate the actual facts.

The Manipulative Nature of an Abusive Relationship

One of the textbook tactics utilized by abusers to maintain control in an abusive relationship is to define the context and facts of anything related to the relationship so as to get in the victim's head so to speak and distort their sense of reality so that they are unable to articulate - even to themselves - the fact of their abuse and victimization.

As we all can see, the constant claims of "facemasks are not a big deal", "there's no conceivable reason for anyone to think that masks can be harmful", etc, accomplished this quite effectively. The goal of this article was to unwind this pernicious and abusive lie in order to re-empower victims of forced masking against the proponents of mask policies who are abusive and manipulative. (Sometimes mask policies are reluctantly put in place in order to accommodate political or legal realities where masking is the least destructive option.)

This can be summed up as one more type of emotional distress inflicted by mask mandate proponents:

> The contention that "facemasks are just an inconvenience" amounts to abusive manipulation that steals the ability of the victims of forced masking to identify and articulate the suffering and harm they experience from forced mask wearing.

To conclude, the quote at the top of this article from DA Henderson - widely credited with the eradication of smallpox - is very revealing:

> “Experience has shown that communities faced with epidemics or other adverse events respond best and with the least anxiety when the normal social functioning of the community is least disrupted”

It is hard to imagine a greater disruption to normal living than the highly visible and symbolic masks ubiquitously worn everywhere.

More than 150 Comparative Studies and Articles on Mask Ineffectiveness and Harms ⋆ Brownstone Institute

Anyone come up with more examples that I missed please feel free to comment.

Plaintiff's Exhibit 98

brownstone.org 167 studies 12-20-21

More than 150 Comparative Studies and Articles on Mask Ineffectiveness and Harms ⋆ Brownstone Institute

Paul Elias Alexander

89-112 minutes

Dr. Paul Alexander is a former assistant professor at McMaster University in evidence-based medicine and research methods. He's also a former COVID Pandemic evidence-synthesis consultant advisor to WHO-PAHO Washington, D.C., and former senior advisor to COVID Pandemic policy in Health & Human Services (HHS) Washington, D.C.

It is not unreasonable to conclude that surgical and cloth masks, used as they currently are being used (without other forms of PPE protection), have no impact on controlling the transmission of Covid-19 virus. Current evidence implies that face masks can be actually harmful. The body of evidence indicates that face masks are largely ineffective.

My focus is on COVID face masks and the prevailing science that we have had for nearly 20 months. Yet I wish to address this mask topic at a 50,000-foot level on the lockdown restrictive policies in general. I build on the backs of the fine work done by Gupta, Kulldorff, and Bhattacharya on the Great Barrington Declaration (GBD) and similar impetus by Dr. Scott Atlas (advisor to POTUS Trump) who, like myself, was a strong proponent for a focused type of protection that was based on an age-risk stratified approach.

Because we saw very early on that the lockdowns were the single greatest mistake in public health history. We knew the history and knew they would not work. We also knew very early of COVID's risk stratification. Sadly, our children will bear the catastrophic consequences and not just educationally, of the deeply flawed school closure policy for decades to come (particularly our minority children who were least able to afford this). Many are still pressured to wear masks and punished for not doing so.

I present the masking 'body of evidence' below (n=167 studies and pieces of evidence), comprised of comparative effectiveness research as well as related evidence and high-level reporting. To date, the evidence has been stable and clear that masks do not work to control the virus and they can be harmful and especially to children.

MASK-INEFFECTIVENESS	
1) Effectiveness of Adding a Mask Recommendation to Other Public Health Measures to Prevent SARS-CoV-2 Infection in Danish Mask Wearers, Bundgaard, 2021	"Infection with SARS-CoV-2 occurred in 42 participants recommended masks (1.8%) and 53 control participants (2.1%). The between-group difference was −0.3 percentage point (95% CI, −1.2 to 0.4 percentage point; P = 0.38) (odds ratio, 0.82 [CI, 0.54 to 1.23]; P = 0.33). Multiple imputation accounting for loss to follow-up yielded similar results…the recommendation to wear surgical masks to supplement other public health measures did not reduce the SARS-CoV-2 infection rate

	among wearers by more than 50% in a community with modest infection rates, some degree of social distancing, and uncommon general mask use."
2) SARS-CoV-2 Transmission among Marine Recruits during Quarantine, Letizia, 2020	"Our study showed that in a group of predominantly young male military recruits, approximately 2% became positive for SARS-CoV-2, as determined by qPCR assay, during a 2-week, strictly enforced quarantine. Multiple, independent virus strain transmission clusters were identified…all recruits wore double-layered cloth masks at all times indoors and outdoors."
3) Physical interventions to interrupt or reduce the spread of respiratory viruses, Jefferson, 2020	"There is low certainty evidence from nine trials (3507 participants) that wearing a mask may make little or no difference to the outcome of influenza-like illness (ILI) compared to not wearing a mask (risk ratio (RR) 0.99, 95% confidence interval (CI) 0.82 to 1.18. There is moderate certainty evidence that wearing a mask probably makes little or no difference to the outcome of laboratory-confirmed influenza compared to not wearing a mask (RR 0.91, 95% CI 0.66 to 1.26; 6 trials; 3005 participants)…the pooled results of randomised trials did not show a clear reduction in respiratory viral infection with the use of medical/surgical masks during seasonal influenza."
4) The Impact of Community Masking on COVID-19: A Cluster-Randomized Trial in Bangladesh, Abaluck, 2021 Heneghan et al.	A cluster-randomized trial of community-level mask promotion in rural Bangladesh from November 2020 to April 2021 (N=600 villages, N=342,126 adults. Heneghan writes: "In a Bangladesh study, surgical masks reduced symptomatic COVID infections by between 0 and 22 percent, while the efficacy of cloth masks led to somewhere between an 11 percent increase to a 21 percent decrease. Hence, based on these randomized studies, adult masks appear to have either no or limited efficacy."
5) Evidence for Community Cloth Face Masking to Limit the Spread of SARS-CoV-2: A Critical Review, Liu/CATO, 2021	"The available clinical evidence of facemask efficacy is of low quality and the best available clinical evidence has mostly failed to show efficacy, with fourteen of sixteen identified randomized controlled trials comparing face masks to no mask controls failing to find statistically significant benefit in the intent-to-treat populations. Of sixteen quantitative meta-analyses, eight were equivocal or critical as to whether evidence supports a public recommendation of masks, and the

	remaining eight supported a public mask intervention on limited evidence primarily on the basis of the precautionary principle."
6) Nonpharmaceutical Measures for Pandemic Influenza in Nonhealthcare Settings—Personal Protective and Environmental Measures, CDC/Xiao, 2020	"Evidence from 14 randomized controlled trials of these measures did not support a substantial effect on transmission of laboratory-confirmed influenza…none of the household studies reported a significant reduction in secondary laboratory-confirmed influenza virus infections in the face mask group…the overall reduction in ILI or laboratory-confirmed influenza cases in the face mask group was not significant in either studies."
7) CIDRAP: Masks-for-all for COVID-19 not based on sound data, Brosseau, 2020	"We agree that the data supporting the effectiveness of a cloth mask or face covering are very limited. We do, however, have data from laboratory studies that indicate cloth masks or face coverings offer very low filter collection efficiency for the smaller inhalable particles we believe are largely responsible for transmission, particularly from pre- or asymptomatic individuals who are not coughing or sneezing…though we support mask wearing by the general public, we continue to conclude that cloth masks and face coverings are likely to have limited impact on lowering COVID-19 transmission, because they have minimal ability to prevent the emission of small particles, offer limited personal protection with respect to small particle inhalation, and should not be recommended as a replacement for physical distancing or reducing time in enclosed spaces with many potentially infectious people."
8) Universal Masking in Hospitals in the Covid-19 Era, Klompas/NEJM, 2020	"We know that wearing a mask outside health care facilities offers little, if any, protection from infection. Public health authorities define a significant exposure to Covid-19 as face-to-face contact within 6 feet with a patient with symptomatic Covid-19 that is sustained for at least a few minutes (and some say more than 10 minutes or even 30 minutes). The chance of catching Covid-19 from a passing interaction in a public space is therefore minimal. In many cases, the desire for widespread masking is a reflexive reaction to anxiety over the pandemic…The calculus may be different, however, in health care settings. First and foremost, a mask is a core component of the personal protective equipment (PPE) clinicians need when caring for

	symptomatic patients with respiratory viral infections, in conjunction with gown, gloves, and eye protection… universal masking alone is not a panacea. A mask will not protect providers caring for a patient with active Covid-19 if it's not accompanied by meticulous hand hygiene, eye protection, gloves, and a gown. A mask alone will not prevent health care workers with early Covid-19 from contaminating their hands and spreading the virus to patients and colleagues. Focusing on universal masking alone may, paradoxically, lead to more transmission of Covid-19 if it diverts attention from implementing more fundamental infection-control measures."
9) Masks for prevention of viral respiratory infections among health care workers and the public: PEER umbrella systematic review, Dugré, 2020	"This systematic review found limited evidence that the use of masks might reduce the risk of viral respiratory infections. In the community setting, a possible reduced risk of influenza-like illness was found among mask users. In health care workers, the results show no difference between N95 masks and surgical masks on the risk of confirmed influenza or other confirmed viral respiratory infections, although possible benefits from N95 masks were found for preventing influenza-like illness or other clinical respiratory infections. Surgical masks might be superior to cloth masks but data are limited to 1 trial."
10) Effectiveness of personal protective measures in reducing pandemic influenza transmission: A systematic review and meta-analysis, Saunders-Hastings, 2017	"Facemask use provided a non-significant protective effect (OR = 0.53; 95% CI 0.16–1.71; I^2 = 48%) against 2009 pandemic influenza infection."
11) Experimental investigation of indoor aerosol dispersion and accumulation in the context of COVID-19: Effects of masks and ventilation, Shah, 2021	"Nevertheless, high-efficiency masks, such as the KN95, still offer substantially higher apparent filtration efficiencies (60% and 46% for R95 and KN95 masks, respectively) than the more commonly used cloth (10%) and surgical masks (12%), and therefore are still the recommended choice in mitigating airborne disease transmission indoors."
12) Exercise with facemask; Are we handling a devil's sword?- A physiological hypothesis, Chandrasekaran, 2020	"Exercising with facemasks may reduce available Oxygen and increase air trapping preventing substantial carbon dioxide exchange. The hypercapnic hypoxia may potentially increase acidic environment, cardiac overload, anaerobic metabolism and renal overload,

	which may substantially aggravate the underlying pathology of established chronic diseases. Further contrary to the earlier thought, no evidence exists to claim the facemasks during exercise offer additional protection from the droplet transfer of the virus."
13) Surgical face masks in modern operating rooms–a costly and unnecessary ritual?, Mitchell, 1991	"Following the commissioning of a new suite of operating rooms air movement studies showed a flow of air away from the operating table towards the periphery of the room. Oral microbial flora dispersed by unmasked male and female volunteers standing one metre from the table failed to contaminate exposed settle plates placed on the table. The wearing of face masks by non-scrubbed staff working in an operating room with forced ventilation seems to be unnecessary."
14) Facemask against viral respiratory infections among Hajj pilgrims: A challenging cluster-randomized trial, Alfelali, 2020	"By intention-to-treat analysis, facemask use did not seem to be effective against laboratory-confirmed viral respiratory infections (odds ratio [OR], 1.4; 95% confidence interval [CI], 0.9 to 2.1, p = 0.18) nor against clinical respiratory infection (OR, 1.1; 95% CI, 0.9 to 1.4, p = 0.40)."
15) Simple respiratory protection–evaluation of the filtration performance of cloth masks and common fabric materials against 20-1000 nm size particles, Rengasamy, 2010	"Results obtained in the study show that common fabric materials may provide marginal protection against nanoparticles including those in the size ranges of virus-containing particles in exhaled breath."
16) Respiratory performance offered by N95 respirators and surgical masks: human subject evaluation with NaCl aerosol representing bacterial and viral particle size range, Lee, 2008	"The study indicates that N95 filtering facepiece respirators may not achieve the expected protection level against bacteria and viruses. An exhalation valve on the N95 respirator does not affect the respiratory protection; it appears to be an appropriate alternative to reduce the breathing resistance."
17) Aerosol penetration and leakage characteristics of masks used in the health care industry, Weber, 1993	"We conclude that the protection provided by surgical masks may be insufficient in environments containing potentially hazardous sub-micrometer-sized aerosols."
18) Disposable surgical face masks for preventing surgical wound infection in clean surgery, Vincent, 2016	"We included three trials, involving a total of 2106 participants. There was no statistically significant difference in infection rates between the masked and unmasked group in any of the trials…from the limited results it is unclear whether the wearing of surgical face masks by members of the surgical team has any impact

	on surgical wound infection rates for patients undergoing clean surgery.”
19) Disposable surgical face masks: a systematic review, Lipp, 2005	“From the limited results it is unclear whether wearing surgical face masks results in any harm or benefit to the patient undergoing clean surgery.”
20) Comparison of the Filter Efficiency of Medical Nonwoven Fabrics against Three Different Microbe Aerosols, Shimasaki , 2018	“We conclude that the filter efficiency test using the phi-X174 phage aerosol may overestimate the protective performance of nonwoven fabrics with filter structure compared to that against real pathogens such as the influenza virus.”
21) The use of masks and respirators to preventtransmission of influenza: a systematic review of thescientific evidence21) The use of masks and respirators to prevent transmission of influenza: a systematic review of the scientific evidence, Bin-Reza, 2012	The use of masks and respirators to preventtransmission of influenza: a systematic review of thescientific evidence“None of the studies established a conclusive relationship between mask/respirator use and protection against influenza infection. Some evidence suggests that mask use is best undertaken as part of a package of personal protection especially hand hygiene.”
22) Facial protection for healthcare workers during pandemics: a scoping review, Godoy, 2020	“Compared with surgical masks, N95 respirators perform better in laboratory testing, may provide superior protection in inpatient settings and perform equivalently in outpatient settings. Surgical mask and N95 respirator conservation strategies include extended use, reuse or decontamination, but these strategies may result in inferior protection. Limited evidence suggests that reused and improvised masks should be used when medical-grade protection is unavailable.”
23) Assessment of Proficiency of N95 Mask Donning Among the General Public in Singapore, Yeung, 2020	“These findings support ongoing recommendations against the use of N95 masks by the general public during the COVID-19 pandemic.[5] N95 mask use by the general public may not translate into effective protection but instead provide false reassurance. Beyond N95 masks, proficiency among the general public in donning surgical masks needs to be assessed.”
24) Evaluating the efficacy of cloth facemasks in reducing particulate matter exposure, Shakya, 2017	“Standard N95 mask performance was used as a control to compare the results with cloth masks, and our results suggest that cloth masks are only marginally beneficial in protecting individuals from particles<2.5 μm.”

25) Use of surgical face masks to reduce the incidence of the common cold among health care workers in Japan: a randomized controlled trial, Jacobs, 2009	"Face mask use in health care workers has not been demonstrated to provide benefit in terms of cold symptoms or getting colds."
26) N95 Respirators vs Medical Masks for Preventing Influenza Among Health Care Personnel, Radonovich, 2019	"Among outpatient health care personnel, N95 respirators vs medical masks as worn by participants in this trial resulted in no significant difference in the incidence of laboratory-confirmed influenza."
27) Does Universal Mask Wearing Decrease or Increase the Spread of COVID-19?, Watts up with that? 2020	"A survey of peer-reviewed studies shows that universal mask wearing (as opposed to wearing masks in specific settings) does not decrease the transmission of respiratory viruses from people wearing masks to people who are not wearing masks."
28) Masking: A Careful Review of the Evidence, Alexander, 2021	"In fact, it is not unreasonable at this time to conclude that surgical and cloth masks, used as they currently are, have absolutely no impact on controlling the transmission of Covid-19 virus, and current evidence implies that face masks can be actually harmful."
29) Community and Close Contact Exposures Associated with COVID-19 Among Symptomatic Adults ≥18 Years in 11 Outpatient Health Care Facilities — United States, July 2020, Fisher, 2020	Reported characteristics of symptomatic adults ≥18 years who were outpatients in 11 US academic health care facilities and who received positive and negative SARS-CoV-2 test results (N = 314)* — United States, July 1–29, 2020, revealed that 80% of infected persons wore face masks almost all or most of the time.
30) Impact of non-pharmaceutical interventions against COVID-19 in Europe: a quasi-experimental study, Hunter, 2020	Face masks in public was not associated with reduced incidence.
31) Masking lack of evidence with politics, CEBM, Heneghan, 2020	"It would appear that despite two decades of pandemic preparedness, there is considerable uncertainty as to the value of wearing masks. For instance, high rates of infection with cloth masks could be due to harms caused by cloth masks, or benefits of medical masks. The numerous systematic reviews that have been recently published all include the same evidence base so unsurprisingly broadly reach the same conclusions."
32) Transmission of COVID-19 in 282 clusters in Catalonia, Spain: a	"We observed no association of risk of transmission with reported mask usage by contacts, with the age or sex of

cohort study, Marks, 2021	the index case, or with the presence of respiratory symptoms in the index case at the initial study visit."
33) Non-pharmaceutical public health measures for mitigating the risk and impact of epidemic and pandemic influenza, WHO, 2020	"Ten RCTs were included in the meta-analysis, and there was no evidence that face masks are effective in reducing transmission of laboratory-confirmed influenza."
34) The Strangely Unscientific Masking of America, Younes, 2020	"One report reached its conclusion based on observations of a "dummy head attached to a breathing simulator." Another analyzed use of surgical masks on people experiencing at least two symptoms of acute respiratory illness. Incidentally, not one of these studies involved cloth masks or accounted for real-world mask usage (or misusage) among lay people, and none established efficacy of widespread mask-wearing by people not exhibiting symptoms. There was simply no evidence whatsoever that healthy people ought to wear masks when going about their lives, especially outdoors."
35) Facemasks and similar barriers to prevent respiratory illness such as COVID-19: A rapid systematic review, Brainard, 2020	"31 eligible studies (including 12 RCTs). Narrative synthesis and random-effects meta-analysis of attack rates for primary and secondary prevention in 28 studies were performed. Based on the RCTs we would conclude that wearing facemasks can be very slightly protective against primary infection from casual community contact, and modestly protective against household infections when both infected and uninfected members wear facemasks. However, the RCTs often suffered from poor compliance and controls using facemasks."

36) The Year of Disguises, Koops, 2020	"The healthy people in our society should not be punished for being healthy, which is exactly what lockdowns, distancing, mask mandates, etc. do… Children should not be wearing face coverings. We all need constant interaction with our environments and that is especially true for children. This is how their immune system develops. They are the lowest of the low-risk groups. Let them be kids and let them develop their immune systems… The "Mask Mandate" idea is a truly ridiculous, knee-jerk reaction and needs to be withdrawn and thrown in the waste bin of disastrous policy, along with lockdowns and school closures. You can vote for a person without blindly supporting all of their proposals!"
37) Open Schools, Covid-19, and Child and Teacher Morbidity in Sweden, Ludvigsson, 2020	"1,951,905 children in Sweden (as of December 31, 2019) who were 1 to 16 years of age, were examined… social distancing was encouraged in Sweden, but wearing face masks was not…No child with Covid-19 died."
38) Double-Masking Benefits Are Limited, Japan Supercomputer Finds, Reidy, 2021	"Wearing two masks offers limited benefits in preventing the spread of droplets that could carry the coronavirus compared to one well-fitted disposable mask, according to a Japanese study that modeled the dispersal of droplets on a supercomputer."
39) Physical interventions to interrupt or reduce the spread of respiratory viruses. Part 1 – Face masks, eye protection and person distancing: systematic review and meta-analysis, Jefferson, 2020	"There was insufficient evidence to provide a recommendation on the use of facial barriers without other measures. We found insufficient evidence for a difference between surgical masks and N95 respirators and limited evidence to support effectiveness of quarantine."
40) Should individuals in the community without respiratory symptoms wear facemasks to reduce the spread of COVID-19?, NIPH, 2020	"Non-medical facemasks include a variety of products. There is no reliable evidence of the effectiveness of non-medical facemasks in community settings. There is likely to be substantial variation in effectiveness between products. However, there is only limited evidence from laboratory studies of potential differences in effectiveness when different products are used in the community."
41) Is a mask necessary in the operating theatre?, Orr, 1981	"It would appear that minimum contamination can best be achieved by not wearing a mask at all but operating in silence. Whatever its relation to contamination,

	bacterial counts, or the dissemination of squames, there is no direct evidence that the wearing of masks reduces wound infection."
42) The surgical mask is a bad fit for risk reduction, Neilson, 2016	"As recently as 2010, the US National Academy of Sciences declared that, in the community setting, "face masks are not designed or certified to protect the wearer from exposure to respiratory hazards." A number of studies have shown the inefficacy of the surgical mask in household settings to prevent transmission of the influenza virus."
43) Facemask versus No Facemask in Preventing Viral Respiratory Infections During Hajj: A Cluster Randomised Open Label Trial, Alfelali, 2019	"Facemask use does not prevent clinical or laboratory-confirmed viral respiratory infections among Hajj pilgrims."
44) Facemasks in the COVID-19 era: A health hypothesis, Vainshelboim, 2021	"The existing scientific evidences challenge the safety and efficacy of wearing facemask as preventive intervention for COVID-19. The data suggest that both medical and non-medical facemasks are ineffective to block human-to-human transmission of viral and infectious disease such SARS-CoV-2 and COVID-19, supporting against the usage of facemasks. Wearing facemasks has been demonstrated to have substantial adverse physiological and psychological effects. These include hypoxia, hypercapnia, shortness of breath, increased acidity and toxicity, activation of fear and stress response, rise in stress hormones, immunosuppression, fatigue, headaches, decline in cognitive performance, predisposition for viral and infectious illnesses, chronic stress, anxiety and depression."
45) The use of masks and respirators to prevent transmission of influenza: a systematic review of the scientific evidence, Bin-Reza, 2011	"None of the studies established a conclusive relationship between mask/respirator use and protection against influenza infection. Some evidence suggests that mask use is best undertaken as part of a package of personal protection especially hand hygiene."
46) Are Face Masks Effective? The Evidence., Swiss Policy Research, 2021	"Most studies found little to no evidence for the effectiveness of face masks in the general population, neither as personal protective equipment nor as a source control."

47) Postoperative wound infections and surgical face masks: A controlled study, Tunevall, 1991	"These results indicate that the use of face masks might be reconsidered. Masks may be used to protect the operating team from drops of infected blood and from airborne infections, but have not been proven to protect the patient operated by a healthy operating team."
48) Mask mandate and use efficacy in state-level COVID-19 containment, Guerra, 2021	"Mask mandates and use are not associated with slower state-level COVID-19 spread during COVID-19 growth surges."
49) Twenty Reasons Mandatory Face Masks are Unsafe, Ineffective and Immoral, Manley, 2021	"A CDC-funded review on masking in May 2020 came to the conclusion: "Although mechanistic studies support the potential effect of hand hygiene or face masks, evidence from 14 randomized controlled trials of these measures did not support a substantial effect on transmission of laboratory-confirmed influenza… None of the household studies reported a significant reduction in secondary laboratory-confirmed influenza virus infections in the face mask group." If masks can't stop the regular flu, how can they stop SAR-CoV-2?"
50) A cluster randomised trial of cloth masks compared with medical masks in healthcare workers, MacIntyre, 2015	"First RCT of cloth masks, and the results caution against the use of cloth masks. This is an important finding to inform occupational health and safety. Moisture retention, reuse of cloth masks and poor filtration may result in increased risk of infection…the rates of all infection outcomes were highest in the cloth mask arm, with the rate of ILI statistically significantly higher in the cloth mask arm (relative risk (RR)=13.00, 95% CI 1.69 to 100.07) compared with the medical mask arm. Cloth masks also had significantly higher rates of ILI compared with the control arm. An analysis by mask use showed ILI (RR=6.64, 95% CI 1.45 to 28.65) and laboratory-confirmed virus (RR=1.72, 95% CI 1.01 to 2.94) were significantly higher in the cloth masks group compared with the medical masks group. Penetration of cloth masks by particles was almost 97% and medical masks 44%."
51) Horowitz: Data from India continues to blow up the 'Delta' fear narrative, Blazemedia, 2021	"Rather than proving the need to sow more panic, fear, and control over people, the story from India — the source of the "Delta" variant — continues to refute every current premise of COVID fascism…Masks failed to stop the spread there."

52) An outbreak caused by the SARS-CoV-2 Delta variant (B.1.617.2) in a secondary care hospital in Finland, May 2021, Hetemäki, 2021	Reporting on a nosocomial hospital outbreak in Finland, Hetemäli et al. observed that "both symptomatic and asymptomatic infections were found among vaccinated health care workers, and secondary transmission occurred from those with symptomatic infections despite use of personal protective equipment."
53) Nosocomial outbreak caused by the SARS-CoV-2 Delta variant in a highly vaccinated population, Israel, July 2021, Shitrit, 2021	In a hospital outbreak investigation in Israel, Shitrit et al. observed "high transmissibility of the SARS-CoV-2 Delta variant among twice vaccinated and masked individuals." They added that "this suggests some waning of immunity, albeit still providing protection for individuals without comorbidities." Again, despite use of personal protective equipment.
54) 47 studies confirm ineffectiveness of masks for COVID and 32 more confirm their negative health effects, Lifesite news staff, 2021	"No studies were needed to justify this practice since most understood viruses were far too small to be stopped by the wearing of most masks, other than sophisticated ones designed for that task and which were too costly and complicated for the general public to properly wear and keep changing or cleaning. It was also understood that long mask wearing was unhealthy for wearers for common sense and basic science reasons."
55) Are EUA Face Masks Effective in Slowing the Spread of a Viral Infection?, Dopp, 2021	The vast evidence shows that masks are ineffective.
56) CDC Study finds overwhelming majority of people getting coronavirus wore masks, Boyd/Federalist, 2021	"A Centers for Disease Control report released in September shows that masks and face coverings are not effective in preventing the spread of COVID-19, even for those people who consistently wear them."
57) Most Mask Studies Are Garbage, Eugyppius, 2021	"The other kind of study, the proper kind, would be a randomised controlled trial. You compare the rates of infection in a masked cohort against rates of infection in an unmasked cohort. Here things have gone much, much worse for mask brigade. They spent months trying to prevent the publication of the Danish randomised controlled trial, which found that masks do zero. When that paper finally squeaked into print, they spent more months trying desperately to poke holes in it. You could feel their boundless relief when the Bangladesh study finally appeared to save them in early September. Every last Twitter blue-check could now proclaim that

	Science Shows Masks Work. Such was their hunger for any scrap of evidence to prop up their prior convictions, that none of them noticed the sad nature of the Science in question. The study found a mere 10% reduction in seroprevalence among the masked cohort, an effect so small that it fell within the confidence interval. Even the study authors couldn't exclude the possibility that masks in fact do zero."
58) Using face masks in the community: first update, ECDC, 2021	"No high-quality evidence in favor of face masks and recommended their use only based on the 'precautionary principle.'
59) Do physical measures such as hand-washing or wearing masks stop or slow down the spread of respiratory viruses?, Cochrane, 2020	"Seven studies took place in the community, and two studies in healthcare workers. 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; 3507 people); and probably makes no difference in how many people have flu confirmed by a laboratory test (6 studies; 3005 people). Unwanted effects were rarely reported, but included discomfort."
60) Mouth-nose protection in public: No evidence of effectiveness, Thieme/ Kappstein, 2020	"The use of masks in public spaces is questionable simply because of the lack of scientific data. If one also considers the necessary precautions, masks must even be considered a risk of infection in public spaces according to the rules known from hospitals… If masks are worn by the population, the risk of infection is potentially increased, regardless of whether they are medical masks or whether they are so-called community masks designed in any way. If one considers the precautionary measures that the RKI as well as the international health authorities have pronounced, all authorities would even have to inform the population that masks should not be worn in public spaces at all. Because no matter whether it is a duty for all citizens or voluntarily borne by the citizens who want it for whatever reason, it remains a fact that masks can do more harm than good in public."
61) US mask guidance for kids is the strictest across the world, Skelding, 2021	"Kids need to see faces," Jay Bhattacharya, a professor of medicine at Stanford University, told The Post. Youngsters watch people's mouths to learn to speak, read and understand emotions, he said."We have this idea that this disease is so bad that we must adopt any means necessary to stop it from spreading," he said.

	"It's not that masks in schools have no costs. They actually do have substantial costs."
62) Masking young children in school harms language acquisition, Walsh, 2021	"This is important because children and/or students do not have the speech or language ability that adults have — they are not equally able and the ability to see the face and especially the mouth is critical to language acquisition which children and/or students are engaged in at all times. Furthermore, the ability to see the mouth is not only essential to communication but also essential to brain development."
63) The Case Against Masks for Children, Makary, 2021	"It's abusive to force kids who struggle with them to sacrifice for the sake of unvaccinated adults… Do masks reduce Covid transmission in children? Believe it or not, we could find only a single retrospective study on the question, and its results were inconclusive. Yet two weeks ago the Centers for Disease Control and Prevention sternly decreed that 56 million U.S. children and adolescents, vaccinated or not, should cover their faces regardless of the prevalence of infection in their community. Authorities in many places took the cue to impose mandates in schools and elsewhere, on the theory that masks can't do any harm. That isn't true. Some children are fine wearing a mask, but others struggle. Those who have myopia can have difficulty seeing because the mask fogs their glasses. (This has long been a problem for medical students in the operating room.) Masks can cause severe acne and other skin problems. The discomfort of a mask distracts some children from learning. By increasing airway resistance during exhalation, masks can lead to increased levels of carbon dioxide in the blood. And masks can be vectors for pathogens if they become moist or are used for too long."
64) Face Covering Mandates, Peavey, 2021	"Face Covering Mandates And Why They AREN'T Effective."
65) Do masks work? A Review of the evidence, Anderson, 2021	"In truth, the CDC's, U.K.'s, and WHO's earlier guidance was much more consistent with the best medical research on masks' effectiveness in preventing the spread of viruses. That research suggests that Americans' many months of mask-wearing has likely provided little to no health benefit and might even have been counterproductive in preventing the spread of the

	novel coronavirus.”
66) Most face masks won’t stop COVID-19 indoors, study warns, Anderer, 2021	“New research reveals that cloth masks filter just 10% of exhaled aerosols, with many people not wearing coverings that fit their face properly.”
67) How face masks and lockdowns failed/the face mask folly in retrospect, Swiss Policy Research, 2021	“Mask mandates and lockdowns have had no discernible impact.”
68) CDC Releases School COVID Transmission Study But Buries One of the Most Damning Parts, Davis, 2021	“The 21% lower incidence in schools that required mask use among students was not statistically significant compared with schools where mask use was optional… With tens of millions of American kids headed back to school in the fall, their parents and political leaders owe it to them to have a clear-sighted, scientifically rigorous discussion about which anti-COVID measures actually work and which might put an extra burden on vulnerable young people without meaningfully or demonstrably slowing the spread of the virus…that a masking requirement of students failed to show independent benefit is a finding of consequence and great interest.”
69) World Health Organization internal meeting, COVID-19 – virtual press conference – 30 March 2020, 2020	“This is a question on Austria. The Austrian Government has a desire to make everyone wear a mask who’s going into the shops. I understood from our previous briefings with you that the general public should not wear masks because they are in short supply. What do you say about the new Austrian measures?… I’m not specifically aware of that measure in Austria. I would assume that it’s aimed at people who potentially have the disease not passing it to others. In general WHO recommends that the wearing of a mask by a member of the public is to prevent that individual giving the disease to somebody else. We don’t generally recommend the wearing to masks in public by otherwise well individuals because it has not been up to now associated with any particular benefit.”
70) Face masks to prevent transmission of influenza virus: a systematic review, Cowling, 2010	“Review highlights the limited evidence base supporting the efficacy or effectiveness of face masks to reduce influenza virus transmission.”“None of the studies reviewed showed a benefit from wearing a mask, in either HCW or community members in households (H).”

71) Effectiveness of N95 respirators versus surgical masks in protecting health care workers from acute respiratory infection: a systematic review and meta-analysis, Smith, 2016	"Although N95 respirators appeared to have a protective advantage over surgical masks in laboratory settings, our meta-analysis showed that there were insufficient data to determine definitively whether N95 respirators are superior to surgical masks in protecting health care workers against transmissible acute respiratory infections in clinical settings."
72) Effectiveness of Masks and Respirators Against Respiratory Infections in Healthcare Workers: A Systematic Review and Meta-Analysis, Offeddu, 2017	"We found evidence to support universal medical mask use in hospital settings as part of infection control measures to reduce the risk of CRI and ILI among HCWs. Overall, N95 respirators may convey greater protection, but universal use throughout a work shift is likely to be less acceptable due to greater discomfort… Our analysis confirms the effectiveness of medical masks and respirators against SARS. Disposable, cotton, or paper masks are not recommended. The confirmed effectiveness of medical masks is crucially important for lower-resource and emergency settings lacking access to N95 respirators. In such cases, single-use medical masks are preferable to cloth masks, for which there is no evidence of protection and which might facilitate transmission of pathogens when used repeatedly without adequate sterilization…We found no clear benefit of either medical masks or N95 respirators against pH1N1…Overall, the evidence to inform policies on mask use in HCWs is poor, with a small number of studies that is prone to reporting biases and lack of statistical power."
73) N95 Respirators vs Medical Masks for Preventing Influenza Among Health Care Personnel, Radonovich, 2019	"Use of N95 respirators, compared with medical masks, in the outpatient setting resulted in no significant difference in the rates of laboratory-confirmed influenza."
Effectiveness of N95 respirators versus surgical masks againstinfluenza: A systematic review and meta-analysis74) Masks Don't Work: A Review of Science Relevant to COVID-19 Social Policy, Rancourt, 2020	The use of N95 respirators compared with surgical masks is not associated with alower risk of laboratory-confirmed influenza. It suggests that N95 respirators should not be rec-ommended for general public and nonhigh-risk medical staff those are not in close contact withinfluenza patients or suspected patients. "No RCT study with verified outcome shows a benefit for HCW or community members in households to wearing a mask or respirator. There is no such study. There are no exceptions. Likewise, no study exists that shows a

	benefit from a broad policy to wear masks in public (more on this below). Furthermore, if there were any benefit to wearing a mask, because of the blocking power against droplets and aerosol particles, then there should be more benefit from wearing a respirator (N95) compared to a surgical mask, yet several large meta-analyses, and all the RCT, prove that there is no such relative benefit."
75) More Than a Dozen Credible Medical Studies Prove Face Masks Do Not Work Even In Hospitals!, Firstenberg, 2020	"Mandating masks has not kept death rates down anywhere. The 20 U.S. states that have never ordered people to wear face masks indoors and out have dramatically lower COVID-19 death rates than the 30 states that have mandated masks. Most of the no-mask states have COVID-19 death rates below 20 per 100,000 population, and none have a death rate higher than 55. All 13 states that have death rates higher 55 are states that have required the wearing of masks in all public places. It has not protected them."
76) Does evidence based medicine support the effectiveness of surgical facemasks in preventing postoperative wound infections in elective surgery?, Bahli, 2009	"From the limited randomized trials it is still not clear that whether wearing surgical face masks harms or benefit the patients undergoing elective surgery."
77) Peritonitis prevention in CAPD: to mask or not?, Figueiredo, 2000	"The current study suggests that routine use of face masks during CAPD bag exchanges may be unnecessary and could be discontinued."
78) The operating room environment as affected by people and the surgical face mask, Ritter, 1975	"The wearing of a surgical face mask had no effect upon the overall operating room environmental contamination and probably work only to redirect the projectile effect of talking and breathing. People are the major source of environmental contamination in the operating room."
79) The efficacy of standard surgical face masks: an investigation using "tracer particles, Ha'eri, 1980	"Particle contamination of the wound was demonstrated in all experiments. Since the microspheres were not identified on the exterior of these face masks, they must have escaped around the mask edges and found their way into the wound."
80) Wearing of caps and masks not necessary during cardiac catheterization, Laslett, 1989	"Prospectively evaluated the experience of 504 patients undergoing percutaneous left heart catheterization, seeking evidence of a relationship between whether caps and/or masks were worn by the operators and the incidence of infection. No infections were found in any

	patient, regardless of whether a cap or mask was used. Thus, we found no evidence that caps or masks need to be worn during percutaneous cardiac catheterization.”
81) Do anaesthetists need to wear surgical masks in the operating theatre? A literature review with evidence-based recommendations, Skinner, 2001	“A questionnaire-based survey, undertaken by Leyland’ in 1993 to assess attitudes to the use of masks, showed that 20% of surgeons discarded surgical masks for endoscopic work. Less than 50% did not wear the mask as recommended by the Medical Research Council. Equal numbers of surgeons wore the mask in the belief they were protecting themselves and the patient, with 20% of these admitting that tradition was the only reason for wearing them.”
82) Mask mandates for children are not backed by data, Faria, 2021	“Even if you want to use the 2018-19 flu season to avoid overlap with the start of the COVID-19 pandemic, the CDC paints a similar picture: It estimated 480 flu deaths among children during that period, with 46,000 hospitalizations. COVID-19, mercifully, is simply not as deadly for children. According to the American Academy of Pediatrics, preliminary data from 45 states show that between 0.00%-0.03% of child COVID-19 cases resulted in death. When you combine these numbers with the CDC study that found mask mandates for students — along with hybrid models, social distancing, and classroom barriers — did not have a statistically significant benefit in preventing the spread of COVID-19 in schools, the insistence that we force students to jump through these hoops for their own protection makes no sense.”
83) The Downsides of Masking Young Students Are Real, Prasad, 2021	“The benefits of mask requirements in schools might seem self-evident—they have to help contain the coronavirus, right?—but that may not be so. In Spain, masks are used in kids ages 6 and older. The authors of one study there examined the risk of viral spread at all ages. If masks provided a large benefit, then the transmission rate among 5-year-olds would be far higher than the rate among 6-year-olds. The results don’t show that. Instead, they show that transmission rates, which were low among the youngest kids, steadily increased with age—rather than dropping sharply for older children subject to the face-covering requirement. This suggests that masking kids in school does not provide a major benefit and might provide none at all.

	And yet many officials prefer to double down on masking mandates, as if the fundamental policy were sound and only the people have failed.”
84) Masks In Schools: Scientific American Fumbles Report On Childhood COVID Transmission, English/ACSH, 2021	“Masking is a low-risk, inexpensive intervention. If we want to recommend it as a precautionary measure, especially in situations where vaccination isn’t an option, great. But that’s not what the public has been told. “Florida governor Ron DeSantis and politicians in Texas say research does not support mask mandates,” SciAm’s sub-headline bellowed. “Many studies show they are wrong.”If that’s the case, demonstrate that the intervention works before you mandate its use in schools. If you can’t, acknowledged what UC San Francisco hematologist-oncologist and Associate Professor of Epidemiology Vinay Prasad wrote over at the Atlantic:”No scientific consensus exists about the wisdom of mandatory-masking rules for schoolchildren … In mid-March 2020, few could argue against erring on the side of caution. But nearly 18 months later, we owe it to children and their parents to answer the question properly: Do the benefits of masking kids in school outweigh the downsides? The honest answer in 2021 remains that we don’t know for sure.”
85) Masks ‘don’t work,’ are damaging health and are being used to control population: Doctors panel, Haynes, 2021	“The only randomized control studies that have ever been done on masks show that they don’t work,” began Dr. Nepute. He referred to Dr. Anthony Fauci’s “noble lie,” in which Fauci “changed his tune,” from his March 2020 comments, where he downplayed the need and efficacy of mask wearing, before urging Americans to use masks later in the year. “Well, he lied to us. So if he lied about that, what else has he lied to you about?” questioned Nepute.Masks have become commonplace in almost every setting, whether indoors or outdoors, but Dr. Popper mentioned how there have been “no studies” which actually examine the “effect of wearing a mask during all your waking hours.”“There’s no science to back any of this and particularly no science to back the fact that wearing a mask twenty four-seven or every waking minute, is health promoting,” added Popper.”
86) Aerosol penetration through surgical masks, Chen, 1992	“The mask that has the highest collection efficiency is not necessarily the best mask from the perspective of the filter-quality factor, which considers not only the

	capture efficiency but also the air resistance. Although surgical mask media may be adequate to remove bacteria exhaled or expelled by health care workers, they may not be sufficient to remove the sub-micrometer-sized aerosols containing pathogens to which these health care workers are potentially exposed."
87) CDC: Schools With Mask Mandates Didn't See Statistically Significant Different Rates of COVID Transmission From Schools With Optional Policies, Miltimore, 2021	"The CDC did not include its finding that "required mask use among students was not statistically significant compared with schools where mask use was optional" in the summary of its report."
88) Horowitz: Data from India continues to blow up the 'Delta' fear narrative, Howorwitz, 2021	"Rather than proving the need to sow more panic, fear, and control over people, the story from India — the source of the "Delta" variant — continues to refute every current premise of COVID fascism…Unless we do that, we must return to the very effective lockdowns and masks. In reality, India's experience proves the opposite true; namely:1) Delta is largely an attenuated version, with a much lower fatality rate, that for most people is akin to a cold.2) Masks failed to stop the spread there.3) The country has come close to the herd immunity threshold with just 3% vaccinated.
89) Transmission of SARS-CoV-2 Delta Variant Among Vaccinated Healthcare Workers, Vietnam, Chau, 2021	While not definitive in the LANCET publication, it can be inferred that the nurses were all masked up and had PPE etc. as was the case in Finland and Israel nosocomial outbreaks, indicating the failure of PPE and masks to constrain Delta spread.
90) Aerosol penetration through surgical masks, Willeke, 1992	"The mask that has the highest collection efficiency is not necessarily the best mask from the perspective of the filter-quality factor, which considers not only the capture efficiency but also the air resistance. Although surgical mask media may be adequate to remove bacteria exhaled or expelled by health care workers, they may not be sufficient to remove the submicrometer-size aerosols containing pathogens to which these health care workers are potentially exposed."
91) The efficacy of standard surgical face masks: an investigation using "tracer particles", Wiley, 1980	"Particle contamination of the wound was demonstrated in all aexperiments. Since the microspheres were not identified on the exterior of these face masks, they must have escped around the mask edges and found their

	way into the wound. The wearing of the mask beneath the headgear curtails this route of contamination."
92) An Evidence Based Scientific Analysis of Why Masks are Ineffective, Unnecessary, and Harmful, Meehan, 2020	"Decades of the highest-level scientific evidence (meta-analyses of multiple randomized controlled trials) overwhelmingly conclude that medical masks are ineffective at preventing the transmission of respiratory viruses, including SAR-CoV-2…those arguing for masks are relying on low-level evidence (observational retrospective trials and mechanistic theories), none of which are powered to counter the evidence, arguments, and risks of mask mandates."
93) Open Letter from Medical Doctors and Health Professionals to All Belgian Authorities and All Belgian Media, AIER, 2020	"Oral masks in healthy individuals are ineffective against the spread of viral infections."
94) Effectiveness of N95 respirators versus surgical masks against influenza: A systematic review and meta-analysis, Long, 2020	"The use of N95 respirators compared with surgical masks is not associated with a lower risk of laboratory-confirmed influenza. It suggests that N95 respirators should not be recommended for general public and nonhigh-risk medical staff those are not in close contact with influenza patients or suspected patients."
95) Advice on the use of masks in the context of COVID-19, WHO, 2020	"However, the use of a mask alone is insufficient to provide an adequate level of protection or source control, and other personal and community level measures should also be adopted to suppress transmission of respiratory viruses."
96) Farce mask: it's safe for only 20 minutes, The Sydney Morning Herald, 2003	"Health authorities have warned that surgical masks may not be an effective protection against the virus."Those masks are only effective so long as they are dry," said Professor Yvonne Cossart of the Department of Infectious Diseases at the University of Sydney."As soon as they become saturated with the moisture in your breath they stop doing their job and pass on the droplets."Professor Cossart said that could take as little as 15 or 20 minutes, after which the mask would need to be changed. But those warnings haven't stopped people snapping up the masks, with retailers reporting they are having trouble keeping up with demand."
97) Study: Wearing A Used Mask Is Potentially Riskier Than No Mask At	"According to researchers from the University of Massachusetts Lowell and California Baptist University,

All, Boyd, 2020 Effects of mask-wearing on the inhalability and deposition of airborne SARS-CoV-2 aerosols in human upper airway	a three-layer surgical mask is 65 percent efficient in filtering particles in the air. That effectiveness, however, falls to 25 percent once it is used."It is natural to think that wearing a mask, no matter new or old, should always be better than nothing," said author Jinxiang Xi."Our results show that this belief is only true for particles larger than 5 micrometers, but not for fine particles smaller than 2.5 micrometers," he continued."
MASK MANDATES	
1) Mask mandate and use efficacy for COVID-19 containment in US States, Guerra, 2021	"Calculated total COVID-19 case growth and mask use for the continental United States with data from the Centers for Disease Control and Prevention and Institute for Health Metrics and Evaluation. We estimated post-mask mandate case growth in non-mandate states using median issuance dates of neighboring states with mandates…did not observe association between mask mandates or use and reduced COVID-19 spread in US states."
2) These 12 Graphs Show Mask Mandates Do Nothing To Stop COVID, Weiss, 2020	"Masks can work well when they're fully sealed, properly fitted, changed often, and have a filter designed for virus-sized particles. This represents none of the common masks available on the consumer market, making universal masking much more of a confidence trick than a medical solution…Our universal use of unscientific face coverings is therefore closer to medieval superstition than it is to science, but many powerful institutions have too much political capital invested in the mask narrative at this point, so the dogma is perpetuated. The narrative says that if cases go down it's because masks succeeded. It says that if cases go up it's because masks succeeded in preventing more cases. The narrative simply assumes rather than proves that masks work, despite overwhelming scientific evidence to the contrary."
3) Mask Mandates Seem to Make CCP Virus Infection Rates Climb, Study Says, Vadum, 2020	"Protective-mask mandates aimed at combating the spread of the CCP virus that causes the disease COVID-19 appear to promote its spread, according to a report from RationalGround.com, a clearinghouse of COVID-19 data trends that's run by a grassroots group of data analysts, computer scientists, and actuaries."

4) Horowitz: Comprehensive analysis of 50 states shows greater spread with mask mandates, Howorwitz, 2020 Justin Hart	"How long do our politicians get to ignore the results?… The results: When comparing states with mandates vs. those without, or periods of times within a state with a mandate vs. without, there is absolutely no evidence the mask mandate worked to slow the spread one iota. In total, in the states that had a mandate in effect, there were 9,605,256 confirmed COVID cases over 5,907 total days, an average of 27 cases per 100,000 per day. When states did not have a statewide order (which includes the states that never had them and the period of time masking states did not have the mandate in place) there were 5,781,716 cases over 5,772 total days, averaging 17 cases per 100,000 people per day."
5) The CDC's Mask Mandate Study: Debunked, Alexander, 2021	"Thus, it is not surprising that the CDC's own recent conclusion on the use of nonpharmaceutical measures such as face masks in pandemic influenza, warned that scientific "evidence from 14 randomized controlled trials of these measures did not support a substantial effect on transmission…" Moreover, in the WHO's 2019 guidance document on nonpharmaceutical public health measures in a pandemic, they reported as to face masks that "there is no evidence that this is effective in reducing transmission…" Similarly, in the fine print to a recent double-blind, double-masking simulation the CDC stated that "The findings of these simulations [supporting mask usage] should neither be generalized to the effectiveness …nor interpreted as being representative of the effectiveness of these masks when worn in real-world settings."
6) Phil Kerpin, tweet, 2021 The Spectator	"The first ecological study of state mask mandates and use to include winter data: "Case growth was independent of mandates at low and high rates of community spread, and mask use did not predict case growth during the Summer or Fall-Winter waves."
7) How face masks and lockdowns failed, SPR, 2021	"Infections have been driven primarily by seasonal and endemic factors, whereas mask mandates and lockdowns have had no discernible impact"
8) Analysis of the Effects of COVID-19 Mask Mandates on Hospital Resource Consumption and Mortality at the County Level,	"There was no reduction in per-population daily mortality, hospital bed, ICU bed, or ventilator occupancy of COVID-19-positive patients attributable to the implementation of a mask-wearing mandate."

Schauer, 2021	
9) Do we need mask mandates, Harris, 2021	"But masks proved far less useful in the subsequent 1918 Spanish flu, a viral disease spread by pathogens smaller than bacteria. California's Department of Health, for instance, reported that the cities of Stockton, which required masks, and Boston, which did not, had scarcely different death rates, and so advised against mask mandates except for a few high-risk professions such as barbers….Randomized controlled trials (RCTs) on mask use, generally more reliable than observational studies, though not infallible, typically show that cloth and surgical masks offer little protection. A few RCTs suggest that perfect adherence to an exacting mask protocol may guard against influenza, but meta-analyses find little on the whole to suggest that masks offer meaningful protection. WHO guidelines from 2019 on influenza say that despite "mechanistic plausibility for the potential effectiveness" of masks, studies showed a benefit too small to be established with any certainty. Another literature review by researchers from the University of Hong Kong agrees. Its best estimate for the protective effect of surgical masks against influenza, based on ten RCTs published through 2018, was just 22 percent, and it could not rule out zero effect."
MASK HARMS	
1) Corona children studies: Co-Ki: First results of a German-wide registry on mouth and nose covering (mask) in children, Schwarz, 2021	"The average wearing time of the mask was 270 minutes per day. Impairments caused by wearing the mask were reported by 68% of the parents. These included irritability (60%), headache (53%), difficulty concentrating (50%), less happiness (49%), reluctance to go to school/kindergarten (44%), malaise (42%) impaired learning (38%) and drowsiness or fatigue (37%)."
2) Dangerous pathogens found on children's face masks, Cabrera, 2021	"Masks were contaminated with bacteria, parasites, and fungi, including three with dangerous pathogenic and pneumonia-causing bacteria."
3) Masks, false safety and real dangers, Part 2: Microbial challenges from masks, Borovoy, 2020/2021	"Laboratory testing of used masks from 20 train commuters revealed that 11 of the 20 masks tested contained over 100,000 bacterial colonies. Molds and yeasts were also found. Three of the masks contained more than one million bacterial colonies… The outside

	surfaces of surgical masks were found to have high levels of the following microbes, even in hospitals, more concentrated on the outside of masks than in the environment. Staphylococcus species (57%) and Pseudomonas spp (38%) were predominant among bacteria, and Penicillium spp (39%) and Aspergillus spp. (31%) were the predominant fungi.”
4) Preliminary report on surgical mask induced deoxygenation during major surgery, Beder, 2008	“Considering our findings, pulse rates of the surgeon’s increase and SpO2 decrease after the first hour. This early change in SpO2 may be either due to the facial mask or the operational stress. Since a very small decrease in saturation at this level, reflects a large decrease in PaO2, our findings may have a clinical value for the health workers and the surgeons.”
5) Mask mandates may affect a child’s emotional, intellectual development, Gillis, 2020	“The thing is we really don’t know for sure what the effect may or may not be. But what we do know is that children, especially in early childhood, they use the mouth as part of the entire face to get a sense of what’s going on around them in terms of adults and other people in their environment as far as their emotions. It also has a role in language development as well… If you think about an infant, when you interact with them you use part of your mouth. They are interested in your facial expressions. And if you think about that part of the face being covered up, there is that possibility that it could have an effect. But we don’t know because this is really an unprecedented time. What we wonder about is if this could play a role and how can we stop it if it would affect child development.”
6) Headaches and the N95 face-mask amongst healthcare providers, Lim, 2006	“Healthcare providers may develop headaches following the use of the N95 face-mask.”
7) Maximizing Fit for Cloth and Medical Procedure Masks to Improve Performance and Reduce SARS-CoV-2 Transmission and Exposure, 2021, Brooks, 2021	“Although use of double masking or knotting and tucking are two of many options that can optimize fit and enhance mask performance for source control and for wearer protection, double masking might impede breathing or obstruct peripheral vision for some wearers, and knotting and tucking can change the shape of the mask such that it no longer covers fully both the nose and the mouth of persons with larger faces.”

8) Facemasks in the COVID-19 era: A health hypothesis, Vainshelboim, 2021	"Wearing facemasks has been demonstrated to have substantial adverse physiological and psychological effects. These include hypoxia, hypercapnia, shortness of breath, increased acidity and toxicity, activation of fear and stress response, rise in stress hormones, immunosuppression, fatigue, headaches, decline in cognitive performance, predisposition for viral and infectious illnesses, chronic stress, anxiety and depression."
9) Wearing a mask can expose children to dangerous levels of carbon dioxide in just THREE MINUTES, study finds, Shaheen/Daily Mail, 2021	"European study found that children wearing masks for only minutes could be exposed to dangerous carbon dioxide levels…Forty-five children were exposed to carbon dioxide levels between three to twelve times healthy levels."
10) How many children must die? Shilhavy, 2020	"How long are parents going to continue masking their children causing great harm to them, even to the point of risking their lives? Dr. Eric Nepute in St. Louis took time to record a video rant that he wants everyone to share, after the 4-year-old child of one of his patients almost died from a bacterial lung infection caused by prolonged mask use."
11) Medical Doctor Warns that "Bacterial Pneumonias Are on the Rise" from Mask Wearing, Meehan, 2021	"I'm seeing patients that have facial rashes, fungal infections, bacterial infections. Reports coming from my colleagues, all over the world, are suggesting that the bacterial pneumonias are on the rise…Why might that be? Because untrained members of the public are wearing medical masks, repeatedly… in a non-sterile fashion… They're becoming contaminated. They're pulling them off of their car seat, off the rear-view mirror, out of their pocket, from their countertop, and they're reapplying a mask that should be worn fresh and sterile every single time."
12) Open Letter from Medical Doctors and Health Professionals to All Belgian Authorities and All Belgian Media, AIER, 2020	"Wearing a mask is not without side effects. Oxygen deficiency (headache, nausea, fatigue, loss of concentration) occurs fairly quickly, an effect similar to altitude sickness. Every day we now see patients complaining of headaches, sinus problems, respiratory problems and hyperventilation due to wearing masks. In addition, the accumulated CO2 leads to a toxic acidification of the organism which affects our immunity. Some experts even warn of an increased transmission

	of the virus in case of inappropriate use of the mask.”
13) Face coverings for covid-19: from medical intervention to social practice, Peters, 2020	“At present, there is no direct evidence (from studies on Covid19 and in healthy people in the community) on the effectiveness of universal masking of healthy people in the community to prevent infection with respiratory viruses, including Covid19. Contamination of the upper respiratory tract by viruses and bacteria on the outside of medical face masks has been detected in several hospitals. Another research shows that a moist mask is a breeding ground for (antibiotic resistant) bacteria and fungi, which can undermine mucosal viral immunity. This research advocates the use of medical / surgical masks (instead of homemade cotton masks) that are used once and replaced after a few hours.”
14) Face masks for the public during the covid-19 crisis, Lazzarino, 2020	“The two potential side effects that have already been acknowledged are: (1) Wearing a face mask may give a false sense of security and make people adopt a reduction in compliance with other infection control measures, including social distancing and hands washing. (2) Inappropriate use of face mask: people must not touch their masks, must change their single-use masks frequently or wash them regularly, dispose them correctly and adopt other management measures, otherwise their risks and those of others may increase. Other potential side effects that we must consider are: (3) The quality and the volume of speech between two people wearing masks is considerably compromised and they may unconsciously come closer. While one may be trained to counteract side effect n.1, this side effect may be more difficult to tackle. (4) Wearing a face mask makes the exhaled air go into the eyes. This generates an uncomfortable feeling and an impulse to touch your eyes. If your hands are contaminated, you are infecting yourself.”
15) Contamination by respiratory viruses on outer surface of medical masks used by hospital healthcare workers, Chughtai, 2019	“Respiratory pathogens on the outer surface of the used medical masks may result in self-contamination. The risk is higher with longer duration of mask use (> 6 h) and with higher rates of clinical contact. Protocols on duration of mask use should specify a maximum time of continuous use, and should consider guidance in high contact settings.”

16) Reusability of Facemasks During an Influenza Pandemic, Bailar, 2006	"After considering all the testimony and other information we received, the committee concluded that there is currently no simple, reliable way to decontaminate these devices and enable people to use them safely more than once. There is relatively little data available about how effective these devices are against flu even the first time they are used. To the extent they can help at all, they must be used correctly, and the best respirator or mask will do little to protect a person who uses it incorrectly. Substantial research must be done to increase our understanding of how flu spreads, to develop better masks and respirators, and to make it easier to decontaminate them. Finally, the use of face coverings is only one of many strategies that will be needed to slow or halt a pandemic, and people should not engage in activities that would increase their risk of exposure to flu just because they have a mask or respirator."
17) Exhalation of respiratory viruses by breathing, coughing, and talking, Stelzer-Braid, 2009	"The exhaled aerosols generated by coughing, talking, and breathing were sampled in 50 subjects using a novel mask, and analyzed using PCR for nine respiratory viruses. The exhaled samples from a subset of 10 subjects who were PCR positive for rhinovirus were also examined by cell culture for this virus. Of the 50 subjects, among the 33 with symptoms of upper respiratory tract infections, 21 had at least one virus detected by PCR, while amongst the 17 asymptomatic subjects, 4 had a virus detected by PCR. Overall, rhinovirus was detected in 19 subjects, influenza in 4 subjects, parainfluenza in 2 subjects, and human metapneumovirus in 1 subject. Two subjects were co-infected. Of the 25 subjects who had virus-positive nasal mucus, the same virus type was detected in 12 breathing samples, 8 talking samples, and in 2 coughing samples. In the subset of exhaled samples from 10 subjects examined by culture, infective rhinovirus was detected in 2."
18) [Effect of a surgical mask on six minute walking distance], Person, 2018	"Wearing a surgical mask modifies significantly and clinically dyspnea without influencing walked distance."
19) Protective masks reduce resilience, Science ORF, 2020	"The German researchers used two types of face masks for their study – surgical masks and so-called FFP2

	masks, which are mainly used by medical personnel. The measurements were carried out with the help of spiroergometry, in which patients or in this case the test persons exert themselves physically on a stationary bicycle – a so-called ergometer – or a treadmill. The subjects were examined without a mask, with surgical masks and with FFP2 masks. The masks therefore impair breathing, especially the volume and the highest possible speed of the air when exhaling. The maximum possible force on the ergometer was significantly reduced."
20) Wearing masks even more unhealthy than expected, Coronoa transition, 2020	"They contain microplastics – and they exacerbate the waste problem…"Many of them are made of polyester and so you have a microplastic problem." Many of the face masks would contain polyester with chlorine compounds: "If I have the mask in front of my face, then of course I breathe in the microplastic directly and these substances are much more toxic than if you swallow them, as they get directly into the nervous system," Braungart continues."
21) Masking Children: Tragic, Unscientific, and Damaging, Alexander, 2021	"Children do not readily acquire SARS-CoV-2 (very low risk), spread it to other children or teachers, or endanger parents or others at home. This is the settled science. In the rare cases where a child contracts Covid virus it is very unusual for the child to get severely ill or die. Masking can do positive harm to children – as it can to some adults. But the cost benefit analysis is entirely different for adults and children – particularly younger children. Whatever arguments there may be for consenting adults – children should not be required to wear masks to prevent the spread of Covid-19. Of course, zero risk is not attainable – with or without masks, vaccines, therapeutics, distancing or anything else medicine may develop or government agencies may impose."
22) The Dangers of Masks, Alexander, 2021	"With that clarion call, we pivot and refer here to another looming concern and this is the potential danger of the chlorine, polyester, and microplastic components of the face masks (surgical principally but any of the mass-produced masks) that have become part of our daily lives due to the Covid-19 pandemic. We hope those with persuasive power in the government will listen to this

	plea. We hope that the necessary decisions will be made to reduce the risk to our populations."
23) 13-year-old mask wearer dies for inexplicable reasons, Corona Transition, 2020	"The case is not only causing speculation in Germany about possible poisoning with carbon dioxide. Because the student "was wearing a corona protective mask when she suddenly collapsed and died a little later in the hospital," writes Wochenblick.Editor's Review: The fact that no cause of death was communicated nearly three weeks after the girl's death is indeed unusual. The carbon dioxide content of the air is usually about 0.04 percent. From a proportion of four percent, the first symptoms of hypercapnia, i.e. carbon dioxide poisoning, appear. If the proportion of the gas rises to more than 20 percent, there is a risk of deadly carbon dioxide poisoning. However, this does not come without alarm signals from the body. According to the medical portal netdoktor, these include "sweating, accelerated breathing, accelerated heartbeat, headaches, confusion, loss of consciousness". The unconsciousness of the girl could therefore be an indication of such poisoning."
24) Student Deaths Lead Chinese Schools to Change Mask Rules, that's, 2020	"During the month of April, three cases of students suffering sudden cardiac death (SCD) while running during gym class have been reported in Zhejiang, Henan and Hunan provinces. Beijing Evening News noted that all three students were wearing masks at the time of their deaths, igniting a critical discussion over school rules on when students should wear masks."
25) Blaylock: Face Masks Pose Serious Risks To The Healthy, 2020	"As for the scientific support for the use of face mask, a recent careful examination of the literature, in which 17 of the best studies were analyzed, concluded that, " None of the studies established a conclusive relationship between mask/respirator use and protection against influenza infection."[1] Keep in mind, no studies have been done to demonstrate that either a cloth mask or the N95 mask has any effect on transmission of the COVID-19 virus. Any recommendations, therefore, have to be based on studies of influenza virus transmission. And, as you have seen, there is no conclusive evidence of their efficiency in controlling flu virus transmission."
26) The mask requirement is	"In fact, the mask has the potential to "trigger strong

responsible for severe psychological damage and the weakening of the immune system, Coronoa Transition, 2020	psychovegetative stress reactions via emerging aggression, which correlate significantly with the degree of stressful after-effects". Prousa is not alone in her opinion. Several psychologists dealt with the mask problem — and most came to devastating results. Ignoring them would be fatal, according to Prousa."
27) The physiological impact of wearing an N95 mask during hemodialysis as a precaution against SARS in patients with end-stage renal disease, Kao, 2004	"Wearing an N95 mask for 4 hours during HD significantly reduced PaO2 and increased respiratory adverse effects in ESRD patients."
28) Is a Mask That Covers the Mouth and Nose Free from Undesirable Side Effects in Everyday Use and Free of Potential Hazards?, Kisielinski, 2021	"We objectified evaluation evidenced changes in respiratory physiology of mask wearers with significant correlation of O_2 drop and fatigue ($p < 0.05$), a clustered co-occurrence of respiratory impairment and O_2 drop (67%), N95 mask and CO_2 rise (82%), N95 mask and O_2 drop (72%), N95 mask and headache (60%), respiratory impairment and temperature rise (88%), but also temperature rise and moisture (100%) under the masks. Extended mask-wearing by the general population could lead to relevant effects and consequences in many medical fields.""Here are the pathophysiological changes and subjective complaints: 1) Increase in blood carbon dioxide 2) Increase in breathing resistance 3) Decrease in blood oxygen saturation 4) Increase in heart rate 5) Decrease in cardiopulmonary capacity 6) Feeling of exhaustion 7) Increase in respiratory rate 8) Difficulty breathing and shortness of breath 9) Headache 10) Dizziness 11) Feeling of dampness and heat 12) Drowsiness (qualitative neurological deficits) 13) Decrease in empathy perception 14) Impaired skin barrier function with acne, itching and skin lesions"
29) Is N95 face mask linked to dizziness and headache?, Ipek, 2021	"Respiratory alkalosis and hypocarbia were detected after the use of N95. Acute respiratory alkalosis can cause headache, anxiety, tremor, muscle cramps. In this study, it was quantitatively shown that the participants' symptoms were due to respiratory alkalosis and hypocarbia."

30) COVID-19 prompts a team of engineers to rethink the humble face mask, Myers, 2020	"But in filtering those particles, the mask also makes it harder to breathe. N95 masks are estimated to reduce oxygen intake by anywhere from 5 to 20 percent. That's significant, even for a healthy person. It can cause dizziness and lightheadedness. If you wear a mask long enough, it can damage the lungs. For a patient in respiratory distress, it can even be life threatening."
31) 70 doctors in open letter to Ben Weyts: 'Abolish mandatory mouth mask at school' – Belgium, World Today News, 2020	"In an open letter to the Flemish Minister of Education Ben Weyts (N-VA), 70 doctors ask to abolish the mandatory mouth mask at school, both for the teachers and for the students. Weyts does not intend to change course. The doctors ask that Minister Ben Weyts immediately reverses his working method: no mouth mask obligation at school, only protect the risk group and only the advice that people with a possible risk profile should consult their doctor."
32) Face masks pose dangers for babies, toddlers during COVID-19 pandemic, UC Davis Health, 2020	"Masks may present a choking hazard for young children. Also, depending on the mask and the fit, the child may have trouble breathing. If this happens, they need to be able to take it off," said UC Davis pediatrician Lena van der List. "Children less than 2 years of age will not reliably be able to remove a face mask and could suffocate. Therefore, masks should not routinely be used for young children…"The younger the child, the more likely they will be to not wear the mask properly, reach under the mask and touch potentially contaminated masks," said Dean Blumberg, chief of pediatric infectious diseases at UC Davis Children's Hospital. "Of course, this depends on the developmental level of the individual child. But I think masks are not likely to provide much potential benefit over risk until the teen years."
33) Covid-19: Important potential side effects of wearing face masks that we should bear in mind, Lazzarino, 2020	"Other potential side effects that we must consider, however, are 1) The quality and volume of speech between people wearing masks is considerably compromised and they may unconsciously come closer2) Wearing a mask makes the exhaled air go into the eyes. This generates an impulse to touch the eyes. 3) If your hands are contaminated, you are infecting yourself, 4) Face masks make breathing more difficult. Moreover, a fraction of carbon dioxide previously exhaled is inhaled at each respiratory cycle. Those

	phenomena increase breathing frequency and deepness, and they may worsen the burden of covid-19 if infected people wearing masks spread more contaminated air. This may also worsen the clinical condition of infected people if the enhanced breathing pushes the viral load down into their lungs, 5) The innate immunity's efficacy is highly dependent on the viral load. If masks determine a humid habitat where SARS-CoV-2 can remain active because of the water vapour continuously provided by breathing and captured by the mask fabric, they determine an increase in viral load (by re-inhaling exhaled viruses) and therefore they can cause a defeat of the innate immunity and an increase in infections."
34) Risks of N95 Face Mask Use in Subjects With COPD, Kyung, 2020	"Of the 97 subjects, 7 with COPD did not wear the N95 for the entire test duration. This mask-failure group showed higher British modified Medical Research Council dyspnea scale scores and lower FEV_1 percent of predicted values than did the successful mask use group. A modified Medical Research Council dyspnea scale score ≥ 3 (odds ratio 167, 95% CI 8.4 to >999.9; P = .008) or a FEV_1 < 30% predicted (odds ratio 163, 95% CI 7.4 to >999.9; P = .001) was associated with a risk of failure to wear the N95. Breathing frequency, blood oxygen saturation, and exhaled carbon dioxide levels also showed significant differences before and after N95 use."
35) Masks too dangerous for children under 2, medical group warns, The Japan Times, 2020	"Children under the age of 2 shouldn't wear masks because they can make breathing difficult and increase the risk of choking, a medical group has said, launching an urgent appeal to parents as the nation reopens from the coronavirus crisis…Masks can make breathing difficult because infants have narrow air passages," which increases the burden on their hearts, the association said, adding that masks also raise the risk of heat stroke for them."
36) Face masks can be problematic, dangerous to health of some Canadians: advocates, Spenser, 2020	"Face masks are dangerous to the health of some Canadians and problematic for some others…Asthma Canada president and CEO Vanessa Foran said simply wearing a mask could create risk of an asthma attack."

37) COVID-19 Masks Are a Crime Against Humanity and Child Abuse, Griesz-Brisson, 2020	"The rebreathing of our exhaled air will without a doubt create oxygen deficiency and a flooding of carbon dioxide. We know that the human brain is very sensitive to oxygen depravation. There are nerve cells for example in the hippocampus, that can't be longer than 3 minutes without oxygen – they cannot survive. The acute warning symptoms are headaches, drowsiness, dizziness, issues in concentration, slowing down of the reaction time – reactions of the cognitive system. However, when you have chronic oxygen depravation, all of those symptoms disappear, because you get used to it. But your efficiency will remain impaired and the undersupply of oxygen in your brain continues to progress. We know that neurodegenerative diseases take years to decades to develop. If today you forget your phone number, the breakdown in your brain would have already started 20 or 30 years ago…The child needs the brain to learn, and the brain needs oxygen to function. We don't need a clinical study for that. This is simple, indisputable physiology. Conscious and purposely induced oxygen deficiency is an absolutely deliberate health hazard, and an absolute medical contraindication."
38) Study shows how masks are harming children, Mercola, 2021	"Data from the first registry to record children's experiences with masks show physical, psychological and behavioral issues including irritability, difficulty concentrating and impaired learning.Since school shutdowns in spring 2020, an increasing number of parents are seeking drug treatment for attention deficit hyperactivity disorder (ADHD) for their children.Evidence from the U.K. shows schools are not the super spreaders health officials said they were; measured rates of infection in schools were the same as the community, not higher.A large randomized controlled trial showed wearing masks does not reduce the spread of SARS-CoV-2."
39) New Study Finds Masks Hurt Schoolchildren Physically, Psychologically, and Behaviorally, Hall, 2021 https://www.researchsquare.com/article/rs-124394/v2	"A new study, involving over 25,000 school-aged children, shows that masks are harming schoolchildren physically, psychologically, and behaviorally, revealing 24 distinct health issues associated with wearing masks…Though these results are concerning, the study also found that 29.7% of children experienced shortness

	of breath, 26.4% experienced dizziness, and hundreds of the participants experiencing accelerated respiration, tightness in chest, weakness, and short-term impairment of consciousness."
40) Protective Face Masks: Effect on the Oxygenation and Heart Rate Status of Oral Surgeons during Surgery, Scarano, 2021	"In all 20 surgeons wearing FFP2 covered by surgical masks, a reduction in arterial O_2 saturation from around 97.5% before surgery to 94% after surgery was recorded with increase of heart rates. A shortness of breath and light-headedness/headaches were also noted."
41) Effects of surgical and FFP2/N95 face masks on cardiopulmonary exercise capacity, Fikenzer, 2020	"Ventilation, cardiopulmonary exercise capacity and comfort are reduced by surgical masks and highly impaired by FFP2/N95 face masks in healthy individuals. These data are important for recommendations on wearing face masks at work or during physical exercise."
42) Headaches Associated With Personal Protective Equipment – A Cross-Sectional Study Among Frontline Healthcare Workers During COVID-19, Ong, 2020	"Most healthcare workers develop de novo PPE-associated headaches or exacerbation of their pre-existing headache disorders."
43) Open letter from medical doctors and health professionals to all Belgian authorities and all Belgian media, The American Institute of Stress, 2020	"Wearing a mask is not without side effects. Oxygen deficiency (headache, nausea, fatigue, loss of concentration) occurs fairly quickly, an effect similar to altitude sickness. Every day we now see patients complaining of headaches, sinus problems, respiratory problems, and hyperventilation due to wearing masks. In addition, the accumulated CO2 leads to a toxic acidification of the organism which affects our immunity. Some experts even warn of increased transmission of the virus in case of inappropriate use of the mask."
44) Reusing masks may increase your risk of coronavirus infection, expert says, Laguipo, 2020	"For the public, they should not wear facemasks unless they are sick, and if a healthcare worker advised them."For the average member of the public walking down a street, it is not a good idea," Dr. Harries said."What tends to happen is people will have one mask. They won't wear it all the time, they will take it off when they get home, they will put it down on a surface they haven't cleaned," she added.Further, she added that behavioral issues could adversely put themselves at more risk of getting the infection. For instance, people

	go out and don't wash their hands, they touch parts of the mask or their face, and they get infected."
45) What's Going On Under the Masks?, Wright, 2021	"Americans today have pretty good chompers on average, at least relative to most other people, past and present. Nevertheless, we do not think enough about oral health as evidenced by the almost complete lack of discussion regarding the effect of lockdowns and mandatory masking on our mouths."
46) Experimental Assessment of Carbon Dioxide Content in Inhaled Air With or Without Face Masks in Healthy ChildrenA Randomized Clinical Trial, Walach, 2021	"A large-scale survey in Germany of adverse effects in parents and children using data of 25 930 children has shown that 68% of the participating children had problems when wearing nose and mouth coverings."
47) NM Kids forced to wear masks while running in 100-degree heat; Parents are striking back, Smith, 2021	"Nationally, children have a 99.997% survival rate from COVID-19. In New Mexico, only 0.7% of child COVID-19 cases have resulted in hospitalization. It is clear that children have an extremely low risk of severe illness or death from COVID-19, and mask mandates are placing a burden upon kids which is detrimental to their own health and well-being."
48) Health Canada issues advisory for disposable masks with graphene, CBC, 2021	"Health Canada is advising Canadians not to use disposable face masks that contain graphene. Health Canada issued the notice on Friday and said wearers could inhale graphene, a single layer of carbon atoms. Masks containing the toxic particles may have been distributed in some health-care facilities."
49) COVID-19: Performance study of microplastic inhalation risk posed by wearing masks, Li, 2021 Is graphene safe?	"Wearing masks considerably reduces the inhalation risk of particles (e.g., granular microplastics and unknown particles) even when they are worn continuously for 720 h. Surgical, cotton, fashion, and activated carbon masks wearing pose higher fiber-like microplastic inhalation risk, while all masks generally reduced exposure when used under their supposed time (<4 h). N95 poses less fiber-like microplastic inhalation risk. Reusing masks after they underwent different disinfection pre-treatment processes can increase the risk of particle (e.g., granular microplastics) and fiber-like microplastic inhalation. Ultraviolet disinfection exerts a relatively weak effect on fiber-like microplastic inhalation, and thus, it can be recommended as a treatment process for reusing masks if proven effective

	from microbiological standpoint. Wearing an N95 mask reduces the inhalation risk of spherical-type microplastics by 25.5 times compared with not wearing a mask."
50) Manufacturers have been using nanotechnology-derived graphene in face masks — now there are safety concerns, Maynard, 2021	"Early concerns around graphene were sparked by previous research on another form of carbon — carbon nanotubes. It turns out that some forms of these fiber-like materials can cause serious harm if inhaled. And following on from research here, a natural next-question to ask is whether carbon nanotubes' close cousin graphene comes with similar concerns.Because graphene lacks many of the physical and chemical aspects of carbon nanotubes that make them harmful (such as being long, thin, and hard for the body to get rid of), the indications are that the material is safer than its nanotube cousins. But safer doesn't mean safe. And current research indicates that this is not a material that should be used where it could potentially be inhaled, without a good amount of safety testing first… As a general rule of thumb, engineered nanomaterials should not be used in products where they might inadvertently be inhaled and reach the sensitive lower regions of the lungs."
51) Masking young children in school harms language acquisition, Walsh, 2021	"This is important because children and/or students do not have the speech or language ability that adults have — they are not equally able and the ability to see the face and especially the mouth is critical to language acquisition which children and/or students are engaged in at all times. Furthermore, the ability to see the mouth is not only essential to communication but also essential to brain development."Studies show that by age four, kids from low-income households will hear 30 million less words than their more affluent counterparts, who get more quality face-time with caretakers." (https://news.stanford.edu/news/2014/november/language-toddlers-fernald-110514.html)."
52) Dangerous pathogens found on children's face masks, Rational Ground, 2021	"A group of parents in Gainesville, FL, sent 6 face masks to a lab at the University of Florida, requesting an analysis of contaminants found on the masks after they had been worn. The resulting report found that five masks were contaminated with bacteria, parasites, and fungi, including three with dangerous pathogenic and

	pneumonia-causing bacteria. Although the test is capable of detecting viruses, including SARS-CoV-2, only one virus was found on one mask (alcelaphine herpesvirus 1)…Half of the masks were contaminated with one or more strains of pneumonia-causing bacteria. One-third were contaminated with one or more strains of meningitis-causing bacteria. One-third were contaminated with dangerous, antibiotic-resistant bacterial pathogens. In addition, less dangerous pathogens were identified, including pathogens that can cause fever, ulcers, acne, yeast infections, strep throat, periodontal disease, Rocky Mountain Spotted Fever, and more."
53) Face mask dermatitis" due to compulsory facial masks during the SARS-CoV-2 pandemic: data from 550 health care and non-health care workers in Germany, Niesert, 2021	"The duration of wearing masks showed a significant impact on the prevalence of symptoms ($p < 0.001$). Type IV hypersensitivity was significantly more likely in participants with symptoms compared to those without symptoms ($p = 0.001$), whereas no increase in symptoms was observed in participants with atopic diathesis. HCWs used facial skin care products significantly more often than non-HCWs ($p = 0.001$)."
54) Effect of Wearing Face Masks on the Carbon Dioxide Concentration in the Breathing Zone, AAQR/Geiss, 2020	"Detected carbon dioxide concentrations ranged from 2150 ± 192 to 2875 ± 323 ppm. The concentrations of carbon dioxide while not wearing a face mask varied from 500–900 ppm. Doing office work and standing still on the treadmill each resulted in carbon dioxide concentrations of around 2200 ppm. A small increase could be observed when walking at a speed of 3 km h–1 (leisurely walking pace)…concentrations in the detected range can cause undesirable symptoms, such as fatigue, headache, and loss of concentration."
55) Surgical masks as source of bacterial contamination during operative procedures, Zhiqing, 2018	"The source of bacterial contamination in SMs was the body surface of the surgeons rather than the OR environment. Moreover, we recommend that surgeons should change the mask after each operation, especially those beyond 2 hours."
56) The Damage of Masking Children Could be Irreparable, Hussey, 2021	"When we surround children with mask-wearers for a year at a time, are we impairing their face barcode recognition during a period of hot neural development, thus putting full development of the FFA at risk? Does the demand for separation from others, reducing social interaction, add to the potential consequences as it

	might in autism? When can we be sure that we won't interfere with visual input to the face recognition visual neurology so we don't interfere with brain development? How much time with stimulus interference can we allow without consequences? Those are all questions currently without answers; we don't know. Unfortunately, the science implies that if we mess up brain development for faces, we may not currently have therapies to undo everything we've done."
57) Masks can be Murder, Grossman, 2021	"Wearing masks can create a sense of anonymity for an aggressor, while also dehumanizing the victim. This prevents empathy, empowering violence, and murder." Masking helps remove empathy and compassion, allowing others to commit unspeakable acts on the masked person."
58) London high school teacher calls face masks an 'egregious and unforgivable form of child abuse, Butler, 2020	"In his email, Farquharson called the campaign to legislate mask wearing a "shameful farce, a charade, an act of political theatre" that's more about enforcing "obedience and compliance" than it is about public health. He also likened children wearing masks to "involuntary self-torture," calling it "an egregious and unforgivable form of child abuse and physical assault."
59) UK Government Advisor Admits Masks Are Just "Comfort Blankets" That Do Virtually Nothing, ZeroHedge, 2021	"As the UK Government heralds "freedom day" today, which is anything but, a prominent government scientific advisor has admitted that face masks do very little to protect from coronavirus and are basically just "comfort blankets…the professor noted that "those aerosols escape masks and will render the mask ineffective," adding "The public were demanding something must be done, they got masks, it is just a comfort blanket. But now it is entrenched, and we are entrenching bad behaviour…all around the world you can look at mask mandates and superimpose on infection rates, you cannot see that mask mandates made any effect whatsoever," Axon further noted, adding that "The best thing you can say about any mask is that any positive effect they do have is too small to be measured."
60) Masks, false safety and real dangers, Part 1: Friable mask particulate and lung vulnerability, Borovoy, 2020	"Surgical personnel are trained to never touch any part of a mask, except the loops and the nose bridge. Otherwise, the mask is considered useless and is to be replaced. Surgical personnel are strictly trained not to touch their masks otherwise. However, the general

	public may be seen touching various parts of their masks. Even the masks just removed from manufacturer packaging have been shown in the above photos to contain particulate and fiber that would not be optimal to inhale… Further concerns of macrophage response and other immune and inflammatory and fibroblast response to such inhaled particles specifically from facemasks should be the subject of more research. If widespread masking continues, then the potential for inhaling mask fibers and environmental and biological debris continues on a daily basis for hundreds of millions of people. This should be alarming for physicians and epidemiologists knowledgeable in occupational hazards."
61) Medical Masks, Desai, 2020	"Face masks should be used only by individuals who have symptoms of respiratory infection such as coughing, sneezing, or, in some cases, fever. Face masks should also be worn by health care workers, by individuals who are taking care of or are in close contact with people who have respiratory infections, or otherwise as directed by a doctor. Face masks should not be worn by healthy individuals to protect themselves from acquiring respiratory infection because there is no evidence to suggest that face masks worn by healthy individuals are effective in preventing people from becoming ill."

Plaintiff's Exhibit 99

Table 1

Physiological and Psychological Effects of Wearing Facemask and Their Potential Health Consequences.

Physiological Effects	Psychological Effect	Health Consequences
• Hypoxemia • Hypercapnia • Shortness of breath • Increase lactate concentration • Decline in pH levels • Acidosis • Toxicity • Inflammation • Self-contamination • Increase in stress hormones level (adrenaline, noradrenaline and cortisol) • Increased muscle tension • Immunosuppression	• Activation of "fight or flight" stress response • Chronic stress condition • Fear • Mood disturbances • Insomnia • Fatigue • Compromised cognitive performance	• Increased predisposition for viral and infection illnesses • Headaches • Anxiety • Depression • Hypertension • Cardiovascular disease • Cancer • Diabetes • Alzheimer disease • Exacerbation of existing conditions and diseases • Accelerated aging process • Health deterioration • Premature mortality

Facemasks in the COVID-19 era: A health hypothesis

Baruch Vainshelboim⁎

37-47 minutes

Abstract

Many countries across the globe utilized medical and non-medical facemasks as non-pharmaceutical intervention for reducing the transmission and infectivity of coronavirus disease-2019 (COVID-19). Although, scientific evidence supporting facemasks' efficacy is lacking, adverse physiological, psychological and health effects are established. Is has been hypothesized that facemasks have compromised safety and efficacy profile and should be avoided from use. The current article comprehensively summarizes scientific evidences with respect to wearing facemasks in the COVID-19 era, providing prosper information for public health and decisions making.

Keywords: Physiology, Psychology, Health, SARS-CoV-2, Safety, Efficacy

Introduction

Facemasks are part of non-pharmaceutical interventions providing some breathing barrier to the mouth and nose that have been utilized for reducing the transmission of respiratory pathogens [1]. Facemasks can be medical and non-medical, where two types of the medical masks primarily used by healthcare workers [1], [2]. The first type is National Institute for Occupational Safety and Health (NIOSH)-certified N95 mask, a filtering face-piece respirator, and the second type is a surgical mask [1]. The designed and intended uses of N95 and surgical masks are different in the type of protection they potentially provide. The N95s are typically composed of electret filter media and seal tightly to the face of the wearer, whereas surgical masks are generally loose fitting and may or may not contain electret-filtering media. The N95s are designed to reduce the wearer's inhalation exposure to infectious and harmful particles from the environment such as during extermination of insects. In contrast, surgical masks are designed to provide a barrier protection against splash, spittle and other body fluids to spray from the wearer (such as surgeon) to the sterile environment (patient during operation) for reducing the risk of contamination [1].

The third type of facemasks are the non-medical cloth or fabric masks. The non-medical facemasks are made from a variety of woven and non-woven materials such as Polypropylene, Cotton, Polyester, Cellulose, Gauze and Silk. Although non-medical cloth or fabric facemasks are neither a medical device nor personal protective equipment, some standards have been developed by the French Standardization Association (AFNOR Group) to define a minimum performance for filtration and breathability capacity [2]. The current article reviews the scientific evidences with respect to safety and efficacy of wearing facemasks, describing the physiological and psychological effects and the potential long-term consequences on health.

Hypothesis

On January 30, 2020, the World Health Organization (WHO) announced a global public health emergency of severe acute respiratory syndrome-coronavirus-2 (SARS-CoV-2) causing illness of coronavirus disease-2019 (COVID-19) [3]. As of October 1, 2020, worldwide 34,166,633 cases were reported and 1,018,876 have died with virus diagnosis. Interestingly, 99% of the detected cases with SARS-CoV-2 are asymptomatic or have mild condition, which contradicts with the virus name (*severe* acute respiratory syndrome-coronavirus-2) [4]. Although infection fatality rate (number of death cases divided by number of reported cases) initially seems quite high 0.029 (2.9%) [4], this overestimation related to limited number of COVID-19 tests performed which biases towards higher rates. Given the fact that asymptomatic or minimally symptomatic cases is several times higher than the number of reported cases, the case fatality rate is considerably less than 1% [5]. This was confirmed by the head of National Institute of Allergy and Infectious Diseases from US stating, "the overall clinical consequences of COVID-19 are similar to those of severe seasonal influenza" [5], having a case fatality rate of approximately 0.1% [5], [6], [7], [8]. In addition, data from hospitalized patients with COVID-19 and general public indicate that the majority of deaths were among older and chronically ill individuals, supporting the possibility that the virus may exacerbates existing conditions but rarely causes death by itself [9], [10]. SARS-CoV-2 primarily affects respiratory system and can cause complications such as acute respiratory distress syndrome (ARDS), respiratory failure and death [3], [9]. It is not clear however, what the scientific and clinical basis for wearing facemasks as protective strategy, given the fact that facemasks restrict breathing, causing hypoxemia and hypercapnia and increase the risk for respiratory complications, self-contamination and exacerbation of existing chronic conditions [2], [11], [12], [13], [14].

Of note, hyperoxia or oxygen supplementation (breathing air with high partial O_2 pressures that above the sea levels) has been well established as therapeutic and curative practice for variety acute and chronic conditions including respiratory complications [11], [15]. It fact, the current standard of care practice for treating hospitalized patients with COVID-19 is breathing 100% oxygen [16], [17], [18]. Although several countries mandated wearing facemask in health care settings and public areas, scientific evidences are lacking supporting their efficacy for reducing morbidity or mortality associated with infectious or viral diseases [2], [14], [19]. Therefore, it has been hypothesized: 1) the practice of wearing facemasks has compromised safety and efficacy profile, 2) Both medical and non-medical facemasks are ineffective to reduce human-to-human transmission and infectivity of SARS-CoV-2 and COVID-19, 3) Wearing facemasks has adverse physiological and psychological effects, 4) Long-term consequences of wearing facemasks on health are detrimental.

Evolution of hypothesis

Breathing Physiology

Breathing is one of the most important physiological functions to sustain life and health. Human body requires a continuous and adequate oxygen (O_2) supply to all organs and cells for normal function and survival. Breathing is also an essential process for removing metabolic byproducts [carbon dioxide (CO_2)] occurring during cell respiration [12], [13]. It is well established that acute significant deficit in O_2 (hypoxemia) and increased levels of CO_2 (hypercapnia) even for few minutes can be severely harmful and lethal, while chronic hypoxemia and hypercapnia cause health deterioration, exacerbation of existing conditions, morbidity and ultimately mortality [11], [20], [21], [22]. Emergency medicine demonstrates that 5–6 min of severe hypoxemia during cardiac arrest will cause brain death with extremely poor survival rates [20], [21], [22], [23]. On the other hand, chronic mild or moderate hypoxemia and hypercapnia such as from wearing facemasks resulting in shifting to higher contribution of anaerobic energy metabolism, decrease in pH levels and increase in cells and blood acidity, toxicity, oxidative stress, chronic inflammation, immunosuppression and health deterioration [24], [11], [12], [13].

Efficacy of facemasks

The physical properties of medical and non-medical facemasks suggest that facemasks are ineffective to block viral particles due to their difference in scales [16], [17], [25]. According to the current knowledge, the virus SARS-CoV-2 has a diameter of 60 nm to 140 nm [nanometers (billionth of a meter)] [16], [17], while medical and non-medical facemasks' thread diameter ranges from 55 µm to 440 µm [micrometers (one millionth of a meter), which is more than 1000 times larger [25]. Due to the difference in sizes between SARS-CoV-2 diameter and facemasks thread diameter (the virus is 1000 times smaller), SARS-CoV-2 can easily pass through any facemask [25]. In addition, the efficiency filtration rate of facemasks is poor, ranging from 0.7% in non-surgical, cotton-gauze woven mask to 26% in cotton sweeter material [2]. With respect to surgical and N95 medical facemasks, the efficiency filtration rate falls to 15% and 58%, respectively when even small gap between the mask and the face exists [25].

Clinical scientific evidence challenges further the efficacy of facemasks to block human-to-human transmission or infectivity. A randomized controlled trial (RCT) of 246 participants [123 (50%) symptomatic)] who were allocated to either wearing or not wearing surgical facemask, assessing viruses transmission including coronavirus [26]. The results of this study showed that among symptomatic individuals (those with fever, cough, sore throat, runny nose ect…) there was no difference between wearing and not wearing facemask for coronavirus droplets transmission of particles of >5 µm. Among asymptomatic individuals, there was no droplets or aerosols coronavirus detected from any participant with or without the mask, suggesting that asymptomatic individuals do not transmit or infect other people [26]. This was further supported by a study on infectivity where 445 asymptomatic individuals were exposed to asymptomatic SARS-CoV-2 carrier (been positive for SARS-CoV-2) using close contact (shared quarantine space) for a median of 4 to 5 days. The study found that none of the 445 individuals was infected with SARS-CoV-2 confirmed by real-time reverse transcription polymerase [27].

A *meta*-analysis among health care workers found that compared to no masks, surgical mask and N95 respirators were not effective against transmission of viral infections or influenza-like illness based on six RCTs [28]. Using separate analysis of 23 observational studies, this *meta*-analysis found no protective effect of medical mask or N95 respirators against SARS virus [28]. A recent systematic review of 39 studies including 33,867 participants in community settings (self-report illness), found no difference between N95 respirators versus surgical masks and surgical mask versus no masks in the risk for developing influenza or influenza-like illness, suggesting their ineffectiveness of blocking viral transmissions in community settings [29].

Another *meta*-analysis of 44 non-RCT studies (n = 25,697 participants) examining the potential risk reduction of facemasks against SARS, middle east respiratory syndrome (MERS) and COVID-19 transmissions [30]. The *meta*-analysis included four specific studies on COVID-19 transmission (5,929 participants, primarily health-care workers used N95 masks). Although the overall findings showed reduced risk of virus transmission with facemasks, the analysis had severe limitations to draw conclusions. One of the four COVID-19 studies had zero infected cases in both arms, and was excluded from *meta*-analytic calculation. Other two COVID-19 studies had unadjusted models, and were also excluded from the overall analysis. The *meta*-analytic results were based on only one COVID-19, one MERS and 8 SARS studies, resulting in high selection bias of the studies and contamination of the results between different viruses. Based on four COVID-19 studies, the *meta*-analysis failed to demonstrate risk reduction of facemasks for COVID-19 transmission, where the authors reported that the results of *meta*-analysis have low certainty and are inconclusive [30].

In early publication the WHO stated that "facemasks are not required, as no evidence is available on its usefulness to protect non-sick persons" [14]. In the same publication, the WHO declared that "cloth (e.g. cotton or gauze) masks are not recommended under any circumstance" [14]. Conversely, in later publication the WHO stated that the usage of fabric-made facemasks (Polypropylene, Cotton, Polyester, Cellulose, Gauze and Silk) is a general community practice for "preventing the infected wearer transmitting the virus to others and/or to offer protection to the healthy wearer against infection (prevention)" [2]. The same publication further conflicted itself by stating that due to the lower filtration, breathability and overall performance of fabric facemasks, the usage of woven fabric mask such as cloth, and/or non-woven fabrics, should only be considered for infected persons and not for prevention practice in asymptomatic individuals [2]. The Central for Disease Control and Prevention (CDC) made similar recommendation, stating that only symptomatic persons should consider wearing facemask, while for asymptomatic individuals this practice is not recommended [31]. Consistent with the CDC, clinical scientists from Departments of Infectious Diseases and Microbiology in Australia counsel against facemasks usage for health-care workers, arguing that there is no justification for such practice while normal caring relationship between patients and medical staff could be compromised [32]. Moreover, the WHO repeatedly announced that "at present, there is no direct evidence (from studies on COVID-19) on the effectiveness face masking of healthy people in the community to prevent infection of respiratory viruses, including COVID-19" [2]. Despite these controversies, the potential harms and risks of wearing facemasks were clearly acknowledged. These including self-contamination due to hand practice or non-replaced when the mask is wet, soiled or damaged, development of facial skin lesions, irritant dermatitis or worsening acne and psychological discomfort. Vulnerable populations such as people with mental health disorders, developmental disabilities, hearing problems, those living in hot and humid environments, children and patients with respiratory conditions are at significant health risk for complications and harm [2].

Physiological effects of wearing facemasks

Wearing facemask mechanically restricts breathing by increasing the resistance of air movement during both inhalation and exhalation process [12], [13]. Although, intermittent (several times a week) and repetitive (10–15 breaths for 2–4 sets) increase in respiration resistance may be adaptive for strengthening respiratory muscles [33], [34], prolonged and continues effect of wearing facemask is maladaptive and could be detrimental for health [11], [12], [13]. In normal conditions at the sea level, air contains 20.93% O_2 and 0.03% CO_2, providing partial pressures of 100 mmHg and 40 mmHg for these gases in the arterial blood, respectively. These gas concentrations significantly altered when breathing occurs through facemask. A trapped air remaining between the mouth, nose and the facemask is rebreathed repeatedly in and out of the body, containing low O_2 and high CO_2 concentrations, causing hypoxemia and hypercapnia [35], [36], [11], [12], [13]. Severe hypoxemia may also provoke cardiopulmonary and neurological complications and is considered an important clinical sign in cardiopulmonary medicine [37], [38], [39], [40], [41], [42]. Low oxygen content in the arterial blood can cause myocardial ischemia, serious arrhythmias, right or left ventricular dysfunction, dizziness, hypotension, syncope and pulmonary hypertension [43]. Chronic low-grade hypoxemia and hypercapnia as result of using facemask can cause exacerbation of existing cardiopulmonary, metabolic, vascular and neurological conditions [37], [38], [39], [40], [41], [42]. Table 1 summarizes the physiological, psychological effects of wearing facemask and their potential long-term consequences for health.

Table 1

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In addition to hypoxia and hypercapnia, breathing through facemask residues bacterial and germs components on the inner and outside layer of the facemask. These toxic components are repeatedly rebreathed back into the body, causing self-contamination. Breathing through facemasks also increases temperature and humidity in the space between the mouth and the mask, resulting a release of toxic particles from the mask's materials [1], [2], [19], [26], [35], [36]. A systematic literature review estimated that aerosol contamination levels of facemasks including 13 to 202,549 different viruses [1]. Rebreathing contaminated air with high bacterial and toxic particle concentrations along with low O_2 and high CO_2 levels continuously challenge the body homeostasis, causing self-toxicity and immunosuppression [1], [2], [19], [26], [35], [36].

A study on 39 patients with renal disease found that wearing N95 facemask during hemodialysis significantly reduced arterial partial oxygen pressure (from PaO_2 101.7 to 92.7 mm Hg), increased respiratory rate (from 16.8 to 18.8 breaths/min), and increased the occurrence of chest discomfort and respiratory distress [35]. Respiratory Protection Standards from Occupational Safety and Health Administration, US Department of Labor states that breathing air with O_2 concentration below 19.5% is considered oxygen-deficiency, causing physiological and health adverse effects. These include increased breathing frequency, accelerated heartrate and cognitive impairments related to thinking and coordination [36]. A chronic state of mild hypoxia and hypercapnia has been shown as primarily mechanism for developing cognitive dysfunction based on animal studies and studies in patients with chronic obstructive pulmonary disease [44].

The adverse physiological effects were confirmed in a study of 53 surgeons where surgical facemask were used during a major operation. After 60 min of facemask wearing the oxygen saturation dropped by more than 1% and heart rate increased by approximately five beats/min [45]. Another study among 158 health-care workers using protective personal equipment primarily N95 facemasks reported that 81% (128 workers) developed new headaches during their work shifts as these become mandatory due to COVID-19 outbreak. For those who used the N95 facemask greater than 4 h per day, the likelihood for developing a headache during the work shift was approximately four times higher [Odds ratio = 3.91, 95% CI (1.35–11.31) p = 0.012], while 82.2% of the N95 wearers developed the headache already within ≤10 to 50 min [46].

With respect to cloth facemask, a RCT using four weeks follow up compared the effect of cloth facemask to medical masks and to no masks on the incidence of clinical respiratory illness, influenza-like illness and laboratory-confirmed respiratory virus infections among 1607 participants from 14 hospitals [19]. The results showed that there were no difference between wearing cloth masks, medical masks and no masks for incidence of clinical respiratory illness and laboratory-confirmed respiratory virus infections. However, a large harmful effect with more than 13 times higher risk [Relative Risk = 13.25 95% CI (1.74 to 100.97) was observed for influenza-like illness among those who were wearing cloth masks [19]. The study concluded that cloth masks have significant health and safety issues including moisture retention, reuse, poor filtration and increased risk for infection, providing recommendation against the use of cloth masks [19].

Psychological effects of wearing facemasks

Psychologically, wearing facemask fundamentally has negative effects on the wearer and the nearby person. Basic human-to-human connectivity through face expression is compromised and self-identity is somewhat eliminated [47], [48], [49]. These dehumanizing movements partially delete the uniqueness and individuality of person who wearing the facemask as well as the connected person [49]. Social connections and relationships are basic human needs, which innately inherited in all people, whereas reduced human-to-human connections are associated with poor mental and physical health [50], [51]. Despite escalation in technology and globalization that would presumably foster social connections, scientific findings show that people are becoming increasingly more socially isolated, and the prevalence of loneliness is increasing in last few decades [50], [52]. Poor social connections are closely related to isolation and loneliness, considered significant health related risk factors [50], [51], [52], [53].

A *meta*-analysis of 91 studies of about 400,000 people showed a 13% increased morality risk among people with low compare to high contact frequency [53]. Another *meta*-analysis of 148 prospective studies (308,849 participants) found that poor social relationships was associated with 50% increased mortality risk. People who were socially isolated or fell lonely had 45% and 40% increased mortality risk, respectively. These findings were consistent across ages, sex, initial health status, cause of death and follow-up periods [52]. Importantly, the increased risk for mortality was found comparable to smoking and exceeding well-established risk factors such as obesity and physical inactivity [52]. An umbrella review of 40 systematic reviews including 10 *meta*-analyses demonstrated that compromised social relationships were associated with increased risk of all-cause mortality, depression, anxiety suicide, cancer and overall physical illness [51].

As described earlier, wearing facemasks causing hypoxic and hypercapnic state that constantly challenges the normal homeostasis, and activates "fight or flight" stress response, an important survival mechanism in the human body [11], [12], [13]. The acute stress response includes activation of nervous, endocrine, cardiovascular, and the immune systems [47], [54], [55], [56]. These include activation of the limbic part of the brain, release stress hormones (adrenalin, neuro-adrenalin and cortisol), changes in blood flow distribution (vasodilation of peripheral blood vessels and vasoconstriction of visceral blood vessels) and activation of the immune system response (secretion of macrophages and natural killer cells) [47], [48]. Encountering people who wearing facemasks activates innate stress-fear emotion, which is fundamental to all humans in danger or life threating situations, such as death or unknown, unpredictable outcome. While acute stress response (seconds to minutes) is adaptive reaction to challenges and part of the survival mechanism, chronic and prolonged state of stress-fear is maladaptive and has detrimental effects on physical and mental health. The repeatedly or continuously activated stress-fear response causes the body to operate on survival mode, having sustain increase in blood pressure, pro-inflammatory state and immunosuppression [47], [48].

Long-Term health consequences of wearing facemasks

Long-term practice of wearing facemasks has strong potential for devastating health consequences. Prolonged hypoxic-hypercapnic state compromises normal physiological and psychological balance, deteriorating health and promotes the developing and progression of existing chronic diseases [23], [38], [39], [43], [47], [48], [57], [11], [12], [13]. For instance, ischemic heart disease caused by hypoxic damage to the myocardium is the most common form of cardiovascular disease and is a number one cause of death worldwide (44% of all non-communicable diseases) with 17.9 million deaths occurred in 2016 [57]. Hypoxia also playing an important role in cancer burden [58]. Cellular hypoxia has strong mechanistic feature in promoting cancer initiation, progression, metastasis, predicting clinical outcomes and usually presents a poorer survival in patients with cancer. Most solid tumors present some degree of hypoxia, which is independent predictor of more aggressive disease, resistance to cancer therapies and poorer clinical outcomes [59], [60]. Worth note, cancer is one of the leading causes of death worldwide, with an estimate of more than 18 million new diagnosed cases and 9.6

million cancer-related deaths occurred in 2018 [61].

With respect to mental health, global estimates showing that COVID-19 will cause a catastrophe due to collateral psychological damage such as quarantine, lockdowns, unemployment, economic collapse, social isolation, violence and suicides [62], [63], [64]. Chronic stress along with hypoxic and hypercapnic conditions knocks the body out of balance, and can cause headaches, fatigue, stomach issues, muscle tension, mood disturbances, insomnia and accelerated aging [47], [48], [65], [66], [67]. This state suppressing the immune system to protect the body from viruses and bacteria, decreasing cognitive function, promoting the developing and exacerbating the major health issues including hypertension, cardiovascular disease, diabetes, cancer, Alzheimer disease, rising anxiety and depression states, causes social isolation and loneliness and increasing the risk for prematurely mortality [47], [48], [51], [56], [66].

Conclusion

The existing scientific evidences challenge the safety and efficacy of wearing facemask as preventive intervention for COVID-19. The data suggest that both medical and non-medical facemasks are ineffective to block human-to-human transmission of viral and infectious disease such SARS-CoV-2 and COVID-19, supporting against the usage of facemasks. Wearing facemasks has been demonstrated to have substantial adverse physiological and psychological effects. These include hypoxia, hypercapnia, shortness of breath, increased acidity and toxicity, activation of fear and stress response, rise in stress hormones, immunosuppression, fatigue, headaches, decline in cognitive performance, predisposition for viral and infectious illnesses, chronic stress, anxiety and depression. Long-term consequences of wearing facemask can cause health deterioration, developing and progression of chronic diseases and premature death. Governments, policy makers and health organizations should utilize prosper and scientific evidence-based approach with respect to wearing facemasks, when the latter is considered as preventive intervention for public health.

CRediT authorship contribution statement

Baruch Vainshelboim: Conceptualization, Data curation, Writing - original draft.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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