

Xodus Medical Face Protection Shield

Informational Review Guide



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ISO 13485 CERTIFIED
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Informational Review Guide

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Product Literature

Brochure

NEW PRODUCT

Face Protection Shield

Clear, quality protection where it's needed most

- Enhanced personal protection against infectious droplets, bodily fluids, contaminants, etc.
- Fog-resistant
- Anti-glare, crystal clear lens
- Wearable with glasses/ goggles and masks
- Secure elastic headband
- Comfortable: breathable and lightweight
- Full face protection: 13"W x 9"L
- Latex-Free



#40767

Case Qty: 60/ea

Ordering Info: (724) 337-5500

Or contact your sales representative



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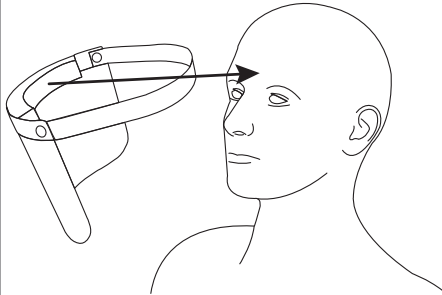
LITBRIC003 R1 6/2/2020

Product Literature

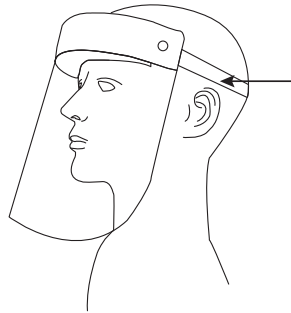
Instructions for Use

Xodus Medical Face Protection Shield Instructions for Use: Product #40767

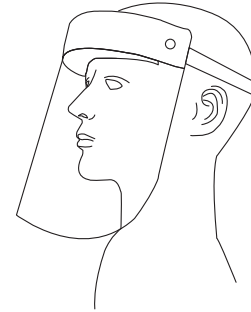
PLACING ON THE HEAD:



- 1** Using one hand grasping the shield where the strap meets the shield, place the shield foam front against your forehead at a location above the eyebrows.

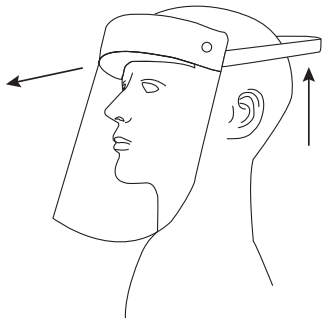


- 2** While holding the foam front against your forehead, using your second hand, secure the elastic band around the back of your head so that the foam rests on your forehead.

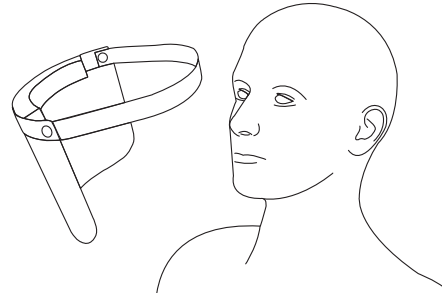


- 3** Once shield is situated in a comfortable position, make sure the shield covers the front and sides of the head and that no areas are left uncovered.
- 4** Adjust the Face Protection Shield as needed to maintain proper coverage.

REMOVING FROM THE HEAD:



- 1** Using one hand, grasp the front of the Face Protection Shield at the where the strap meets the shield.
- 2** With your second hand, grasp the rear of the elastic band and lift the elastic band upward and forward above your head.



- 3** Pull the shield away from your face.
- 4** Dispose of the shield according to hospital protocol for the device.

WHEN USING YOUR FACE MASK:

1. Wear the face protection shield in addition to other personal protective equipment
2. Replace if wet
3. Avoid exposure to high heat
4. Handle gently to prevent drops and scratches
5. Do not share with others
6. Shield may be disinfected during any single use; the shield may be disinfected based on hospital protocol for this type of device



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Independent Product Testing

University of Colorado Denver: Face Shield Test Report Xodus Face Shield

Face Shield Test Report Xodus Face Shield
May 27, 2020



1. Summary

This report provides results from testing conducted by the Bioengineering Department on the Anschutz Medical Campus in Aurora Colorado. Test procedures were adapted from the American National Standards Institute (ANSI) standard Z87.1-2003 [1] and guidelines compiled for the Journal of Occupational and Environmental Hygiene [2]. This test does not assess mechanical impacts.

1.1. Test Articles

Test articles reported on are described in Table 1.

Table 1: Test articles.

Test Article	Part #/Lot #	Number of Samples	Material	Date
Xodus Medical Face Shield	REF: 40767 LOT: 200427	2	PET	5/27/2020

1.2. Results Summary

Results are summarized in Table 2. Specifications were derived from the ANSI standards and the clinical guidelines [1,2]. When the shields arrived, one had visible creasing in a corner, likely from shipping (Fig. 1 & 2). The shields studied were functional, demonstrating no flammability, no liquid penetration during spraying, and no vision impairment or degradation after cleaning. The shields studied were biocompatible, demonstrating no skin irritation during use. The shields studied demonstrated no shifting during use over a 1-hour period time. Overall, the shields passed all tests.



Figure 1: Shield upon arrival.



Figure 2: Creasing at corner.

1.3. Recommendations

The shield creasing upon arrival could have caused visual distortion if it occurred higher on the shield in the user's direct line of sight. Alternative shipping and handling methods should be considered to maintain optimal visual clarity of the shields.

Table 2: Test Results Summary.

Face Shield Test Matrix Summary					
All standards per ANSI Z87.1 [1]. Methods are modified.					
Tests developed from healthcare face shield guidelines [2].					
	Description	Specification	Test	Result	P/F
Functionality	Flammability	Burn rate < 76 mm/minute	Expose to butane torch per ASTM 635	No flames observed, just curling	Pass
	Cleanability	No loss of vision or observed degradation	Clean with 70% ethanol, 10% bleach and Quaternary Ammonia solution.	No degradation or vision loss	Pass
	Spray Test	No penetration from colored water spray.	Spray shield from several angles with red colored water, assess for penetration	No penetration observed	Pass
	Visibility	No significant loss of vision	Perform standard eye test with and without, assess for change	No vision impairment	Pass
Biocompatibility	Biocompatible Material?	Is the material listed in the bill of materials known to be biocompatible?	Research	PET is known to be biocompatible	Pass
	Irritability	Irritation of skin?	Tester feedback	None Noted	Pass
Human	Wear test	No shift in position greater than 3 cm	Perform typical nursing duties, assess for motion	No shifting during use	Pass
	Don/Doff time	Takes no more than 30 seconds to don or doff	Measure time	10 seconds	Pass

2. Results

2.1. Human Factors

When moving the head side-to-side and up-and-down repeatedly, the shield did not shift. In the initial wear test up to 1 hour, there was no skin irritation or noticeable contact points from the shield.

2.2. Spray Testing

After spraying the shield three times at eye-level from three sides, no liquid penetration was observed - no liquid was absorbed on areas protected by the face shield.

2.3. Cleaning and Vision

Three test solutions, 70% ethanol, 10% bleach, and a quaternary ammonia solution, were individually applied to the shield before a subsequent vision test. No damage, hazing, or reduction in vision was observed after cleaning the shield with the test solutions.

2.4. Flammability

When applying a butane flame to the shield material, no flames or burning were observed. The material demonstrated curling but did not ignite. Burn rate was not recorded as no burning was observed.

3. Conclusion

The shield provided good spray protection, satisfactory visual quality, good cleanability, and was easy to take on and off. The material is not flammable and is known to be biocompatible. The tester experienced no discomfort during wear.

4. References

[1] American National Standards Institute. "ANSI Z87. 1-2003 Standard Practice for Occupational and Educational Eye and Face Protection." (2003).

[2] Roberge, Raymond J. "Face shields for infection control: A review." *Journal of Occupational and Environmental Hygiene*, 13.4 (2016): 235-242.

Compliance Statements



May 28, 2020

Xodus Medical
702 Prominence Dr
New Kensington, PA 15068

RE: Statement of Compliance – Face Protection Shield

Product Name: Face Protection Shield

Product Description: Personal Protection Device to be mounted on the head of healthcare personnel; made of plastic PET with a polyurethane foam brow

Intended Use: Enhanced personal protection of a healthcare workers face against infectious droplets, bodily fluids, contaminants, etc.

Product Compliance: The Face Protection Shield complies with the following requirements:

- ANSI Z87.1-2003: Standard Practice for Occupational and Educational Eye and Face Protection for the following:
 - Functionality: Flammability; Cleanability; Spray Test; Visibility
 - Biocompatibility: Material-PET Biocompatible; Irritability
 - Human: Wear Test
 - Don/Doff Time: <30 seconds
- Guidelines compiled for the Journal of Occupational and Environmental Hygiene - Face Shields for Infection Control: A Review; 13.4 (2016). This test does not assess mechanical impacts.

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Clinical Validation

Article Highlights

- “Dr. Adalja thinks face shields have potential to be more effective than face masks alone because “people are much less likely to touch their face when wearing a face shield. They can also be taken off and cleaned. In many ways, they’re a much more attractive option.”
- “While medical professionals often wear a surgical mask or N95 mask under a face shield, Dr. Schaffner says that’s not really necessary for the general public. “That combination is used by doctors in invasive procedures where they’re creating an aerosol, such as an intubation,” he says. “The average person isn’t going to encounter that. If some people choose to use a face shield going out and about, that might provide a degree of protection that’s comparable to a surgical mask.”
 - Miller, Korin. **“Can Face Shields Help Prevent COVID-19? Here’s How They Compare to Face Masks.”** Prevention, Prevention, 28 May 2020.
- “Face shields, which can be quickly and affordably produced and distributed, should be included as part of strategies to safely and significantly reduce transmission in the community setting. Now is the time for adoption of this practical intervention.”
- “Most important, face shields appear to significantly reduce the amount of inhalation exposure to influenza virus, another droplet-spread respiratory virus. In a simulation study, face shields were shown to reduce immediate viral exposure by 96% when worn by a simulated health care worker within 18 inches of a cough. Even after 30 minutes, the protective effect exceeded 80% and face shields blocked 68% of small particle aerosols, which are not thought to be a dominant mode of transmission of SARS-CoV-2.”
 - Eli N. Perencevich, MD, MS1,2; Daniel J. Diekema, MD, MS2; Michael B. Edmond, MD, MPH, MPA2.
“Moving Personal Protective Equipment Into the Community Face Shields and Containment of COVID-19.” JAMA, April 29, 2020
- “Face shields have the potential to overcome some of the major drawbacks of face masks. Face shields provide better coverage of the face, compared with masks, thus reducing the risk of self-contamination. Additionally, face shields are durable, and they can be cleaned and reused. Given their simpler design, durability, and reuse potential, face shields are less likely to be in short supply, like face masks. Additionally, face shields do not impede facial nonverbal communication; they can be worn concurrently with other face and eye protective equipment, and they do not impact vocalization.”
 - Sonali D. Advani MBBS, MPH1,2 , Becky A. Smith MD1,2, Sarah S. Lewis MD, MPH1,2, Deverick J. Anderson MD, MPH1,2 and Daniel J. Sexton MD1,2 **“Universal masking in hospitals in the COVID-19 era: Is it time to consider shielding?”** The Society for Healthcare Epidemiology of America. April 29, 2020
- “What’s clear is that their (Face Shields) success in hospital settings provides the basis for their utility in the community setting as we relax physical distancing going forward.”
 - Robert Glatter, M.D., emergency physician, Lenox Hill Hospital, New York City; Journal of the American Medical Association, April 30, 2020.
- “In 13 unadjusted studies and two adjusted studies... eye protection was associated with lower risk of infection”
 - Derek K Chu, Elie A Akl, Stephanie Duda, Karla Solo, Sally Yaacoub, Holger J Schünemann, on behalf of the COVID-19 Systematic Urgent Review Group Effort (SURGE) study authors* **“Physical distancing, face masks, and eye protection to prevent person-to-person transmission of SARS-CoV-2 and COVID-19: a systematic review and meta-analysis.”** The Lancet, June 1, 2020.

VIEWPOINT

Moving Personal Protective Equipment Into the Community Face Shields and Containment of COVID-19

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On March 19, 2020, California became the first state to issue a stay-at-home order in response to the evolving coronavirus disease 2019 (COVID-19) pandemic. It was quickly recognized that widespread diagnostic testing with contact tracing, used successfully in countries such as South Korea and Singapore, would not be available in time to significantly contain the spread of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).^{1,2} Over the following month, additional nonpharmaceutical mitigation strategies, including school closures, bans on large in-person gatherings, and partial closures of restaurants and retail stores, were applied to “flatten the epidemic curve” and limit the peak effects of a surge of patients on health care systems. Yet, even as the benefits of mitigation bundles have not fully been realized, there are widespread calls to reopen businesses, given the immense economic and social consequences of extreme physical distancing strategies.

Recently, public health, infectious disease, and policy experts have outlined recommendations for gradually reopening society using combinations of containment and mitigation strategies.^{3,4} Proposed containment strategies have followed the South Korean model and include rapidly expanding public health infrastructure for widespread testing and data-driven contact tracing, while ensuring that safe medical care is delivered by health care

that most of their infections are acquired in the community where PPE is typically not worn.⁵ Thus, it becomes important to know if practice from occupational safety can be used in the community as a bridge to longer-lasting measures, such as vaccines. Could a simple and affordable face shield, if universally adopted, provide enough added protection when added to testing, contact tracing, and hand hygiene to reduce transmissibility below a critical threshold?

COVID-19 Transmission in the Community

The mode of transmission of respiratory viruses has long been a subject of debate. Evidence to date suggests that SARS-CoV-2 is spread like other respiratory viruses: by infectious droplets emitted in close proximity (ie, within 6 feet) to the eyes, nose, or mouth of a susceptible person, or by direct contact with those droplets (eg, touching a contaminated surface and then touching the eyes, nose, or mouth).⁶ Although droplet vs airborne transmission is likely to be a continuum, with smaller droplets able to be propelled further than 3 to 6 feet and remaining airborne longer after certain respiratory emissions,⁷ the implications of limited aerosol spread are most important in health care settings after aerosol-generating procedures, such as open suctioning of airways and endotracheal intubation or extubation.

Contact investigations for SARS-CoV-2 have confirmed community transmission rates that are consistent with droplet and contact spread (household attack rates of 10%, health care and community attack rates of <1%, and R_0 [the effective reproduction number, or average number of new infections caused by an infected individual during their infection] of 2-3),⁵ and much different than for airborne viral pathogens, such as varicella zoster virus or measles (household attack rates of 85%-90% and R_0 of 10-18).

This implies that simple and easy-to-use barriers to respiratory droplets, along with hand hygiene and avoidance of touching the face, could help prevent community transmission when physical distancing and stay-at-home measures are relaxed or no longer possible. The 2 major options for such barriers are face masks and face shields.

Face Masks and Face Shields

The supply chain for medical masks is concentrated in China and the origin of the outbreak there resulted in factory closures and critical shortages. To preserve medical masks for health care facilities, the Centers for Disease Control and Prevention has recommended that

Face shields, which can be quickly and affordably produced and distributed, should be included as part of strategies to safely and significantly reduce transmission in the community setting.

workers wearing adequate personal protective equipment (PPE), such as N95 respirators, medical masks, eye protection, gowns, and gloves. However, there is growing recognition that containment strategies that rely on testing will be inadequate because the necessary testing capacity may not be available for weeks to months, and in the US the ability to track, trace, and quarantine is unclear. In addition, countries where testing was not limited and containment was achieved, eg, Singapore, have seen substantial second waves of infection and mandated extreme distancing interventions that the US and other countries are trying to scale back.

The Infectious Diseases Society of America (IDSA) has included societal use of PPE, such as masks and face shields, in its recommendations for easing restrictions.⁴ Experience and evidence, even during this pandemic, suggest that health care workers rarely acquire infections during patient care when proper PPE is used and

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all persons wear a cloth mask in public for source control. Cloth masks have been shown to be less effective than medical masks for prevention of communicable respiratory illnesses,⁸ although in vitro testing suggests that cloth masks provide some filtration of virus-sized aerosol particles.⁹ Face shields may provide a better option.

Face shields come in various forms, but all provide a clear plastic barrier that covers the face. For optimal protection, the shield should extend below the chin anteriorly, to the ears laterally, and there should be no exposed gap between the forehead and the shield's headpiece. Face shields require no special materials for fabrication and production lines can be repurposed fairly rapidly. Numerous companies, including Apple, Nike, GM, and John Deere, have all started producing face shields. These shields can be made from materials found in craft or office supply stores. Thus, availability of face shields is currently greater than that of medical masks.

Face shields offer a number of advantages. While medical masks have limited durability and little potential for reprocessing, face shields can be reused indefinitely and are easily cleaned with soap and water, or common household disinfectants. They are comfortable to wear, protect the portals of viral entry, and reduce the potential for autoinoculation by preventing the wearer from touching their face. People wearing medical masks often have to remove them to communicate with others around them; this is not necessary with face shields. The use of a face shield is also a reminder to maintain social distancing, but allows visibility of facial expressions and lip movements for speech perception.

Most important, face shields appear to significantly reduce the amount of inhalation exposure to influenza virus, another droplet-spread respiratory virus. In a simulation study, face shields were shown to reduce immediate viral exposure by 96% when worn by a simulated health care worker within 18 inches of a cough.¹⁰ Even after 30 minutes, the protective effect exceeded 80% and face shields blocked 68% of small particle aerosols,¹⁰ which are not thought to be a dominant mode of transmission of SARS-CoV-2. When the study was repeated at the currently recommended physical distancing distance of 6 feet, face shields reduced inhaled

virus by 92%,¹⁰ similar to distancing alone, which reinforces the importance of physical distancing in preventing viral respiratory infections. Of note, no studies have evaluated the effects or potential benefits of face shields on source control, ie, containing a sneeze or cough, when worn by asymptomatic or symptomatic infected persons. However, with efficacy ranges of 68% to 96% for a single face shield, it is likely that adding source control would only improve efficacy, and studies should be completed quickly to evaluate this.

Major policy recommendations should be evaluated using clinical studies. However, it is unlikely that a randomized trial of face shields could be completed in time to verify efficacy. No clinical trial has been conducted to assess the efficacy of widespread testing and contact tracing, but that approach is based on years of experience. Taken as a bundle, the effectiveness of adding face shields as a community intervention to the currently proposed containment strategies should be evaluated using existing mathematical models. The implicit goal of face shields alone or in combination with other interventions should be to interrupt transmission by reducing the R_0 to less than 1. Notably, effective control of even the most infectious pathogens, such as measles, does not require a vaccine with 100% efficacy. No burden of 100% efficacy should be placed on face shields or any containment policy because this level of control is both impossible to achieve and unnecessary to drive SARS-CoV-2 infection levels into a manageable range.

Conclusions

The COVID-19 pandemic arrived swiftly and found many countries unprepared. Even highly prepared countries are now facing second-wave outbreaks that have forced implementation of extreme social distancing measures. To minimize the medical and economic consequences, it is important to rapidly assess and adopt a containment intervention bundle that drives transmissibility to manageable levels. Face shields, which can be quickly and affordably produced and distributed, should be included as part of strategies to safely and significantly reduce transmission in the community setting. Now is the time for adoption of this practical intervention.

ARTICLE INFORMATION

Published Online: April 29, 2020.
doi:10.1001/jama.2020.7477

Conflict of Interest Disclosures: Dr Diekema reported receiving research funding from bioMerieux. No other disclosures were reported.

Disclaimer: The views expressed in this article are those of the authors and do not necessarily reflect the position or policy of the Department of Veterans Affairs or the US government.

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Clinical Validation


The Society for Healthcare Epidemiology of America

Infection Control & Hospital Epidemiology (2020), 1–2
doi:10.1017/ice.2020.179



Commentary

Universal masking in hospitals in the COVID-19 era: Is it time to consider shielding?

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Abstract

With concerns for presymptomatic transmission of COVID-19 and increasing burden of contact tracing and employee furloughs, several hospitals have supplemented pre-existing infection prevention measures with universal masking of all personnel in hospitals. Other hospitals are currently faced with the dilemma of whether or not to proceed with universal masking in a time of critical mask shortages. We summarize the rationale behind a universal masking policy in healthcare settings, important considerations before implementing such a policy and the challenges with universal masking. We also discuss proposed solutions such as universal face shields.

(Received 21 April 2020; accepted 25 April 2020)

As the novel coronavirus (SARS-CoV-2) public health crisis escalates, several hospitals have supplemented pre-existing infection prevention measures, such as visitor restrictions and employee screening, with universal masking of all healthcare professionals (HCPs). A universal masking policy usually requires that all HCPs (clinical and nonclinical) wear some sort of face mask while on hospital premises. These new policies also continue pre-existing policies requiring the use of N95 respirators (when available) when performing aerosol-generating procedures on patients with known or suspected SARS-CoV-2. In a nutshell, the rationale of implementing a universal masking policy in hospitals is to limit the transmission of SARS-CoV-2 from patients to HCP and from HCP to patients and/or to other HCPs. In the following sections, we summarize the rationale for universal masking in hospitals, important considerations before implementing this policy, and the challenges with universal masking, and we discuss proposed solutions such as universal face shields.

Rationale for universal masking

Atypical presentations and presymptomatic transmission of SARS-CoV-2 have now been shown to cause clusters of COVID-19 in community settings, nursing homes, cruise ships, and returning travelers.^{1–3} For example, approximately half of the residents in a skilled nursing facility in Washington who tested positive as a result of an exposure investigation were not symptomatic on the day of testing.¹ Of the 114 persons in a cohort of returning travelers who tested positive for SARS-CoV-2, 2 (1.8%) were asymptomatic on screening.² Similarly, almost half of the 712 persons with a positive

test result on the Diamond Princess cruise ship were asymptomatic at the time of testing.³ Most recently, an investigation of 7 clusters in Singapore provided further evidence that viral shedding can occur before symptom onset.⁴ This may result in transmission from presymptomatic HCPs to patients and other HCPs, although frequency of transmission from such individuals is an unresolved question. However, these exposure investigations usually occur after symptom onset, which increases the burden of contact tracing and the number of exposed HCPs placed on furlough. A surgical mask also provides a physical barrier between hands and mucus membranes of mouth and nose. An average person touches their face spontaneously ~23–26 times per hour. A mask serves as a constant reminder to reduce hand-to-face contact.

Important considerations when implementing universal masking

An adequate supply of masks is an obvious prerequisite for implementing a universal masking policy. Hospitals without an adequate supply of masks should continue to focus on measures such as extended use, reuse, and reprocessing of their existing supply of masks and respirators. A universal masking policy should always be considered an adjunct to concurrent policies such as visitor restrictions and employee screening for fever and other symptoms of a respiratory illness at their point of entry into the hospital. Similar screening of visitors who are given special exemptions to visit pediatric, obstetric, or hospice patients should also occur daily as they enter the hospital. HCP and exempted visitors who “pass” their daily symptom and signs screen are usually given 1 mask to wear during their entire shift or visit. HCPs are instructed to handle masks only after performing hand hygiene. Masking policies differ slightly across institutions, with some facilities promoting the use of cloth masks versus surgical masks, but the basic premise is the same.

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Cite this article: Advani SD, et al. (2020). Universal masking in hospitals in the COVID-19 era: Is it time to consider shielding?. *Infection Control & Hospital Epidemiology*, <https://doi.org/10.1017/ice.2020.179>

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Challenges with universal masking

There are some theoretical drawbacks to a universal masking policy, the most important of which is the increased cost and depletion of supply of masks in health systems that are already dealing with shortages. Specifically, serious unanticipated supply-chain issues could lead to shortages of masks at a time when the risk of both community and healthcare-associated spread of COVID-19 has increased. Also, logistical issues such as storage of masks during meals or breaks may lead to unanticipated problems such as contamination or loss of masks. Inadvertent self-contamination of masks during a long work shift could theoretically and paradoxically increase the risk of acquisition of SARS-CoV-2. A false sense of security by staff could lead to unintended consequences such as poor hand hygiene or poor adherence to other measures such as social distancing. Compliance with universal masking policies is an additional concern and may in turn lead to time and resource utilization toward compliance monitoring programs or audits.

Published data on the efficacy of universal masking policies to prevent healthcare-associated transmission of respiratory viruses are limited, and the generalizability of these results to the ongoing SARS-CoV-2 pandemic is uncertain. One prospective single-center study that implemented a universal masking policy for all individuals in direct contact with stem cell transplant patients showed a significant reduction in all respiratory viral illnesses on the units where this policy was implemented.⁵ Similar masking policies have been utilized for HCPs who opted out of mandatory influenza vaccination across British Columbia, Canada.⁶ No prospective studies comparing the effectiveness of masking policies during the SARS-CoV-2 pandemic have been undertaken to our knowledge.

Universal face shields as an alternative

Face shields are face coverings made of clear material attached to a headpiece to cover the eyes, nose, and mouth. This design is intended to protect the facial area and associated mucous membranes from infectious droplets and spatter of body fluids. Face shields have the potential to overcome some of the major drawbacks of face masks. Face shields provide better coverage of the face, compared with masks, thus reducing the risk of self-contamination. Additionally, face shields are durable, and they can be cleaned and reused. Given their simpler design, durability, and reuse potential, face shields are less likely to be in short supply, like face masks. Additionally, face shields do not impede facial nonverbal communication; they can be worn concurrently with other face and eye protective equipment, and they do not impact vocalization. However, lack of a good seal around the face shield may lead to aerosol penetration and may be subject to fogging or glare.⁷ Although additional studies are needed to assess universal face shielding, it offers a promising solution in a time of critical mask shortages.

In conclusion, universal masking when implemented together with strict visitor restrictions and employee screening may

incrementally reduce healthcare-associated transmission of SARS-CoV-2. Additionally, such a policy will reduce the burden of contact tracing and subsequent furloughs of HCPs in a time of acute HCP shortages. It also provides reassurance to HCPs as they care for patients with known or suspected COVID-19 infection.

A universal masking policy may not be appropriate for all hospitals because successful implementation of this policy requires an adequate supply of face masks. Furthermore, whether such a policy can indeed prevent transmission of SARS-CoV-2 is uncertain, nor is it known whether the benefits of such a policy outweigh the disadvantages discussed above. Masks are not a substitute for other public health interventions; they must always be used in combination with social distancing and hand hygiene. Future studies are needed to examine the frequency of viral contamination of masks worn for long hours or multiple shifts, as are studies needed to compare rates of healthcare-associated SARS-CoV-2 in hospitals and long-term care facilities that do and do not utilize universal masking policies. Finally, exploring other approaches such as universal use of face shields or more durable face masks could provide much-needed scientific evidence related to the efficacy of universal masking policies or the use of other barrier methods.

Acknowledgments. The authors thank members of the Infection Prevention Department at Duke University Health System for their support.

Financial support. No financial support was provided relevant to this article.

Conflicts of interest. All authors report no conflicts of interest relevant to this article, except that Duke University Health System has implemented a universal masking policy.

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Face shields a more effective deterrent to COVID?

By E.J. Mundell

HealthDay Reporter

THURSDAY, April 30, 2020 (HealthDay News) -- Hundreds of millions of Americans heeded recent government advice and rushed to wear cloth face masks, hoping they might prevent transmission of the new coronavirus.

But there's another option: The clear plastic face shield, already in use by many health care personnel.

Now, a team of experts say face shields might replace masks as a more comfortable and more effective deterrent to COVID-19.

"Face shields, which can be quickly and affordably produced and distributed, should be included as part of strategies to safely and significantly reduce transmission in the community setting," said a trio of physicians from the University of Iowa.

Reporting in the April 29 *Journal of the American Medical Association*, experts led by Dr. Eli Perencevich, of the university's department of internal medicine, and the Iowa City VA Health Care System, said the face shield's moment may have come.

While the U.S. Centers for Disease Control and Prevention began advocating the use of cloth masks to help stop COVID-19 transmission in April, laboratory testing "suggests that cloth masks provide [only] some filtration of virus-sized aerosol particles."

According to Perencevich's group, "face shields may provide a better option."

To be most effective in stopping viral spread, a face shield should extend to below the chin. It should also cover the ears and "there should be no exposed gap between the forehead and the shield's headpiece," the Iowa team members said.

Shields have a number of advantages over masks, they added. First of all, they are endlessly reusable, simply requiring cleaning with soap and water or common disinfectants. Shields are usually more comfortable to wear than masks, and they form a barrier that keeps people from easily touching their own faces.

When speaking, people sometimes pull down a mask to make things easier -- but that isn't necessary with a face shield. And "the use of a face shield is also a reminder to maintain social distancing, but allows visibility of facial expressions and lip movements for speech perception," the authors pointed out.

And what about the ability of a face shield to prevent coronavirus transmission?

According to the Iowa team, large-scale studies haven't yet been conducted. But "in a simulation study, face shields were shown to reduce immediate viral exposure by 96% when worn by a simulated health care worker within 18 inches of a cough."

"When the study was repeated at the currently recommended physical distancing distance of 6 feet, face shields reduced inhaled virus by 92%," the authors said.

No studies have yet been conducted to see how well face shields help keep exhaled or coughed virus from spreading outwards from an infected wearer, Perencevich and his colleagues said, and they hope that studies on that issue will be conducted.

And they stressed that face shields should only be one part of any infection control effort, along with social distancing and hand-washing.

There will never be any intervention -- even a vaccine -- that can guarantee 100% effectiveness against the coronavirus, the authors said, so face shields shouldn't be held to that standard.

Dr. Robert Glatter is on the front lines of the COVID-19 pandemic in his role as emergency physician at Lenox Hill Hospital in New York City. Reading over the new report, he agreed that "common sense" measures are crucial in curbing infections.

"One approach that makes the most sense, especially in light of the limitations of face masks and face coverings, is the use of face shields," Glatter said.

"While we don't have hard trials or data on the efficacy of face shields at this time, early data from their use in patients with influenza [which is droplet-spread] is promising," he noted. "What's clear is that their success in hospital settings provides the basis for their utility in the community setting as we relax physical distancing going forward."

WebMD News from HealthDay

Sources 

SOURCES: Robert Glatter, M.D., emergency physician, Lenox Hill Hospital, New York City; *Journal of the American Medical Association*, April 29, 2020, online



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Clinical Validation

The Lancet: A Systematic Review and Meta-Analysis

Physical distancing, face masks, and eye protection to prevent person-to-person transmission of SARS-CoV-2 and COVID-19: a systematic review and meta-analysis



Derek K Chu, Elie A Akl, Stephanie Duda, Karla Solo, Sally Yaacoub, Holger J Schünemann, on behalf of the COVID-19 Systematic Urgent Review Group Effort (SURGE) study authors*

Summary

Background Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) causes COVID-19 and is spread person-to-person through close contact. We aimed to investigate the effects of physical distance, face masks, and eye protection on virus transmission in health-care and non-health-care (eg, community) settings.

Methods We did a systematic review and meta-analysis to investigate the optimum distance for avoiding person-to-person virus transmission and to assess the use of face masks and eye protection to prevent transmission of viruses. We obtained data for SARS-CoV-2 and the betacoronaviruses that cause severe acute respiratory syndrome, and Middle East respiratory syndrome from 21 standard WHO-specific and COVID-19-specific sources. We searched these data sources from database inception to May 3, 2020, with no restriction by language, for comparative studies and for contextual factors of acceptability, feasibility, resource use, and equity. We screened records, extracted data, and assessed risk of bias in duplicate. We did frequentist and Bayesian meta-analyses and random-effects meta-regressions. We rated the certainty of evidence according to Cochrane methods and the GRADE approach. This study is registered with PROSPERO, CRD42020177047.

Findings Our search identified 172 observational studies across 16 countries and six continents, with no randomised controlled trials and 44 relevant comparative studies in health-care and non-health-care settings (n=25 697 patients). Transmission of viruses was lower with physical distancing of 1 m or more, compared with a distance of less than 1 m (n=10736, pooled adjusted odds ratio [aOR] 0.18, 95% CI 0.09 to 0.38; risk difference [RD] -10.2%, 95% CI -11.5 to -7.5; moderate certainty); protection was increased as distance was lengthened (change in relative risk [RR] 2.02 per m; $p_{\text{interaction}}=0.041$; moderate certainty). Face mask use could result in a large reduction in risk of infection (n=2647; aOR 0.15, 95% CI 0.07 to 0.34, RD -14.3%, -15.9 to -10.7; low certainty), with stronger associations with N95 or similar respirators compared with disposable surgical masks or similar (eg, reusable 12–16-layer cotton masks; $p_{\text{interaction}}=0.090$; posterior probability >95%, low certainty). Eye protection also was associated with less infection (n=3713; aOR 0.22, 95% CI 0.12 to 0.39, RD -10.6%, 95% CI -12.5 to -7.7; low certainty). Unadjusted studies and subgroup and sensitivity analyses showed similar findings.

Interpretation The findings of this systematic review and meta-analysis support physical distancing of 1 m or more and provide quantitative estimates for models and contact tracing to inform policy. Optimum use of face masks, respirators, and eye protection in public and health-care settings should be informed by these findings and contextual factors. Robust randomised trials are needed to better inform the evidence for these interventions, but this systematic appraisal of currently best available evidence might inform interim guidance.

Funding World Health Organization.

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Introduction

As of May 28, 2020, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has infected more than 5.85 million individuals worldwide and caused more than 359 000 deaths.¹ Emergency lockdowns have been initiated in countries across the globe, and the effect on health, wellbeing, business, and other aspects of daily life are felt

throughout societies and by individuals. With no effective pharmacological interventions or vaccine available in the imminent future, reducing the rate of infection (ie, flattening the curve) is a priority, and prevention of infection is the best approach to achieve this aim.

SARS-CoV-2 spreads person-to-person through close contact and causes COVID-19. It has not been solved if

Published Online
June 1, 2020
[https://doi.org/10.1016/S0140-6736\(20\)31142-9](https://doi.org/10.1016/S0140-6736(20)31142-9)

See Online/Comment
[https://doi.org/10.1016/S0140-6736\(20\)31183-1](https://doi.org/10.1016/S0140-6736(20)31183-1)

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See Online for appendix

Research in context

Evidence before this study

We searched 21 databases and resources from inception to May 3, 2020, with no restriction by language, for studies of any design evaluating physical distancing, face masks, and eye protection to prevent transmission of the viruses that cause COVID-19 and related diseases (eg, severe acute respiratory syndrome [SARS] and Middle East respiratory syndrome [MERS]) between infected individuals and people close to them (eg, household members, caregivers, and health-care workers). Previous related meta-analyses have focused on randomised trials and reported imprecise data for common respiratory viruses such as seasonal influenza, rather than the pandemic and epidemic betacoronaviruses causative of COVID-19 (severe acute respiratory syndrome coronavirus 2 [SARS-CoV-2]), SARS (SARS-CoV), or MERS (MERS-CoV). Other meta-analyses have focused on interventions in the health-care setting and have not included non-health-care (eg, community) settings. Our search did not retrieve any systematic review of information on physical distancing, face masks, or eye protection to prevent transmission of SARS-CoV-2, SARS-CoV, and MERS-CoV.

Added value of this study

We did a systematic review of 172 observational studies in health-care and non-health-care settings across 16 countries and six continents; 44 comparative studies were included in a meta-analysis, including 25 697 patients with COVID-19, SARS, or MERS. Our findings are, to the best of our knowledge, the first to rapidly synthesise all direct information on COVID-19 and, therefore, provide the best available evidence to inform optimum use of three common and simple interventions to help reduce the rate of infection and inform non-pharmaceutical interventions, including pandemic mitigation in non-health-care settings. Physical distancing of 1 m or more was associated with a much lower risk of infection, as was use of face masks (including N95 respirators or similar and surgical or similar masks [eg, 12–16-layer cotton or gauze masks]) and eye protection (eg, goggles or face shields). Added benefits are likely with even larger physical distances (eg, 2 m or more based on modelling) and might be present with N95 or similar respirators versus medical masks or similar. Across 24 studies in health-care and non-health-care settings of contextual factors to consider when formulating recommendations, most stakeholders found these

personal protection strategies acceptable, feasible, and reassuring but noted harms and contextual challenges, including frequent discomfort and facial skin breakdown, high resource use linked with the potential to decrease equity, increased difficulty communicating clearly, and perceived reduced empathy of care providers by those they were caring for.

Implications of all the available evidence

In view of inconsistent guidelines by various organisations based on limited information, our findings provide some clarification and have implications for multiple stakeholders. The risk for infection is highly dependent on distance to the individual infected and the type of face mask and eye protection worn. From a policy and public health perspective, current policies of at least 1 m physical distancing seem to be strongly associated with a large protective effect, and distances of 2 m could be more effective. These data could also facilitate harmonisation of the definition of exposed (eg, within 2 m), which has implications for contact tracing. The quantitative estimates provided here should inform disease-modelling studies, which are important for planning pandemic response efforts. Policy makers around the world should strive to promptly and adequately address equity implications for groups with currently limited access to face masks and eye protection. For health-care workers and administrators, our findings suggest that N95 respirators might be more strongly associated with protection from viral transmission than surgical masks. Both N95 and surgical masks have a stronger association with protection compared with single-layer masks. Eye protection might also add substantial protection. For the general public, evidence shows that physical distancing of more than 1 m is highly effective and that face masks are associated with protection, even in non-health-care settings, with either disposable surgical masks or reusable 12–16-layer cotton ones, although much of this evidence was on mask use within households and among contacts of cases. Eye protection is typically underconsidered and can be effective in community settings. However, no intervention, even when properly used, was associated with complete protection from infection. Other basic measures (eg, hand hygiene) are still needed in addition to physical distancing and use of face masks and eye protection.

SARS-CoV-2 might spread through aerosols from respiratory droplets; so far, air sampling has found virus RNA in some studies^{2–4} but not in others.^{5–8} However, finding RNA virus is not necessarily indicative of replication-competent and infection-competent (viable) virus that could be transmissible. The distance from a patient that the virus is infective, and the optimum person-to-person physical distance, is uncertain. For the currently foreseeable future (ie, until a safe and effective vaccine or treatment becomes available), COVID-19 prevention will continue to rely on non-pharmaceutical interventions, including pandemic mitigation in community settings.⁹

Thus, quantitative assessment of physical distancing is relevant to inform safe interaction and care of patients with SARS-CoV-2 in both health-care and non-health-care settings. The definition of close contact or potentially exposed helps to risk stratify, contact trace, and develop guidance documents, but these definitions differ around the globe.

To contain widespread infection and to reduce morbidity and mortality among health-care workers and others in contact with potentially infected people, jurisdictions have issued conflicting advice about physical or social distancing. Use of face masks with or

without eye protection to achieve additional protection is debated in the mainstream media and by public health authorities, in particular the use of face masks for the general population;¹⁰ moreover, optimum use of face masks in health-care settings, which have been used for decades for infection prevention, is facing challenges amid personal protective equipment (PPE) shortages.¹¹

Any recommendations about social or physical distancing, and the use of face masks, should be based on the best available evidence. Evidence has been reviewed for other respiratory viral infections, mainly seasonal influenza,^{12,13} but no comprehensive review is available of information on SARS-CoV-2 or related betacoronaviruses that have caused epidemics, such as severe acute respiratory syndrome (SARS) or Middle East respiratory syndrome (MERS). We, therefore, systematically reviewed the effect of physical distance, face masks, and eye protection on transmission of SARS-CoV-2, SARS-CoV, and MERS-CoV.

Methods

Search strategy and selection criteria

To inform WHO guidance documents, on March 25, 2020, we did a rapid systematic review.¹⁴ We created a large international collaborative and we used Cochrane methods¹⁵ and the GRADE approach.¹⁶ We prospectively submitted the systematic review protocol for registration on PROSPERO (CRD42020177047; appendix pp 23–29). We have followed PRISMA¹⁷ and MOOSE¹⁸ reporting guidelines (appendix pp 30–33).

From database inception to May 3, 2020, we searched for studies of any design and in any setting that included patients with WHO-defined confirmed or probable COVID-19, SARS, or MERS, and people in close contact with them, comparing distances between people and COVID-19 infected patients of 1 m or larger with smaller distances, with or without a face mask on the patient, or with or without a face mask, eye protection, or both on the exposed individual. The aim of our systematic review was for quantitative assessment to ascertain the physical distance associated with reduced risk of acquiring infection when caring for an individual infected with SARS-CoV-2, SARS-CoV, or MERS-CoV. Our definition of face masks included surgical masks and N95 respirators, among others; eye protection included visors, faceshields, and goggles, among others.

We searched (up to March 26, 2020) MEDLINE (using the Ovid platform), PubMed, Embase, CINAHL (using the Ovid platform), the Cochrane Library, COVID-19 Open Research Dataset Challenge, COVID-19 Research Database (WHO), Epistemonikos (for relevant systematic reviews addressing MERS and SARS, and its COVID-19 Living Overview of the Evidence platform), EPPI Centre living systematic map of the evidence, ClinicalTrials.gov, WHO International Clinical Trials Registry Platform, relevant documents on the websites of governmental and other relevant organisations, reference lists of included

papers, and relevant systematic reviews.^{19,20} We hand-searched (up to May 3, 2020) preprint servers (bioRxiv, medRxiv, and Social Science Research Network First Look) and coronavirus resource centres of *The Lancet*, *JAMA*, and *N Engl J Med* (appendix pp 3–5). We did not limit our search by language. We initially could not obtain three full texts for evaluation, but we obtained them through interlibrary loan or contacting a study author. We did not restrict our search to any quantitative cutoff for distance.

Data collection

We screened titles and abstracts, reviewed full texts, extracted data, and assessed risk of bias by two authors and independently, using standardised prepiloted forms (Covidence; Veritas Health Innovation, Melbourne, VIC, Australia), and we cross-checked screening results using artificial intelligence (Evidence Prime, Hamilton, ON, Canada). We resolved disagreements by consensus. We extracted data for study identifier, study design, setting, population characteristics, intervention and comparator characteristics, quantitative outcomes, source of funding

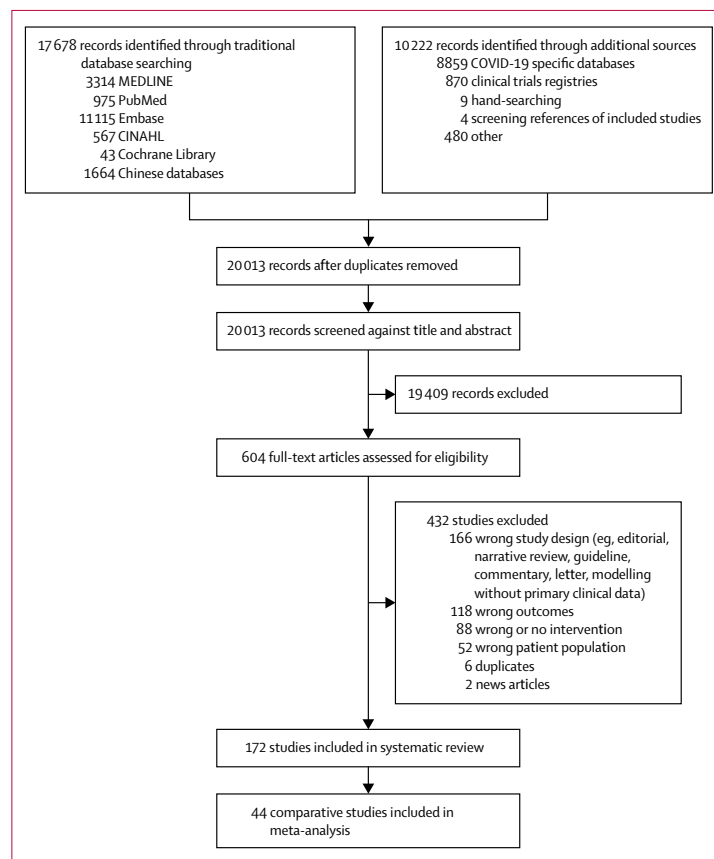


Figure 1: Study selection

	Population size (n)	Country	Setting	Disease caused by virus	Case definition (WHO)	Adjusted estimates	Risk of bias*
Alraddadi et al (2016) ³⁴	283	Saudi Arabia	Health care	MERS	Confirmed	Yes	*****
Arwady et al (2016) ³⁵	79	Saudi Arabia	Non-health care (household and family contacts)	MERS	Confirmed	No	*****
Bai et al (2020) ³⁶	118	China	Health care	COVID-19	Confirmed	No	****
Burke et al (2020) ³⁷	338	USA	Health care and non-health care (including household and community)	COVID-19	Confirmed	No	****
Caputo et al (2006) ³⁸	33	Canada	Health care	SARS	Confirmed	No	*****
Chen et al (2009) ³⁹	758	China	Health care	SARS	Confirmed	Yes	*****
Cheng et al (2020) ⁴⁰	226	China	Non-health care (household and family contacts)	COVID-19	Confirmed	No	*****
Ha et al (2004) ⁴²	117	Vietnam	Health care	SARS	Confirmed	No	**
Hall et al (2014) ⁴³	48	Saudi Arabia	Health care	MERS	Confirmed	No	***
Heinzerling et al (2020) ⁴⁴	37	USA	Health care	COVID-19	Confirmed	No	****
Ho et al (2004) ⁴⁵	372	Taiwan	Health care	SARS	Confirmed	No	*****
Ki et al (2019) ⁴⁷	446	South Korea	Health care	MERS	Confirmed	No	*****
Kim et al (2016) ⁴⁸	9	South Korea	Health care	MERS	Confirmed	No	*****
Kim et al (2016) ⁴⁹	1169	South Korea	Health care	MERS	Confirmed	No	*****
Lau et al (2004) ⁵⁰	2270	China	Non-health care (households)	SARS	Probable	Yes	*****
Liu et al (2009) ⁵¹	477	China	Health care	SARS	Confirmed	Yes	****
Liu et al (2020) ⁵²	20	China	Non-health care (close contacts)	COVID-19	Confirmed	No	*****
Loeb et al (2004) ⁵³	43	Canada	Health care	SARS	Confirmed	No	**
Ma et al (2004) ⁵⁴	426	China	Health care	SARS	Confirmed	Yes	*****
Nishiura et al (2005) ⁵⁵	115	Vietnam	Health care	SARS	Confirmed	Yes	*****
Nishiyama et al (2008) ⁵⁶	146	Vietnam	Health care	SARS	Confirmed	Yes	*****
Olsen et al (2003) ⁵⁷	304	China	Non-health care (airplane)	SARS	Confirmed	No	*****
Park et al (2004) ⁵⁸	110	USA	Health care	SARS	Confirmed	No	*****
Park et al (2016) ⁵⁹	80	South Korea	Health care	MERS	Confirmed and probable	No	***
Peck et al (2004) ⁶⁰	26	USA	Health care	SARS	Confirmed	No	*****
Pei et al (2006) ⁶¹	443	China	Health care	SARS	Confirmed	No	*****
Rea et al (2007) ⁶²	8662	Canada	Non-health care (community contacts)	SARS	Probable	No	****
Reuss et al (2014) ⁶³	81	Germany	Health care	MERS	Confirmed	No	****
Reynolds et al (2006) ⁶⁴	153	Vietnam	Health care	SARS	Confirmed	No	**
Ryu et al (2019) ⁶⁵	34	South Korea	Health care	MERS	Confirmed	No	*****
Scales et al (2003) ⁶⁶	69	Canada	Health care	SARS	Probable	No	**
Seto et al (2003) ⁶⁷	254	China	Health care	SARS	Confirmed	Yes	*****
Teleman et al (2004) ⁶⁸	86	Singapore	Health care	SARS	Confirmed	Yes	*****
Tuan et al (2007) ⁶⁹	212	Vietnam	Non-health care (household and community contacts)	SARS	Confirmed	Yes	*****
Van Kerkhove et al (2019) ⁷⁰	828	Saudi Arabia	Non-health care (dormitory)	MERS	Confirmed	Yes	*****
Wang et al (2020) ⁴¹	493	China	Health care	COVID-19	Confirmed	Yes	****

(Table 1 continues on next page)

	n	Country	Setting	Disease caused by virus	Case definition (WHO)	Adjusted estimates	Risk of bias*
(Continued from previous page)							
Wang et al (2020) ²⁰	5442	China	Health care	COVID-19	Confirmed	No	*****
Wiboonchutikul et al (2016) ²¹	38	Thailand	Health care	MERS	Confirmed	No	*****
Wilder-Smith et al (2005) ²²	80	Singapore	Health care	SARS	Confirmed	No	*****
Wong et al (2004) ²³	66	China	Health care	SARS	Confirmed	No	*****
Wu et al (2004) ²⁴	375	China	Non-health care (community)	SARS	Confirmed	Yes	*****
Yin et al (2004) ²⁵	257	China	Health care	SARS	Confirmed	Yes	*****
Yu et al (2005) ²⁶	74	China	Health care	SARS	Confirmed	No	*****
Yu et al (2007) ²⁷	124 wards	China	Health care	SARS	Confirmed	Yes	*****

Across studies, mean age was 30–60 years. SARS=severe acute respiratory syndrome. MERS=Middle East respiratory syndrome. *The Newcastle-Ottawa Scale was used for the risk of bias assessment, with more stars equalling lower risk.

Table 1: Characteristics of included comparative studies

and reported conflicts of interests, ethics approval, study limitations, and other important comments.

Outcomes

Outcomes of interest were risk of transmission (ie, WHO-defined confirmed or probable COVID-19, SARS, or MERS) to people in health-care or non-health-care settings by those infected; hospitalisation; intensive care unit admission; death; time to recovery; adverse effects of interventions; and contextual factors such as acceptability, feasibility, effect on equity, and resource considerations related to the interventions of interest. However, data were only available to analyse intervention effects for transmission and contextual factors. Consistent with WHO, studies generally defined confirmed cases with laboratory confirmation (with or without symptoms) and probable cases with clinical evidence of the respective infection (ie, suspected to be infected) but for whom confirmatory testing either had not yet been done for any reason or was inconclusive.

Data analysis

Our search did not identify any randomised trials of COVID-19, SARS, or MERS. We did a meta-analysis of associations by pooling risk ratios (RRs) or adjusted odds ratios (aORs) depending on availability of these data from observational studies, using DerSimonian and Laird random-effects models. We adjusted for variables including age, sex, and severity of source case; these variables were not the same across studies. Because between-study heterogeneity can be misleadingly large when quantified by I^2 during meta-analysis of observational studies,^{21,22} we used GRADE guidance to assess between-study heterogeneity.²¹ Throughout, we present RRs as unadjusted estimates and aORs as adjusted estimates.

We used the Newcastle-Ottawa scale to rate risk of bias for comparative non-randomised studies corresponding

to every study's design (cohort or case-control).^{23,24} We planned to use the Cochrane Risk of Bias tool 2.0 for randomised trials,²⁵ but our search did not identify any eligible randomised trials. We synthesised data in both narrative and tabular formats. We graded the certainty of evidence using the GRADE approach. We used the GRADEpro app to rate evidence and present it in GRADE evidence profiles and summary of findings tables^{26,27} using standardised terms.^{28,29}

We analysed data for subgroup effects by virus type, intervention (different distances or face mask types), and setting (health care vs non-health care). Among the studies assessing physical distancing measures to prevent viral transmission, the intervention varied (eg, direct physical contact [0 m], 1 m, or 2 m). We, therefore, analysed the effect of distance on the size of the associations by random-effects univariate meta-regressions, using restricted maximum likelihood, and we present mean effects and 95% CIs. We calculated tests for interaction using a minimum of 10000 Monte Carlo random permutations to avoid spurious findings.³⁰ We formally assessed the credibility of potential effect-modifiers using GRADE guidance.²¹ We did two sensitivity analyses to test the robustness of our findings. First, we used Bayesian meta-analyses to reinterpret the included studies considering priors derived from the effect point estimate and variance from a meta-analysis of ten randomised trials evaluating face mask use versus no face mask use to prevent influenza-like illness in health-care workers.³¹ Second, we used Bayesian meta-analyses to reinterpret the efficacy of N95 respirators versus medical masks on preventing influenza-like illness after seasonal viral (mostly influenza) infection.¹³ For these sensitivity analyses, we used hybrid Metropolis-Hastings and Gibbs sampling, a 10000 sample burn-in, 40000 Markov chain Monte Carlo samples, and we tested non-informative and sceptical priors (eg, four time variance)^{32,33} to inform

For more on the GRADEpro app see <https://www.gradepr.org>

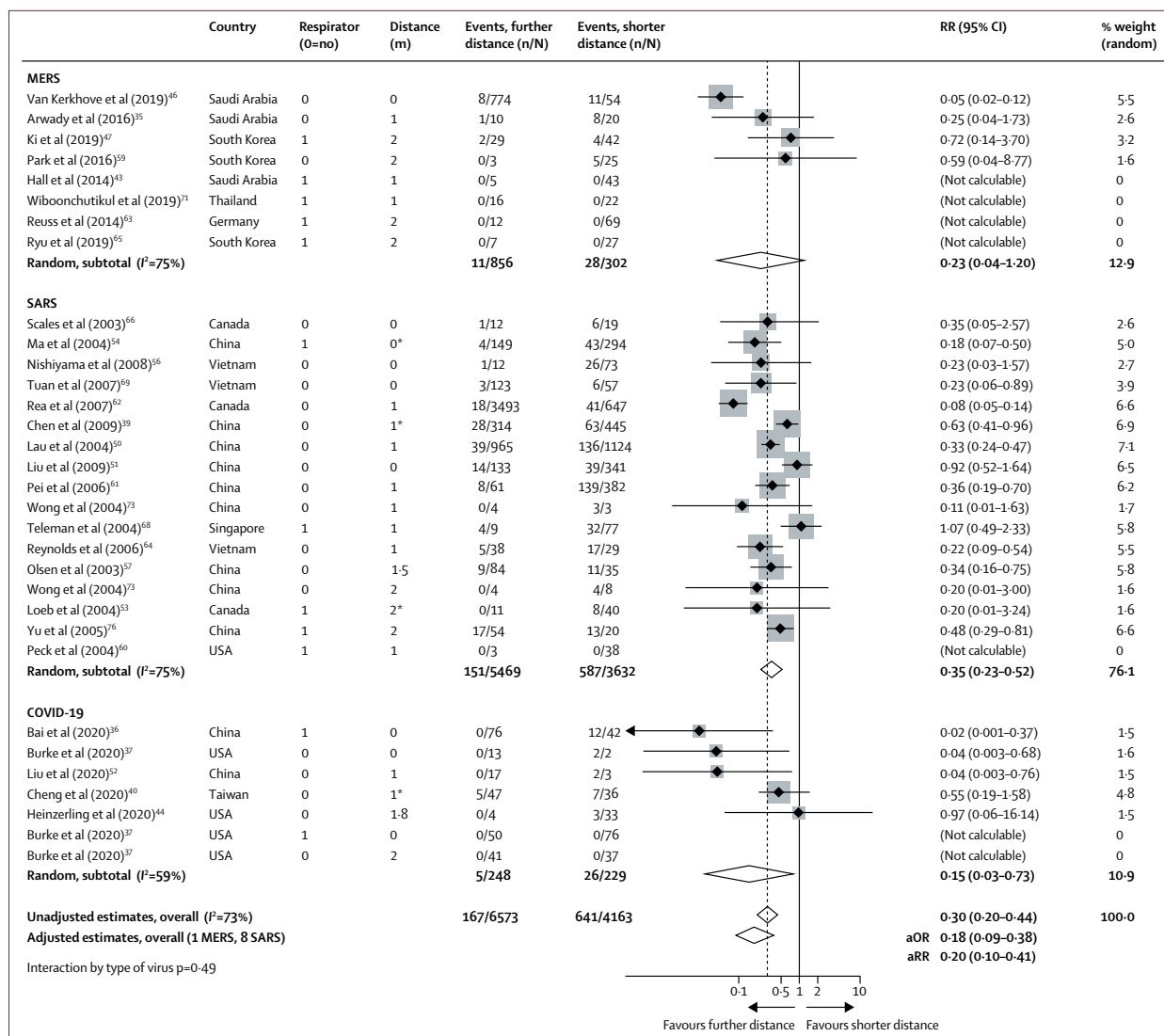


Figure 2: Forest plot showing the association of COVID-19, SARS, or MERS exposure proximity with infection
 SARS=severe acute respiratory syndrome. MERS=Middle East respiratory syndrome. RR=relative risk. aOR=adjusted odds ratio. aRR=adjusted relative risk. *Estimated values; sensitivity analyses excluding these values did not meaningfully alter findings.

mean estimates of effect, 95% credibility intervals (CrIs), and posterior distributions. We used non-informative hyperpriors to estimate statistical heterogeneity. Model convergence was confirmed in all cases with good mixing in visual inspection of trace plots, autocorrelation plots, histograms, and kernel density estimates in all scenarios. Parameters were blocked, leading to acceptance of approximately 50% and efficiency greater than 1% in all cases (typically about 40%). We did analyses using Stata version 14.3.

Role of the funding source

The funder contributed to defining the scope of the review but otherwise had no role in study design and data collection. Data were interpreted and the report drafted and submitted without funder input, but according to contractual agreement, the funder provided review at the time of final publication. The corresponding author had full access to all data in the study and had final responsibility for the decision to submit for publication.

	Studies and participants	Relative effect (95% CI)	Anticipated absolute effect (95% CI), eg, chance of viral infection or transmission		Difference (95% CI)	Certainty*	What happens (standardised GRADE terminology) ³⁹
			Comparison group	Intervention group			
Physical distance ≥1 m vs <1 m	Nine adjusted studies (n=7782); 29 unadjusted studies (n=10 736)	aOR 0.18 (0.09 to 0.38); unadjusted RR 0.30 (95% CI 0.20 to 0.44)	Shorter distance, 12.8%	Further distance, 2.6% (1.3 to 5.3)	-10.2% (-11.5 to -7.5)	Moderate†	A physical distance of more than 1 m probably results in a large reduction in virus infection; for every 1 m further away in distancing, the relative effect might increase 2.02 times
Face mask vs no face mask	Ten adjusted studies (n=2647); 29 unadjusted studies (n=10 170)	aOR 0.15 (0.07 to 0.34); unadjusted RR 0.34 (95% CI 0.26 to 0.45)	No face mask, 17.4%	Face mask, 3.1% (1.5 to 6.7)	-14.3% (-15.9 to -10.7)	Low‡	Medical or surgical face masks might result in a large reduction in virus infection; N95 respirators might be associated with a larger reduction in risk compared with surgical or similar masks§
Eye protection (faceshield, goggles) vs no eye protection	13 unadjusted studies (n=3713)	Unadjusted RR 0.34 (0.22 to 0.52)¶	No eye protection, 16.0%	Eye protection, 5.5% (3.6 to 8.5)	-10.6% (-12.5 to -7.7)	Low	Eye protection might result in a large reduction in virus infection

Table based on GRADE approach.²⁶⁻²⁹ Population comprised people possibly exposed to individuals infected with SARS-CoV-2, SARS-CoV, or MERS-CoV. Setting was any health-care or non-health-care setting. Outcomes were infection (laboratory-confirmed or probable) and contextual factors. Risk (95% CI) in intervention group is based on assumed risk in comparison group and relative effect (95% CI) of the intervention. All studies were non-randomised and evaluated using the Newcastle-Ottawa Scale; some studies had a higher risk of bias than did others but no important difference was noted in sensitivity analyses excluding studies at higher risk of bias; we did not further rate down for risk of bias. Although there was a high *I* value (which can be exaggerated in non-randomised studies)³¹ and no overlapping CIs, point estimates generally exceeded the thresholds for large effects and we did not rate down for inconsistency. We did not rate down for indirectness for the association between distance and infection because SARS-CoV-2, SARS-CoV, and MERS-CoV all belong to the same family and have each caused epidemics with sufficient similarity; there was also no convincing statistical evidence of effect-modification across viruses; some studies also used bundled interventions but the studies include only those that provide adjusted estimates. aOR=adjusted odds ratio. RR=relative risk. SARS-CoV-2=severe acute respiratory syndrome coronavirus 2. SARS-CoV=severe acute respiratory syndrome coronavirus. MERS-CoV=Middle East respiratory syndrome coronavirus. *GRADE category of evidence; high certainty (we are very confident that the true effect lies close to that of the estimate of the effect); moderate certainty (we are moderately confident in the effect estimate; the true effect is probably close to the estimate, but it is possibly substantially different); low certainty (our confidence in the effect estimate is limited; the true effect could be substantially different from the estimate of the effect); very low certainty (we have very little confidence in the effect estimate; the true effect is likely to be substantially different from the estimate of effect). †The effect is very large considering the thresholds set by GRADE, particularly at plausible levels of baseline risk, which also mitigated concerns about risk of bias; data also suggest a dose-response gradient, with associations increasing from smaller distances to 2 m and beyond, by meta-regression; we did not rate up for this domain alone but it further supports the decision to rate up in combination with the large effects. ‡The effect was very large, and the certainty of evidence could be rated up, but we made a conservative decision not to because of some inconsistency and risk of bias; hence, although the effect is qualitatively highly certain, the precise quantitative effect is low certainty. §In a subgroup analysis comparing N95 respirators with surgical or similar masks (eg, 12-16-layer cotton), the association was more pronounced in the N95 group (aOR 0.04, 95% CI 0.004-0.30) compared with other masks (0.33, 0.17-0.61; *p*_{interaction}=0.090); there was also support for effect-modification by formal analysis of subgroup credibility. ¶Two studies^{34,75} provided adjusted estimates with n=295 in the eye protection group and n=406 in the group not wearing eye protection; results were similar to the unadjusted estimate (aOR 0.22, 95% CI 0.12-0.39). ||The effect is large considering the thresholds set by GRADE assuming that ORs translate into similar magnitudes of RR estimates; this mitigates concerns about risk of bias, but we conservatively decided not to rate up for large or very large effects.

Table 2: GRADE summary of findings

Results

We identified 172 studies for our systematic review from 16 countries across six continents (figure 1; appendix pp 6-14, 41-47). Studies were all observational in nature; no randomised trials were identified of any interventions that directly addressed the included study populations. Of the 172 studies, 66 focused on how far a virus can travel by comparing the association of different distances on virus transmission to people (appendix pp 42-44). Of these 66 studies, five were mechanistic, assessing viral RNA, virions, or both cultured from the environment of an infected patient (appendix p 45).

44 studies were comparative³⁴⁻⁷⁷ and fulfilled criteria for our meta-analysis (n=25 697; figure 1; table 1). We used these studies rather than case series and qualitative studies (appendix pp 41-47) to inform estimates of effect. 30 studies^{34,37,41-45,47-51,53-56,58-61,64-70,72,74,75} focused on the association between use of various types of face masks and respirators by health-care workers, patients, or both with virus transmission. 13 studies^{34,37-39,47,49,51,54,58,60,61,65,75} addressed the association of eye protection with virus transmission.

Some direct evidence was available for COVID-19 (64 studies, of which seven were comparative in

design),^{36,37,40,41,44,52,70} but most studies reported on SARS (n=55) or MERS (n=25; appendix pp 6-12). Of the 44 comparative studies, 40 included WHO-defined confirmed cases, one included both confirmed and probable cases, and the remaining three studies included probable cases. There was no effect-modification by case-definition (distance *p*_{interaction}=0.41; mask *p*_{interaction}=0.46; all cases for eye protection were confirmed). Most studies reported on bundled interventions, including different components of PPE and distancing, which was usually addressed by statistical adjustment. The included studies all occurred during recurrent or novel outbreak settings of COVID-19, SARS, or MERS.

Risk of bias was generally low-to-moderate after considering the observational designs (table 1), but both within studies and across studies the overall findings were similar between adjusted and unadjusted estimates. We did not detect strong evidence of publication bias in the body of evidence for any intervention (appendix pp 15-18). As we did not use case series data to inform estimates of effect of each intervention, we did not systematically rate risk of bias of these data. Therefore, we report further only those studies with comparative data.

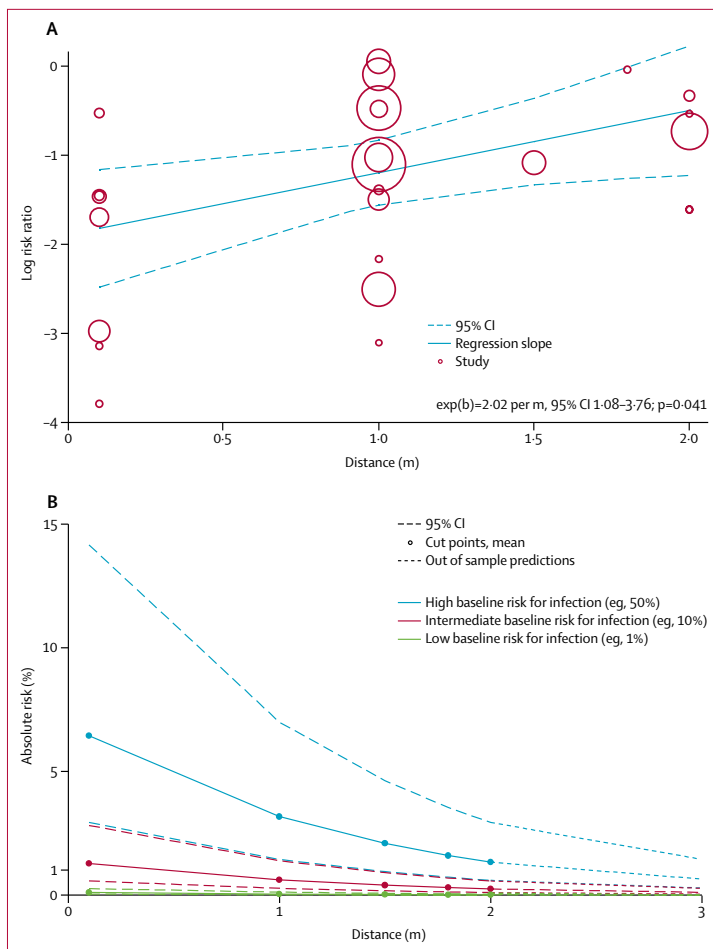


Figure 3: Change in relative risk with increasing distance and absolute risk with increasing distance
Meta-regression of change in relative risk with increasing distance from an infected individual (A). Absolute risk of transmission from an individual infected with SARS-CoV-2, SARS-CoV, or MERS-CoV with varying baseline risk and increasing distance (B). SARS-CoV-2=severe acute respiratory syndrome coronavirus 2. SARS-CoV=severe acute respiratory syndrome coronavirus. MERS-CoV=Middle East respiratory syndrome coronavirus.

Across 29 unadjusted and nine adjusted studies,^{35–37,39,40,43,44,46,47,50–54,56,57,59–66,68,69,71,73,76} a strong association was found of proximity of the exposed individual with the risk of infection (unadjusted $n=10736$, RR 0.30, 95% CI 0.20 to 0.44; adjusted $n=7782$, aOR 0.18, 95% CI 0.09 to 0.38; absolute risk [AR] 12.8% with shorter distance vs 2.6% with further distance, risk difference [RD] -10.2% , 95% CI -11.5 to -7.5 ; moderate certainty; figure 2; table 2; appendix p 16). Although there were six studies on COVID-19, the association was seen irrespective of causative virus ($p_{\text{interaction}}=0.49$), health-care setting versus non-health-care setting ($p_{\text{interaction}}=0.14$), and by type of face mask ($p_{\text{interaction}}=0.95$; appendix pp 17, 19). However, different studies used different distances for the intervention. By meta-regression, the strength of

association was larger with increasing distance (2.02 change in RR per m, 95% CI 1.08 to 3.76; $p_{\text{interaction}}=0.041$; moderate credibility subgroup effect; figure 3A; table 2). AR values with increasing distance given different degrees of baseline risk are shown in figure 3B, with potential values at 3 m also shown.

Across 29 unadjusted studies and ten adjusted studies,^{34,37,41–45,47–51,53–56,58–61,64–70,72,74,75} the use of both N95 or similar respirators or face masks (eg, disposable surgical masks or similar reusable 12–16-layer cotton masks) by those exposed to infected individuals was associated with a large reduction in risk of infection (unadjusted $n=10170$, RR 0.34, 95% CI 0.26 to 0.45; adjusted studies $n=2647$, aOR 0.15, 95% CI 0.07 to 0.34; AR 3.1% with face mask vs 17.4% with no face mask, RD -14.3% , 95% CI -15.9 to -10.7 ; low certainty; figure 4; table 2; appendix pp 16, 18) with stronger associations in health-care settings (RR 0.30, 95% CI 0.22 to 0.41) compared with non-health-care settings (RR 0.56, 95% CI 0.40 to 0.79; $p_{\text{interaction}}=0.049$; low-to-moderate credibility for subgroup effect; figure 4; appendix p 19). When differential N95 or similar respirator use, which was more frequent in health-care settings than in non-health-care settings, was adjusted for the possibility that face masks were less effective in non-health-care settings, the subgroup effect was slightly less credible ($p_{\text{interaction}}=0.11$, adjusted for differential respirator use; figure 4). Indeed, the association with protection from infection was more pronounced with N95 or similar respirators (aOR 0.04, 95% CI 0.004 to 0.30) compared with other masks (aOR 0.33, 95% CI 0.17 to 0.61; $p_{\text{interaction}}=0.090$; moderate credibility subgroup effect; figure 5). The interaction was also seen when additionally adjusting for three studies that clearly reported aerosol-generating procedures ($p_{\text{interaction}}=0.048$; figure 5). Supportive evidence for this interaction was also seen in within-study comparisons (eg, N95 had a stronger protective association compared with surgical masks or 12–16-layer cotton masks); both N95 and surgical masks also had a stronger association with protection versus single-layer masks.^{38,39,51,53,54,61,66,67,75}

We did a sensitivity analysis to test the robustness of our findings and to integrate all available information on face mask treatment effects for protection from COVID-19. We reconsidered our findings using random-effects Bayesian meta-analysis. Although non-informative priors showed similar results to frequentist approaches (aOR 0.16, 95% CrI 0.04–0.40), even using informative priors from the most recent meta-analysis on the effectiveness of masks versus no masks to prevent influenza-like illness (RR 0.93, 95% CI 0.83–1.05)³¹ yielded a significant association with protection from COVID-19 (aOR 0.40, 95% CrI 0.16–0.97; posterior probability for RR <1 , 98%). Minimally informing (25% influence with or without four-fold smaller mean effect size) the most recent and rigorous meta-analysis of the effectiveness of N95

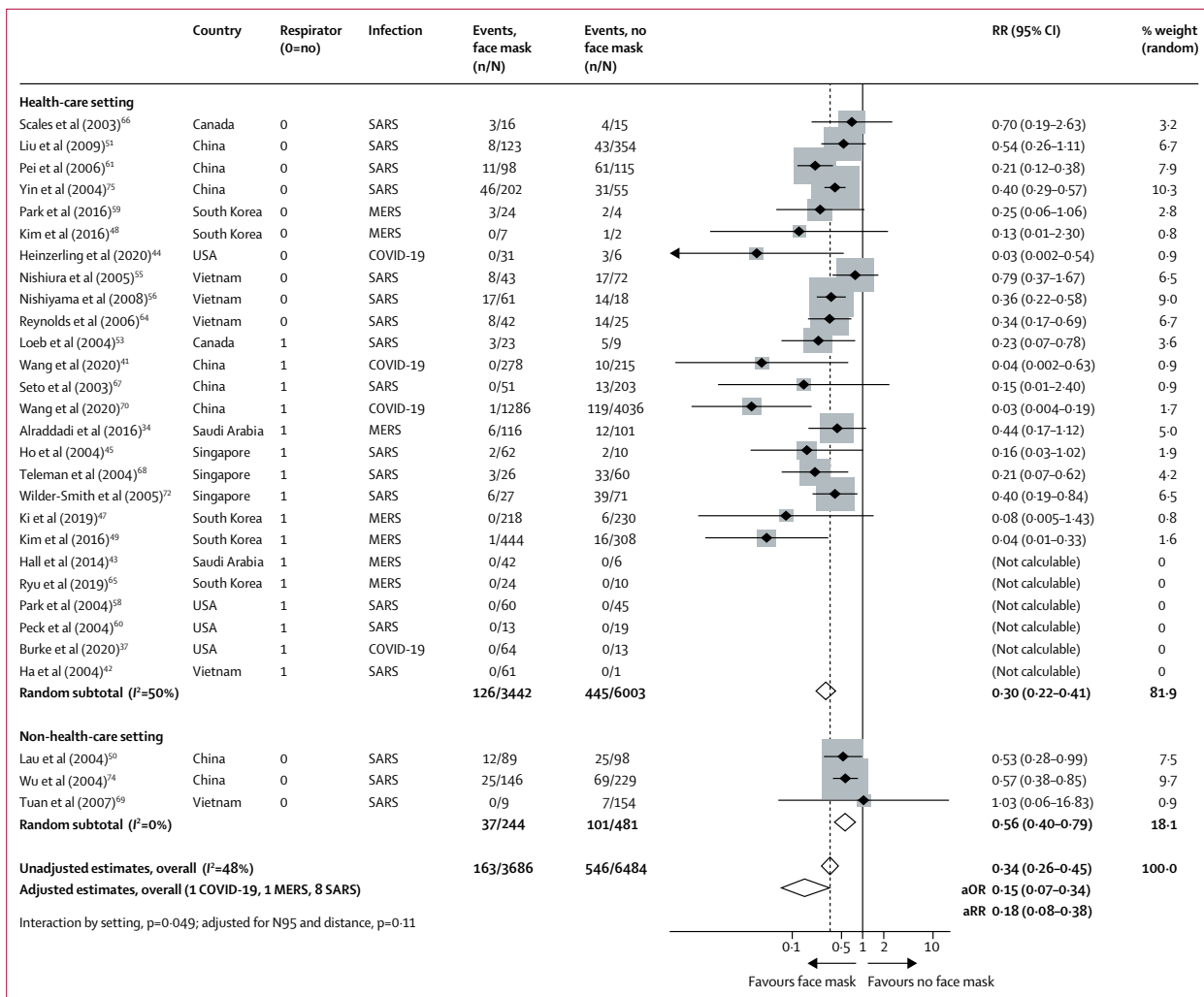


Figure 4: Forest plot showing unadjusted estimates for the association of face mask use with viral infection causing COVID-19, SARS, or MERS. SARS=severe acute respiratory syndrome. MERS=Middle East respiratory syndrome. RR=relative risk. aOR=adjusted odds ratio. aRR=adjusted relative risk.

respirators versus medical masks in randomised trials (OR 0.76, 95% CI 0.54–1.06)¹³ with the effect-modification seen in this meta-analysis on COVID-19 (ratio of aORs 0.14, 95% CI 0.02–1.05) continued to support a stronger association of protection from COVID-19, SARS, or MERS with N95 or similar respirators versus other face masks (posterior probability for RR <1, 100% and 95%, respectively).

In 13 unadjusted studies and two adjusted studies,^{34,37-39,47,49,51,54,58,60,61,65,75} eye protection was associated with lower risk of infection (unadjusted n=3713, RR 0.34, 95% CI 0.22 to 0.52; AR 5.5% with eye protection vs 16.0% with no eye protection, RD -10.6%, 95% CI -12.5 to -7.7; adjusted n=701, aOR 0.22,

95% CI 0.12 to 0.39; low certainty; figure 6; table 2; appendix pp 16–17).

Across 24 studies in health-care and non-health-care settings during the current pandemic of COVID-19, previous epidemics of SARS and MERS, or in general use, looking at contextual factors to consider in recommendations, most stakeholders found physical distancing and use of face masks and eye protection acceptable, feasible, and reassuring (appendix pp 20–22). However, challenges included frequent discomfort, high resource use linked with potentially decreased equity, less clear communication, and perceived reduced empathy of care providers by those they were caring for.

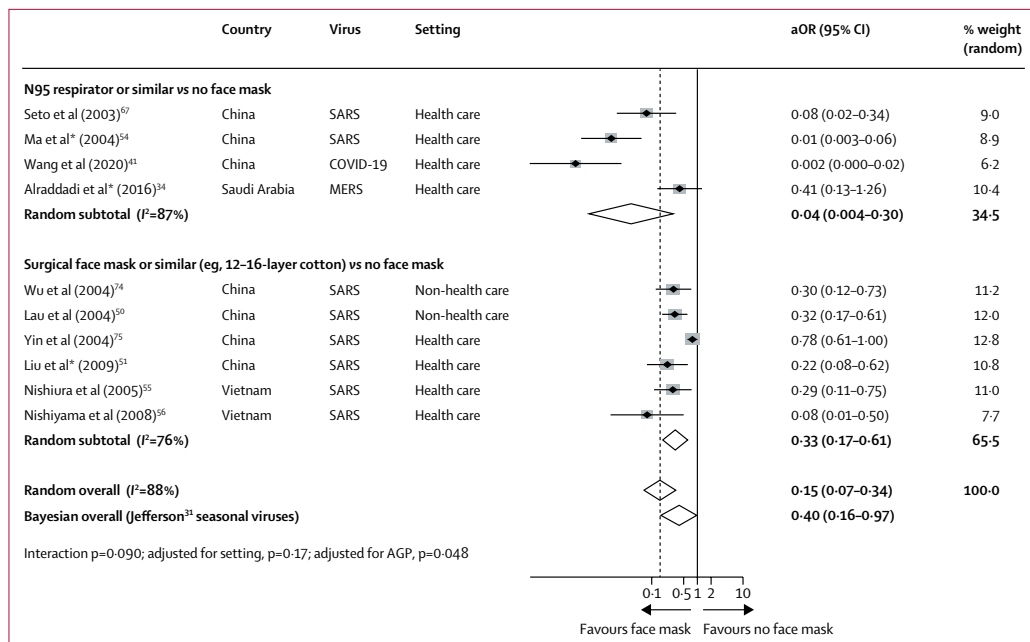


Figure 5: Forest plot showing adjusted estimates for the association of face mask use with viral infection causing COVID-19, SARS, or MERS. SARS=severe acute respiratory syndrome. MERS=Middle East respiratory syndrome. RR=relative risk. aOR=adjusted odds ratio. AGP=aerosol-generating procedures. *Studies clearly reporting AGP.

Discussion

The findings of this systematic review of 172 studies (44 comparative studies; n=25 697 patients) on COVID-19, SARS, and MERS provide the best available evidence that current policies of at least 1 m physical distancing are associated with a large reduction in infection, and distances of 2 m might be more effective. These data also suggest that wearing face masks protects people (both health-care workers and the general public) against infection by these coronaviruses, and that eye protection could confer additional benefit. However, none of these interventions afforded complete protection from infection, and their optimum role might need risk assessment and several contextual considerations. No randomised trials were identified for these interventions in COVID-19, SARS, or MERS.

Previous reviews are limited in that they either have not provided any evidence from COVID-19 or did not use direct evidence from other related emerging epidemic betacoronaviruses (eg, SARS and MERS) to inform the effects of interventions to curtail the current COVID-19 pandemic.^{13,19,31,78} Previous data from randomised trials are mainly for common respiratory viruses such as seasonal influenza, with a systematic review concluding low certainty of evidence for extrapolating these findings to COVID-19.¹³ Further, previous syntheses of available randomised controlled trials have not accounted for cluster effects in analyses, leading to substantial

imprecision in treatment effect estimates. In between-study and within-study comparisons, we noted a larger effect of N95 or similar respirators compared with other masks. This finding is inconsistent with conclusions of a review of four randomised trials,¹³ in which low certainty of evidence for no larger effect was suggested. However, in that review, the CIs were wide so a meaningful protective effect could not be excluded. We harmonised these findings with Bayesian approaches, using indirect data from randomised trials to inform posterior estimates. Despite this step, our findings continued to support the ideas not only that masks in general are associated with a large reduction in risk of infection from SARS-CoV-2, SARS-CoV, and MERS-CoV but also that N95 or similar respirators might be associated with a larger degree of protection from viral infection than disposable medical masks or reusable multilayer (12-16-layer) cotton masks. Nevertheless, in view of the limitations of these data, we did not rate the certainty of effect as high.²¹ Our findings accord with those of a cluster randomised trial showing a potential benefit of continuous N95 respirator use over medical masks against seasonal viral infections.⁷⁹ Further high-quality research, including randomised trials of the optimum physical distance and the effectiveness of different types of masks in the general population and for health-care workers' protection, is urgently needed. Two trials are registered to better inform the optimum use of face masks for COVID-19 (NCT04296643 [n=576] and

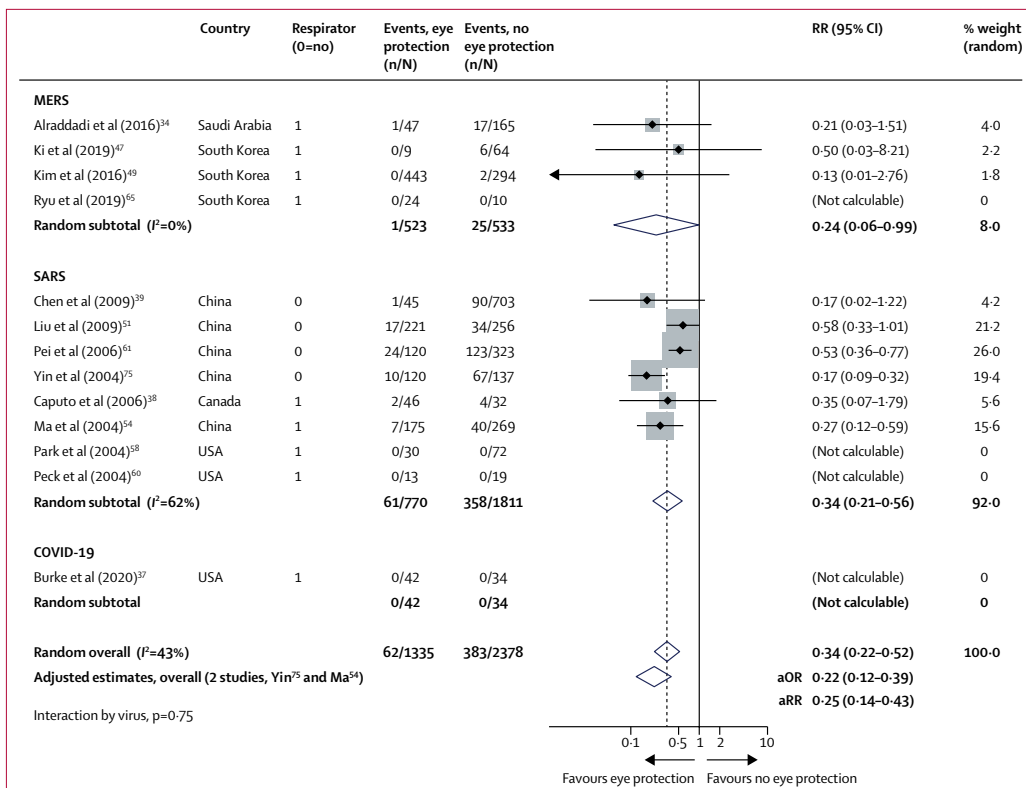


Figure 6: Forest plot showing the association of eye protection with risk of COVID-19, SARS, or MERS transmission
 Forest plot shows unadjusted estimates. SARS=severe acute respiratory syndrome. MERS=Middle East respiratory syndrome. RR=relative risk. aOR=adjusted odds ratio. aRR=adjusted relative risk.

NCT04337541 [n=6000]). Until such data are available, our findings represent the current best estimates to inform face mask use to reduce infection from COVID-19. We recognise that there are strong, perhaps opposing, sentiments about policy making during outbreaks. In one viewpoint, the 2007 SARS Commission report stated:

“...recognize, as an aspect of health worker safety, the precautionary principle that reasonable action to reduce risk, such as the use of a fitted N95 respirator, need not await scientific certainty”.⁸⁰

“...if we do not learn from SARS and we do not make the government fix the problems that remain, we will pay a terrible price in the next pandemic”.⁸¹

A counter viewpoint is that the scientific uncertainty and contextual considerations require a more nuanced approach. Although challenging, policy makers must carefully consider these two viewpoints along with our findings.

We found evidence of moderate certainty that current policies of at least 1 m physical distancing are probably

associated with a large reduction in infection, and that distances of 2 m might be more effective, as implemented in some countries. We also provide estimates for 3 m. The main benefit of physical distancing measures is to prevent onward transmission and, thereby, reduce the adverse outcomes of SARS-CoV-2 infection. Hence, the results of our current review support the implementation of a policy of physical distancing of at least 1 m and, if feasible, 2 m or more. Our findings also provide robust estimates to inform models and contact tracing used to plan and strategise for pandemic response efforts at multiple levels.

The use of face masks was protective for both health-care workers and people in the community exposed to infection, with both the frequentist and Bayesian analyses lending support to face mask use irrespective of setting. Our unadjusted analyses might, at first impression, suggest use of face masks in the community setting to be less effective than in the health-care setting, but after accounting for differential N95 respirator use between health-care and non-health-care settings, we did not detect any striking differences in effectiveness of

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Declaration of interests

ML is an investigator of an ongoing clinical trial on medical masks versus N95 respirators for COVID-19 (NCT04296643). All other authors declare no competing interests.

Acknowledgments

This systematic review was commissioned and in part paid for by WHO. The authors alone are responsible for the views expressed in this article and they do not necessarily represent the decisions, policy, or views of WHO. We thank Susan L Norris, April Baller, and Benedetta Allegranzi (WHO) for input in the protocol or the final article; Xuan Yu (Evidence Based Medicine Center of Lanzhou University, China), Eliza Poon, and Yuqing (Madison) Zhang for assistance with Chinese literature support; Neera Bhatnagar and Aida Farha (information specialists) for peer-reviewing the search strategy; Artur Nowak (Evidence Prime, Hamilton, ON, Canada) for help with searching and screening using artificial intelligence; and Christine Keng for additional support. DKC is a CAAIF-CSACI-AllerGen Emerging Clinician-Scientist Research Fellow, supported by the Canadian Allergy, Asthma and Immunology Foundation (CAAIF), the Canadian Society of Allergy and Clinical Immunology (CSACI), and AllerGen NCE (the Allergy, Genes and Environment Network).

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Clinical Validation

The Wall Street Journal: What We Know About Face Shields and Coronavirus

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What We Know About Face Shields and Coronavirus

Here's how shields offer protection from Covid-19 and how that differs from what face masks offer



Caroline Osman wears a protective face shield as customers arrive on the first day of business since the coronavirus lockdown at W.J. French and Son, a shoe store in Southampton, England on June 15.

PHOTO: ADRIAN DENNIS/AGENCE FRANCE-PRESSE/GETTY IMAGES

By Alina Dizik

June 16, 2020 11:38 am ET

With face shields a growing part of hospital protocol, some infectious disease doctors are calling for greater adoption outside the medical setting. Unlike masks that protect the nose and mouth, face shields may also keep the virus from entering through the eyes. We asked experts for advice:

How do face shields offer protection from coronavirus?

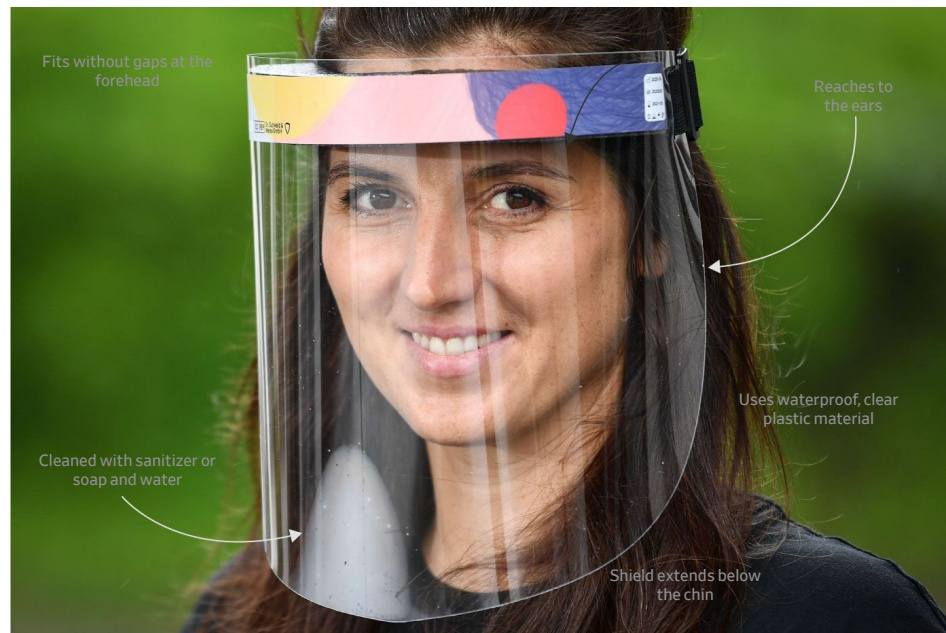
The new coronavirus spreads mostly through droplets expelled from an infected person coughing, sneezing or talking. Face shields cover the eyes, mouth and nose—the areas of

potential infection. “If someone coughs and it catches your eyes, you are going to get the infection,” says Daniel McQuillen, vice president of the Infectious Diseases Society of America and an infectious disease physician at Beth Israel Lahey Health in Boston.

Face shields block droplets, which are larger particles that drop to the floor due to gravity, but not aerosols, smaller particles that may linger in the air when exhaled during a dental procedure or intubation. “The general way that this virus spread is by droplets, despite the scary pictures you see of aerosols and things hanging in the air,” Dr. McQuillen says.

Covering Your Bases

A well-fitting face shield can be a good option for additional coverage.



Sources: Dr. Michael Edmond; Dr. Daniel McQuillen
Photo: Philipp Guelland/Shutterstock

What are the benefits of wearing a face shield?

The shield covers more of the face than a mask, so infected droplets are less likely to land anywhere near your eyes, mouth or nose.

A meta-analysis that looked at nearly 26,000 patients affected by Covid-19 and similar conditions that was published in the Lancet this month found “eye protection might result in a **large reduction in virus infection**” and provides additional benefit to mask wearers. In health-care settings, eye protection reduced risk compared with no eye protection in 13 studies, but more evidence is needed, says co-author Derek Chu of McMaster University in Hamilton, Ontario.

And in countries including China and South Korea “PPE is starting to shift from masks to shields,” says Luis Ostrosky, professor of infectious diseases at UTHealth’s McGovern Medical School in Houston.

What scientists don’t yet know is what portion of infections start in the eyes, or whether face shields are superior to face masks.

Shields can be easier to wear for prolonged periods, especially for those with breathing problems. You may also be less likely to touch your face while wearing a shield or fidget with the shield itself, says Michael Edmond, chief quality officer at the University of Iowa

Hospitals & Clinics. “Universal face shielding would help stop the outbreak and let people have less restrictions on what they do,” says Dr. Edmond, an infectious disease doctor who co-wrote an opinion piece on the [community use of face shields](#) in JAMA this April.

Should you still wear a mask under the face shield?

There’s no consensus. Infectious disease experts calling for greater adoption still disagree on whether wearing a face shield alone offers enough protection for yourself or others.

Dr. Edmond says a face shield on its own is enough to wear in most community settings, especially if keeping a social distance. “For general life, I just wear a shield,” he says. He also believes face shields alone are just as effective in preventing an infected person from infecting others.

Other experts, including Saad Omer, director of the Yale Institute for Global Health, say that face shields should be used in conjunction with masks until more research is available. “There is no harm in taking extra precautions, especially in a closed setting,” he says.

Not all doctors think shields can stop people from receiving or spreading infection, including Aaron Glatt, chairman of the department of medicine at Mount Sinai South Nassau in Oceanside, N.Y. “Droplets can go out the side. It’s a risk,” he says.

Dr. Glatt, who is also the hospital’s chief of infectious diseases, thinks they can help in a hospital setting. He doesn’t recommend wearing face shields in the community because he doesn’t feel it will reduce risk for the everyday wearer who is already wearing a mask. But he does think it makes sense to pair shields with masks for barbers, dentists and personal trainers who may require more protection.

When do face shields alone make the most sense?

Schools, especially with younger children, may benefit from offering face shields to students and teachers. Dr. Ostrosky says children liable to touch the masks or take them off need an alternative.

Face shields may also work best in settings like restaurants or coffee shops where employees must communicate with people. Masks “are a communication barrier in some settings,” Dr. McQuillen says.

Which materials and other specs are best?

Opt for shields with any kind of sturdy, clear, waterproof plastic and those that use foam to fill gaps at the forehead or attach securely to a hat or visor, Dr. Edmond says. “If the coughing person is on the taller side, the droplets may come over,” he says. The shield also needs to reach to the ears and just slightly below the chin, he says.

What’s the most effective way to clean and take off the shield?

Taking off personal protective equipment is key to preventing infection, Dr. Omer says. He recommends face-shield users disinfect their hands and slip off the shield without touching the clear plastic, especially the inside. Use a disinfectant spray, alcohol wipe or rinse with soap and water before putting it away in a place where it cannot get contaminated.

How can consumers purchase them?

Online retailers like [Amazon](#) and office stores like OfficeMax offer face shields for \$3 to \$15 each. [Etsy](#) offers colorful face shields for children.

Some companies, including Midwest Prototyping, that already provide shields to hospitals are also starting to sell to consumers. Additionally, the University of Wisconsin-Madison offers open-source shield design for its [Badger Shield](#), which is being used both in hospitals and nonmedical settings, says Lennon Rodgers, director of the university's Grainger Engineering Design Innovation Lab.

What are the downsides to wearing a face shield?

With masks more popular, many are reluctant to switch or add additional face covering. "It's awkward and puts a barrier between you and others. We've never done that," says Dr. Ostrosky. "To a certain extent it's a big behavioral and appearance change."

SHARE YOUR THOUGHTS

Have you tried a face shield? If so, how does it compare with a mask? Join the conversation below.
