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Masks and respirators for prevention of respiratory infections: a state of the science review

Trisha Greenhalgh,[1] C. Raina MacIntyre,[2] Michael G. Baker,[3] Shovon Bhattacharjee,[2,4] Abrar A. Chughtai,[5] David Fisman,[6] Mohana Kunasekaran,[2] Amanda Kvalsvig,[3] Deborah Lupton,[7] Matt Oliver,[8] Essa Tawfiq,[2] Mark Ungrin,[9] Joe Vipond[10]

AUTHOR AFFILIATIONS See affiliation list on p. 48.

Editor Ferric C. Fang, University of Washington School of Medicine, Seattle, Washington, USA

Ad Hoc Peer Reviewer Linsey Marr, Virginia Tech, Blacksburg, Virginia, USA

Address correspondence to Trisha Greenhalgh, trish.greenhalgh@phc.ox.ac.uk.

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We dedicate this paper to the memories of those who died in the COVID-19 pandemic. We hope that this review will prompt a much-needed debate about the role of masks and respirators in respiratory epidemics and pandemics, allowing the research community and policymakers to better address the ongoing challenge of SARS-CoV-2 and deal with future (unknown) threats.

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SUMMARY This narrative review and meta-analysis summarizes a broad evidence base on the benefits—and also the practicalities, disbenefits, harms and personal, sociocultural and environmental impacts—of masks and masking. Our synthesis of evidence from over 100 published reviews and selected primary studies, including re-analyzing contested meta-analyses of key clinical trials, produced seven key findings. First, there is strong and consistent evidence for airborne transmission of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and other respiratory pathogens. Second, masks are, if correctly and consistently worn, effective in reducing transmission of respiratory diseases and show a dose-response effect. Third, respirators are significantly more effective than medical or cloth masks. Fourth, mask mandates are, overall, effective in reducing community transmission of respiratory pathogens. Fifth, masks are important sociocultural symbols; non-adherence to masking is sometimes linked to political and ideological beliefs and to widely circulated mis- or disinformation. Sixth, while there is much evidence that masks are not generally harmful to the general population, masking may be relatively contraindicated in individuals with certain medical conditions, who may require exemption. Furthermore, certain groups (notably D/deaf people) are disadvantaged when others are masked. Finally, there are risks to the environment from single-use masks and respirators. We propose an agenda for future research, including improved characterization of the situations in which masking should be recommended or mandated; attention to comfort and acceptability; generalized and disability-focused communication support in settings where masks are worn; and development and testing of novel materials and designs for improved filtration, breathability, and environmental impact.

KEYWORDS masks, respirators, respiratory infections, methodology, meta-analysis, narrative review, SARS-CoV-2, infection prevention and control, non-pharmaceutical interventions

INTRODUCTION

Rationale and aim

The efficacy, acceptability, and safety of masks and other face coverings have been among the most important and contested scientific questions of the coronavirus disease 2019 (COVID-19) pandemic. Masks have long been used to try to reduce transmission of respiratory diseases, both in endemic conditions such as tuberculosis and in epidemics such as European bubonic plague (1619), the Great Manchurian plague (1910), influenza (1918–1919), severe acute respiratory syndrome (SARS) (2003), and Middle East respiratory syndrome (MERS) (2013) (1–8). Current debates relating to masks have origins which stretch back decades and even centuries (7, 8).

The need for a new review on masks was highlighted by a widely publicized polarization in scientific opinion. The masks section of a 2023 Cochrane review of non-pharmaceutical interventions (9) was—controversially—limited to randomized controlled trials (RCTs). It was interpreted by the press and by some but not all of its own authors to mean that “masks don’t work” and “mask mandates did nothing” (10). Cochrane’s editor-in-chief felt the need to state publicly that in Cochrane’s view, the review’s findings did *not* support such a conclusion (11). Some scholars were quick to question the review’s methodology, especially key flaws in the meta-analysis and omission of a vast body of non-RCT evidence (12–16).

There are many additional complexities in the mask debate. As we explain in The Basic Science of Masking, the term “mask” covers a multitude of devices with different material properties; respirators have a more standardized design but are not widely used even in health-care settings. Some clinical trials of masks and respirators did not adequately define or optimize the intervention or maintain its fidelity, used heterogenous interventions and outcomes, or failed to measure whether masks were actually worn (see Clinical Trials of Masks and Respirators). In non-RCT studies, it has been difficult to isolate the effect of masking from that of confounding, effect modification, and bias, such as use of other mitigations, concurrent lockdown, or changes in disease prevalence (see Non-experimental Evidence on Efficacy). Whatever their protective effects, masks have some drawbacks, and some people find it difficult or impossible to wear them (see Adverse Effects and Harms of Masks). Masks are not just protective devices—they are cultural and even political symbols about which people may feel strongly. People’s beliefs about masks may be influenced by misinformation, which may be widely circulated (see Social and Political Aspects of Masking). Mask mandates, which require everyone to wear a mask in certain circumstances, have played out differently in different jurisdictions and sociocultural settings (see Masking as Policy). Single-use masks and respirators contribute to non-biodegradable waste and environmental pollution, though research on recycling, reuse, and novel materials points to some potential solutions (see Single-Use Masks and Respirators: Environmental Impact).

This review had three main objectives: first, to summarize the evidence base from multiple disciplines and study designs for the benefits—and also the practicalities, disbenefits, and harms—of masks and masking; second, to examine why the evidence on these topics is so widely misunderstood, misinterpreted, or dismissed; and third, to outline an agenda for future research.

Methodological approach

The review was registered on the International Platform of Registered Systematic Review and Meta-analysis Protocols (number 202410087). An initial scoping search on masks and masking in respiratory infections identified thousands of studies and more than 100 reviews. In view of this, our chosen review design was an in-depth narrative review in the hermeneutic tradition, whose primary aim was to make sense of this vast literature (17). We sought to summarize previous reviews and also, where necessary, to analyze and critique the key primary studies on which those reviews were based. In a hermeneutic review, a thorough literature search is undertaken to identify the most influential sources in each tradition. A narrative summary is prepared based on these key sources and progressively refined by adding further sources as they are identified (17). This method allowed us to tease out the multiple ways in which masks and masking have been framed and examined by different groups of scientists. A systematic review and meta-analysis of RCTs on masks in community and health-care settings was conducted within the larger narrative review. Details of the methods can be found in the section A New Meta-Analysis: Justification of Approach.

Part of the confusion on this topic can be traced back to philosophical issues such as ontology (what is the nature of reality?) and epistemology (how can we know that reality?), on which different scholars took widely differing views. The Cochrane review of non-pharmaceutical interventions, for example, appears to rest on the assumption that trustworthy evidence on this topic comes primarily or exclusively from RCTs and that if RCTs have been identified, non-RCT evidence can be ignored (9). An alternative view is that evidence-based medicine’s “hierarchy of evidence” (with RCTs as the assumed gold standard) is inappropriate for multifaceted topics such as masking (12, 14, 18, 19). Some have argued that the scientific value of the RCT has become inflated, particularly among doctors, leading them to overlook high-quality non-RCT evidence (e.g., mechanistic evidence about how the virus spreads can inform optimization of intervention design, and studies of how masking policies played out in real-world settings can provide useful case studies for policymakers in other settings). Overvaluing the RCT as a design also allows poor-quality RCTs (e.g., of intervention designs which do not take account of mechanism and which may therefore mislead rather than inform) to be published in high-impact journals and gain undue influence (20, 21). PubMed lists 88 meta-analyses of trials and other comparative studies of masks undertaken since 2020, with varying research questions, methods, and interpretations. Importantly, systematic review and meta-analysis can be subject to significant biases, flaws, and mistakes, just as in any other research design (22). These synthesis methods are limited by the quality of primary studies included and should not be considered definitive without critical analysis.

To identify key reviews and primary studies, we recruited authors familiar with relevant literature in a wide range of disciplines (public health, epidemiology, infectious diseases, biosecurity, fluid dynamics, materials science, modeling, data science, clinical trials, meta-analysis, sociology, anthropology, psychology, and occupational hygiene). We began with sources known to these authors and supplemented them by searching PubMed, Embase, and Social Science Citation Index using key words. We citation-tracked seminal sources using Google Scholar. We also sent requests to colleagues in relevant fields and posted on social media (X, Mastodon, and BlueSky).

Table 1 summarizes the study designs which we captured as relevant to a comprehensive hermeneutic review of masks and masking. Column 2 in Table 1 explains the potential contribution each design makes; columns 3 and 4, respectively, give the strengths and limitations of each design. The table is not exhaustive; additional designs may be relevant.

THE BASIC SCIENCE OF MASKING

Transmission of respiratory infections

To reduce spread of respiratory diseases, we need to understand the mechanisms of spread. There is strong and consistent evidence that respiratory pathogens including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), respiratory syncytial virus (RSV), influenza, tuberculosis, and other coronaviruses such as MERS and SARS-1, are transmitted predominantly via aerosols (32). Infected individuals, whether symptomatic or not, continuously shed particles containing pathogens, which remain viable for several hours and can travel long distances (33). SARS-CoV-2 is shed mainly from deep in the lungs, not the upper respiratory tract, and the viral load is higher in small aerosols (generated in the lower airways) than in larger droplets (generated in upper airways) (34, 35). Whereas large respiratory droplets emitted when people cough or sneeze fall quickly by force of gravity without much evaporation, those below 100 µm in diameter become (bio)aerosols. Even particles tens of microns in diameter at release will shrink almost immediately by evaporation to the point that under typical conditions they can remain airborne for many minutes (36). In contrast with droplet transmission, which is generally assumed to occur via a single ballistic hit, the risk of airborne transmission increases incrementally with the amount of time the lung lining is exposed to pathogen-laden air, in other words, with time spent indoors inhaling contaminated air (37).

Respiratory infections may theoretically also be transmitted by droplets, by direct contact, and possibly by fomites (objects that have been contaminated by droplets) (38), but the dominant route is via respiratory aerosols. The multiple streams of evidence to support this claim for SARS-CoV-2 include the patterning of spread (mostly indoors and especially during mass indoor activities involving singing, shouting, or heavy breathing), direct isolation of viable virus from the air and in air ducts in ventilation systems, transmission between cages of animals connected by air ducts, the high rate of asymptomatic transmission (i.e., passing on the virus when not coughing or

TABLE 1 Different study designs contributing to mask research

Study design	Contribution	Strengths	Limitations
Laboratory studies			
Laboratory studies of aerosols and aerosolized pathogens	Developing and testing hypotheses about how aerosols (and pathogens in aerosols) behave	Generates mechanistic evidence about how transmission occurs and how masks might work to reduce it; relatively low cost	Requires an understanding of physics, engineering and fluid dynamics, plus specialized equipment (see Transmission of Respiratory Infections and Table 2 for further details)
Material and engineering studies	Developing and refining physical properties needed for masks (notably, filtration standards)	Generates mechanistic evidence on filtration properties of mask materials; randomization and controls routinely used as appropriate, informs engineering standards, relatively low cost	Requires an understanding of chemistry, materials and engineering, plus specialized equipment (see What Are Masks and How Do They Work? and Table 2 for further details)
Randomized controlled trials			
RCTs randomized by individual participant	Testing hypotheses about the efficacy of a specific intervention in preventing wearers from getting infected or testing the efficacy of source control (preventing outward transmission from infected to uninfected people)	High internal validity (can demonstrate efficacy of a specific intervention in a particular context and *potential* for efficacy in other contexts); a specific intervention can be developed or selected; strong design to use when unmeasured confounding is a concern	Expensive and long duration; unless informed by mechanistic understanding, interventions may be suboptimally designed, leading to underestimation of efficacy; cannot measure bidirectional effects (on wearer *and* source control) (23). Some methodological variations include mismeasurement of outcomes (e.g. 24, 25)]; interventions may be heterogeneously applied across trials (e.g., continuous vs intermittent N95 use); variation in disease prevalence may lead to underpowering; if outcome is a communicable disease, outcomes in individuals randomized to different interventions within a closed setting such as a household or hospital are not independent (cluster randomization must be used); limited external validity (a negative result cannot prove lack of efficacy under other conditions); and lack of difference between arms in the absence of a no-mask control arm may reflect equal inefficacy or equal efficacy; ethical concerns if researchers are not in equipoise (26)
RCTs randomized by locality or organization (cluster RCTs)	Testing hypotheses about the efficacy of a specific intervention in reducing disease transmission in a population	High internal validity; a specific intervention can be developed or selected; bias due to non-independence of outcomes is less problematic than in individually randomized RCTs (27, 28)	May be even more expensive than RCTs randomized by individual; long duration. Interventions developed without mechanistic understanding or poor choice of intervention or outcome measures may be suboptimally designed, resulting in underestimation of efficacy. May still be unable to tease apart direct

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TABLE 1 Different study designs contributing to mask research (*Continued*)

Study design	Contribution	Strengths	Limitations
			and indirect impacts of masks, potentially resulting in overestimation of efficacy; ethical concerns if researchers are not in equipoise
Observational designs and modeling			
Observational studies: cohort and case-control	Assessing the likelihood of an outcome based on exposure status	Can be conducted more rapidly, retrospectively, or prospectively, and at lower cost than RCTs (14)	Common to all observational studies is the risk of bias, confounding, or effect modification (e.g., due to
Observational studies: ecological studies and quasi-experiments	Documenting what happens before and after an intervention is introduced in a real-world setting (e.g., community mask mandates).	Can be rapid and low cost; geographical variation can permit adjustment for unmeasured confounding (pseudo-randomization) using instrumental variable analysis	concurrent policy changes such as lockdown); known confounders can be adjusted to some extent using multivariate regression analysis.
Observational studies: "real-world evidence"	Large observational, epidemiological studies using data derived from administrative databases	Can be rapid and low cost	Studies that use surveillance data may be subject to ascertainment bias (e.g., if cases are identified only on the basis of symptomatic illness, rather than evidence of infection). There may be confounding by indication (e.g., masks tend to be introduced when risk is elevated). Such biases, if present, would lead to an underestimate of the protective effect from masking.
Modeling studies	Models are simplified versions of reality, which can provide insights into complex phenomena and test hypothetical future scenarios. There are many different modeling methods (e.g., SEIR, agent based, and statistical).	Can impute indirect effects of an intervention (e.g., impact of some people masking on others who do not mask). Helps optimize interventions by answering "what-if" questions (e.g., to assess costs vs benefits of modifications); useful for future scenarios (e.g., pandemic planning) or crisis response. Good models are transparent and can be reproduced, use evidence-based parameters, and deal with uncertainty by using sensitivity analyses.	Depends on the quality of input data, which be unavailable or suboptimal ("garbage in, garbage out"), and on the assumptions and parameters used. There is always a need for some simplifying assumptions, but models that are too simple may be less accurate. Interpretation and critique of mathematical models of pandemic policies require advanced interdisciplinary knowledge, including mathematics, statistics, medicine, behavioral science, and economics (29). Modeling that lacks interdisciplinary expertise may be less robust.
Social and psychological studies			
Surveys of masking behavior	People's self-reported masking behavior	Relatively easy and quick to administer; can gain large sample sizes (e.g., using online methods)	Subject to recall bias and participant bias (people who feel strongly about masks either negatively or positively may be more likely to respond). Other predictor variables are also self-reported, so may not be reliable. Low-literacy and marginalized individuals may be underrepresented.
Observational studies of masking behavior	Direct observation of whether people are masking (e.g., in a public place)	Relatively easy to undertake as a one-shot survey; may use video data (e.g., as people pass by) (30, 31).	Cross sectional studies represent a snapshot in time, so cannot capture dynamic changes in behavior.

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TABLE 1 Different study designs contributing to mask research (*Continued*)

Study design	Contribution	Strengths	Limitations
Surveys of attitudes and intentions	People's stated reasons for masking or not	Relatively easy and quick to administer; can gain large sample sizes (e.g., using online methods)	Responses may not reflect attitudes or reasons (due to, e.g., social desirability bias). Sampling biases and low response rates reduce validity of findings (non-responders differ from responders). Low-literacy and marginalized individuals may be underrepresented.
Communication studies	Identifying how mask-wearing advice can be communicated and incentivized to communities	Draws on multiple (qualitative and quantitative) methods. Can generate mechanistic understanding	Communications research on majority groups may not be directly transferable to minority or marginalized groups.
Policy analyses	Qualitative analyses of how policy is made and what good policy is, including what is morally right and politically feasible	Can help identify the root causes of a problem, clarify the goals of a proposed policy and assess its potential effectiveness	Depends on high-quality data on the options and their outcomes; may be impossible if such knowledge is lacking. May produce an overly sanitized and technical view of policy.
Sociomaterial analyses	Qualitative studies of the symbolic meaning of masks in different cultural and social settings	Combines multiple methods to examine why some groups feel strongly (positively or negatively) about masks; takes into account social, cultural, historical, and political contexts of attitudes and practices	Requires advanced training in sociological theories and methods; often limited to specific sampled groups, hence are not usually generalizable to the broader population
Social media studies	Quantitative and qualitative analyses of how (mis)information spreads on social media	Combines multiple methods to track the spread of (mis)information on particular platforms and the sentiments demonstrated in these media	May require advanced technical skill, such as machine learning, and computing power; qualitative studies require advanced training in interpretation and analysis
Health economic studies	Cost-benefit and cost-effectiveness of interventions	Estimates the direct (and some indirect) financial costs and benefits of a particular approach to masking; cost-effectiveness analysis requires a common unit of outcome measurement such as quality-adjusted life years gained or lost; can use a government payer or societal perspective	May have limited external validity since costs are locality or country specific, and change over time; subject to the same limitations of modeling studies, such as quality of data and model assumptions. Studies that consider only the government payer perspective or only the acute infectious episode underestimate true societal costs. Metrics such as quality-adjusted life years are difficult to operationalize in children.
Evidence syntheses			
Systematic review	Review undertaken according to explicit and reproducible criteria	If undertaken well, tends to identify all or most relevant studies and produces accurate assessment of key biases and contributions of included primary studies; prospective registration (e.g., on the international prospective register of systematic reviews [PROSPERO]) increases transparency	Data extraction and evaluation of primary evidence depend on reviewers' judgments, especially if multiple reviewers share flawed assumptions and biases, can lead to spurious findings that are given undue credibility because of the "systematic" kitemark. Inappropriate application of rigid evidence

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TABLE 1 Different study designs contributing to mask research (*Continued*)

Study design	Contribution	Strengths	Limitations
			hierarchies may lead to systematic biases (e.g., omission of all non-RCT evidence) (22).
Meta-analyses (some limited to RCTs, some focusing on or including observational evidence)	Testing various hypotheses, depending on primary studies	Combining findings from primary studies may increase power of estimates; relatively low cost; prospective registration increases transparency.	A meta-analysis is only as robust as the primary studies on which it is based and the methodology used. If primary studies are few and poor quality, or if different methods and outcomes are combined inappropriately, conclusions will be unreliable. When a specific bias mechanism is common in primary studies, pooled estimates of effect will reproduce and magnify this bias. If interventions or outcomes that are dissimilar are combined for meta-analysis, results may not be informative or valid. Reviewers lacking key content expertise may miss, misunderstand, or misinterpret key data or concepts.
Narrative reviews	Broad-ranging syntheses drawing on multiple sources of evidence	Goal is typically to draw together and make sense of a complex literature; can combine mechanistic and probabilistic evidence	Traditionally criticized for being non-systematic, though high-quality narrative reviews have a systematic and rigorous methodology, with a focus on interpretation (17).
Environmental impact reviews	Narrative reviews which summarize epidemiological, chemical, engineering, and toxicological evidence	Combines multiple methods to produce depth and detail on the specific issue of environmental impact	Requires multiple sources of high-quality evidence; such data may not be available or may be suboptimal
Historical studies	Narrative reviews drawing on data from past outbreaks	Provides rich case studies of historical events and how they unfolded over time	Can be hard to confirm whether interventions were informed by field-specific expertise; data sources may be incomplete; transferability to present-day outbreaks may be questioned

[a]RCT, randomized controlled trial; SEIR, susceptible, exposed, infected, recovered.

sneezing), and transmission in quarantine hotels when individuals in different rooms shared corridor air but did not meet or touch any common surface (32, 39, 40).

Historically, droplet modes of transmission were erroneously categorized as a discrete mode and considered dominant for many respiratory diseases, including influenza, measles, smallpox, SARS-1, and tuberculosis. This was partly because influential infectious disease physicians in the early 20th century (notably Charles Chapin) initiated a number of flawed assumptions and logical fallacies in their pronouncements and publications (Box 1) (41–43). We summarize these errors here because they underpin a linked set of flawed arguments relevant to the masking debate which persist, particularly within the infection prevention and control (IPC) community, to this day (44, 45).

Chapin's statements in a 1914 article (without empirical evidence) that respiratory diseases are transmitted primarily by "spray" and that airborne transmission is "negligible" (page 430) (46) became a bibliographic virus, reproduced in numerous subsequent books and articles. Then as now, the idea that airborne transmission had to be "demonstrated" but droplet transmission could be "assumed" was rarely challenged. Airborne transmission is uniquely difficult to demonstrate empirically. To do so requires sophisticated equipment (e.g., air needs to be concentrated or passed through an air sampler prior to analysis, and this is hard to do without damaging the virus). IPC physicians unfamiliar with these techniques attempted and failed to isolate viable virus from air samples obtained in simple "cough bags" and interpreted their findings (erroneously) as evidence that there was no viable virus in the air (47). Yet numerous studies, many done back in 2020, identified SARS-CoV-2 RNA or viable virus in the air in hospital rooms, and on ceiling air vents. Lednicky et al. made the point that the method of air sampling determined the likelihood of detecting viable virus, as most air samplers use high shear force, which destroys viable virus (48).

Large droplet transmission is generally assumed to occur only at close quarters (within 1–2 m), but it does not follow that any transmission within this distance must be via large droplets. Similarly, just because aerosols travel beyond 2 m, it does not follow that airborne transmission occurs only at these longer distances. While some IPC clinicians (among others) conflate close-contact transmission with droplet transmission, basic physics tells us that the closer one is to a source of airborne pathogens, the more likely one is to inhale those pathogens (just as the closer one sits to a smoker, the more smoke one inhales), and that close contact involves exposure to aerosols of all sizes.

Because some droplets above 100 μm in diameter are smaller than the lumen of the smallest bronchioles (approximately 1 mm) and follow ballistic trajectories (e.g., in sneezes), it is sometimes assumed that they can be carried deep into the lungs on these trajectories, allowing SARS-CoV-2 to infect its target cell (type II alveolar pneumocytes) directly via inhalation of large droplets. In fact, access to the alveoli via the air requires transport as aerosol particles *below* 5 μm (33, 49, 50). For the same reason a motorcycle can negotiate a tighter corner than a laden truck moving at similar speed, larger particles collide with the walls of the upper respiratory tract and are deposited there and prevented from penetrating further by mucociliary clearance mechanisms (49).

Droplet transmission was given undue credence by an incorrect cut-off for the size of a droplet (51). A 1934 article by engineer William Wells (whose wife and co-investigator was a physician) correctly hypothesized that tuberculosis was airborne and correctly proposed a cut-off of 100 μm to distinguish between droplets and aerosols (52). Wells' work was ignored in the medical literature until 1962, when he demonstrated the airborne nature of tuberculosis in a series of elegant experiments involving guinea pigs (53). In another experiment, Wells exposed rabbits to fine aerosols (below 5 μm) and coarse aerosols (above 5 μm) containing tuberculosis bacteria; only those exposed to the fine aerosols became sick (54). This was because, like SARS-CoV-2, tuberculosis infects the alveolar pneumocytes, and in Wells' experiment, the larger particles, even though airborne, did not reach the target cells. Flawed conflation of the maximum size at which a particle is infectious (below 5 μm) with the maximum size at which it can be airborne (100 μm) led to many in the IPC community (including the World Health Organization [WHO] and the U.S. Centers for Disease Control and Prevention [CDC]) coming to view 5 μm as the maximum size of an airborne particle (42). This reinforced the false conclusion that many of the viral-laden particles entering the lungs were droplets, not aerosols.

Another assumption among infectious disease physicians in early 2020 was that because the most well-established airborne viruses such as measles and chickenpox had very high reproduction number, R_0 (estimates of up to 18), the novel coronavirus SARS-CoV-2 (with an estimated R_0 of 2–5) was therefore not significantly airborne. The R_0 is not, however, a scientific indicator of mode of transmission (55, 56). As the example of tuberculosis illustrates, a pathogen may be airborne but have low transmissibility, as indicated by the average R_0 value (57), especially when R_0 is overdispersed (i.e., skewed) (58). Furthermore, as the SARS-CoV-2 virus has evolved, there is evidence that the transmissibility of this virus is now substantially higher than the original estimate (59).

The so-called "aerosol-generating medical procedure" (AGMP) is based on the assumption that a patient with a respiratory infection will generate bioaerosols only during certain medical procedures such as bronchoscopy or physical therapy (60). The patient is assumed to be non-infectious unless actively provoked. In fact, breathing, speaking, shouting, and singing all generate similar or higher levels of aerosols to many so-called AGMPs (35, 61). Further, breathing is continuous and speaking occurs repeatedly over long periods, so the cumulative aerosol exposure is much higher from routine human emissions than from a single medical procedure.

An assumed droplet and contact mode of transmission leads to prevention policies that center on handwashing and surface cleansing, maintaining 2-m physical distancing, wearing medical masks (whose waterproof backing is designed to stop droplets) within that 2-m distance (especially when attending an infected patient), using physical barriers (e.g., plastic screens) and providing health-care workers with higher-grade respiratory protection only when undertaking AGMPs. However, if the virus is transmitted significantly by the airborne route, different prevention policies are needed, oriented to controlling air quality in indoor spaces (e.g., ventilation and filtration), reducing indoor crowding and time spent indoors, wearing masks whenever indoors, careful attention to mask quality (to maximize filtration) and fit (to avoid air passing through gaps), taking particular care during indoor activities that generate aerosols (e.g., speaking, singing, coughing, and exercising), and providing respirator-grade facial protection to all staff who work directly with patients (not just those doing AGMPs) (62, 63).

The misconceptions listed in Box 1 have been complicated by differences in terminology among aerosol scientists and IPC clinicians. IPC clinicians make a distinction between "airborne" and "aerosol" and have tended to use the term "droplet nuclei" to refer to small airborne particles, terms that are not used by aerosol scientists. The detail of this linguistic impasse is beyond the scope of the article, but it has contributed to persistent misunderstandings and a dismissal of much evidence by the WHO during a key period of the COVID-19 pandemic (62). A recent attempt to "standardize" the language of airborne transmission (64) has been criticized as naïve and unworkable (65).

In sum, despite claims to the contrary, the evidence on airborne transmission of SARS-CoV-2 is clear, consistent, and definitive. It has been built from many different kinds of evidence including a variety of laboratory-based designs (Table 2).

What are masks and how do they work?

Imposing any filtering material in the respiratory path will remove particulates or aerosols (83). Face coverings for respiratory protection occupy a broad continuum from simple one-layer improvised cloth coverings (84) to medical (or surgical) masks and

BOX 1: FLAWED ASSUMPTIONS AND LOGICAL FALLACIES ABOUT AIRBORNE TRANSMISSION

The following incorrect assumptions have led to flawed conceptual models and ineffective policies (see text for details and references):

1. Absence of direct evidence in favor of airborne transmission can be taken as evidence refuting airborne transmission.
2. Because contact and droplet transmission can occur only during close contact, all close-contact transmission must be contact and droplet.
3. Because large droplets are smaller than the lumen of the smallest bronchioles, they can reach the key target cell for SARS-CoV-2 in the alveoli.
4. Particles above 5 µm in diameter are droplets and not aerosols.
5. Aerosols are produced in significant numbers from infectious patients only when aerosol-generating medical procedures (AGMPs) are done.
6. Only respiratory diseases with a high R_0 (such as measles) are airborne.

TABLE 2 Summary of how laboratory studies have contributed to mask research[a]

Type of study	Goal	Examples of key findings
Laboratory studies of aerosol dynamics	Developing and testing hypotheses about the physical behavior of aerosols	Data on, for example, rate of evaporation in particles of different size (66)
Laboratory studies of aerosol measurement systems	Developing and testing hypotheses about how aerosols may be captured and quantified	Specific techniques for generating and measuring aerosols in the laboratory (67–69)
Laboratory studies of pathogen behavior within aerosols	Developing and testing hypotheses about how the evolving aerosol environment affects pathogens	Insights into how an airborne pathogens' viability changes over time and in different ambient conditions (70)
Laboratory and animal studies of aerosol-generating processes	Developing and testing hypotheses about generation of aerosols by host organisms	Demonstration that many regular activities such as breathing, speaking, and singing generate similar levels of aerosol to conventional AGMPs (71, 72)
Laboratory studies of fluid dynamics and airflow	Developing and testing hypotheses about the airflow that transports infectious aerosols	Efficacy of different approaches to ventilation, comparing turbulent vs laminar flow, toilet plumes, cough plumes (73, 74)
Laboratory studies of how materials interact with suspended particles	Developing and testing hypotheses about how particles are captured on surfaces	Insights into processes of, for example, filtration, deposition, adsorption, absorption, and electrostatics (75–77)
Laboratory studies of how pathogens interact with materials	Developing and testing hypotheses about how materials affect pathogens	Insights into, for example, killing, persistence, permanent capture, and retention vs later release of pathogens (78)
Laboratory studies of respiratory dynamics	Developing and testing hypotheses about how air flows within the respiratory tract	Insights into how alveoli behave in inflation vs deflation (79)
Laboratory studies of respiratory aerosol deposition	Developing and testing hypotheses about how aerosols move within the respiratory tract	Demonstration that particles above 5–20 μm do not reach the alveoli (33, 80)
Laboratory contribution to studies of PPE effectiveness	Testing how PPE protection performs under "real-world" conditions and how well PPE blocks aerosols	Data on comfort and compliance; durability quantitative performance assessment via, for example, fit factor, workplace protection factor, and assigned protection factor (81); aerosol-blocking ability of different PPEs (82)

[a]AGMP, aerosol-generating medical procedure; PPE, personal protective equipment.

respirators, which are certified to a national or international standard such as NIOSH-42 CFR Part 84, EN149:2001 + A1:2009, or CSA/CAN Z94.4–18 (85). Respirators have been developed and used mainly in the occupational health context (i.e., to protect workers from hazards in their jobs).

All masks and respirators need to be assessed for four key properties. First, filtration efficacy. This is influenced by the filter material, filtration methods, air velocity, and pore size (86, 87). The most challenging particle size range for masks and respirators to filter is 0.05–0.5 μm, since such particles are most able to evade both mechanical and electrostatic filtration methods, posing an increased infection risk (87). This inefficiency is particularly critical for virus-laden aerosols and particles, underscoring the need to incorporate reliable filtration capabilities in mask and respirator design. Accumulated dust and microbial growth on the mask can reduce filtration efficiency (88). Respirators are regulated on filtration efficiency but also on their ability to achieve a specified minimum protection factor or fit factor when worn, but surgical masks are not. Surgical masks for medical use are typically certified based on synthetic blood penetration resistance (ASTM F1862), bacterial filtration efficiency (ASTM F2101), and submicron particulate filtration efficiency (F2299), but these tests are performed on a sample coupon in a test fixture with no fit factor or protection factor requirements when worn. This reflects a key difference between surgical masks and certified respirators: the respirator must meet standards when worn in an occupational setting, integrated into a complex system which includes the wearer, the work tasks, and all respiratory hazards.

Second, fit and seal. Poorly fitting masks and respirators allow air and micro-organisms to bypass the filter, leading to inhalation of unfiltered air and significantly reducing their effectiveness. Improper fit can also compromise the mask's ability to contain exhaled droplets, undermining source control and leading to issues like fogging of goggles and glasses, which can affect visibility and safety (89, 90). Respirators are designed with fit and seal in mind; masks, generally, are not. A systematic review of fit testing studies of masks and respirators identified (from 137 studies) numerous factors influencing fit: brand/model, style, gender, ethnicity, facial dimensions, facial hair, age, reuse, extensive movement, seal check, comfort and usability assessment, and training (91). Facial hair was a particular key factor contributing to poor fit.

Third, breathing resistance. This is a key factor influencing wearer comfort and safety (92). Lower resistance ensures greater comfort but must be balanced against filtration efficiency.

Fourth, potential for contamination. Filter materials can, at least hypothetically, accumulate viruses and bacteria over time, particularly if they lack anti-microbial properties. While viable SARS-CoV-2 can be detected on plastic (including the outer layer of a surgical mask) for several days (93–95), to our knowledge, no study has ever demonstrated direct contagion with SARS-CoV-2 from a contaminated mask or respirator. A simulation study using artificial skin showed that viable virus was not transferred from mask to skin (though viral RNA was), suggesting that the risk of contagion may be less than previously assumed (96). Nevertheless, many masks and respirators are designed with anti-microbial properties (see Toward Better Masks). The sequence of donning and doffing of personal protective equipment (PPE) is important in reducing risk of self-contamination (97).

These properties are inter-related. Materials not designed for filtration typically provide poorer filtration and may have higher breathing resistance (though broadly speaking, resistance tends to correspond with filtration). A layered cotton bandana, for example, provides some protection against large particulates but may resist airflow and lose filtration effectiveness as respiratory moisture saturates the material (98, 99). Hao et al. found 7.1% filtration efficiency for 0.3-µm particles through four layers of bandana (100). While improvised or uncertified masks provide some reduction in dose exposure against aerosol pathogens (101), they may not do so reliably or repeatably (102). The low water and fluid resistance of cloth masks reduces the filtration effectiveness compared to surgical masks or respirators, highlighting the need for more research (86).

A broad category of ear-loop style or tied rectangular pleated masks is referred to variously as surgical, medical, or procedure masks. Surgical masks are primarily intended for interception of liquids and ballistic droplets as either source or exposure control. *Certified* surgical or medical masks require objective testing, including against fluid penetration and skin irritation, and for bacterial filtering efficiency under standards such as ASTM F2100-21. Standards for such masks do not require achieving a leak-free seal on the wearer's face. Many consumer masks appear similar and may be labeled "surgical" masks, but if not formally certified, their performance cannot be predicted. While surgical masks reduce respiratory aerosols (103), culture-positive SARS-CoV-2 has been detected in exhaled air from loose-fitting surgical masks (104). Unsurprisingly, masks and respirators with integrated exhaust valves allow respiratory aerosols from the wearer to escape into the air even when fit is good (105–108).

A respirator, or more correctly, a "filtering facepiece respirator" (FFP) or "air-purifying respirator", is designed to seal to the face and ensure that all inhaled and exhaled air passes through the material rather than short-circuiting it. Respirators may be half or full face and "disposable" (single-use) or elastomeric (reusable with a replaceable filter). To achieve certification, respirators must be independently tested to confirm they meet the standard, typically including a manufacturing quality management system and ability to achieve a low-leak seal (109). Respiratory protection standards generally prescribe not only the minimum level of protection required under different conditions but also an effective workplace respiratory protection program (110), an important consideration that was not incorporated into the design of most RCTs (see Clinical Trials of Masks and Respirators).

The pore size in typical non-woven materials used in surgical masks and respirators is larger than many viruses like SARS-CoV-2 (65–125 nm in diameter) (111). However, viruses travel through the air as passengers in or on respiratory aerosols, rather than alone. In addition, masks and respirators are not simple sieves. They use a variety of filter media which work in multiple ways, influenced by the size of the particle (85):

- Sedimentation of larger particles (1–10 µm) under the influence of gravity.
- Inertial impaction, in which larger (above 1 µm) particles are blocked by fibers in the filter matrix.
- Interception, in which medium-sized particles (smaller than 0.6 µm) following the airflow collide with fibers.
- Diffusion, in which smaller lighter particles (0.02–0.40 µm) impact fibers with Brownian motion.
- Electrostatic effects, in which particles passing near electrostatically charged fibers are attracted and captured; effective for all particle sizes, but particularly for smaller particles (0.1–0.5 µm).

Electret-type filter material (possessing a non-dispersing electrostatic charge) is in widespread use because of high performance derived by integrating these mechanisms.

Standards and certification

The International Standards Organization (ISO) defines standards as providing for "achievement of the optimum degree of order in a given context" based on the "consolidated results of science, technology and experience, and aimed at the promotion of optimum community benefits" (112).

Respiratory protection standards for respirators are designed to provide adequate protection in realistic use settings; they include metrics like bench-test filtration and sizing to fit a broad range of face types. They typically require a worker to achieve a minimum fit factor through objective testing (e.g., conducting a set of standard exercises while facing a challenge contaminant) before using a respirator (113). When a quantitative fit factor of over 100 is achieved for a half-face respirator (a 100-fold reduction of the challenge contaminant penetrating the respirator), the respirator is considered to meet legal requirements under occupational health and safety legislation (114). While fit testing and training are important and legally mandated for occupational health, some studies have shown similar levels of performance in non-fit-tested respirators used by untrained individuals, and this arrangement still outperforms other, uncertified types of face coverings (115, 116). Standards for protection against bioaerosols vary, depending on whether the hazard is fully known and quantified, compared with situations when the risk level cannot be fully quantified (e.g., novel diseases), when a precautionary approach should be taken (117).

Schmitt and Wang summarized measured fit factors for a variety of types of face coverings. Their findings are shown diagrammatically in Fig. 1 (118).

Certified respirators are rated by the degree of filtration efficiency provided, for example, "N95" reflects a minimum 95% reduction in 0.3-µm particles in a non-oily atmosphere; "P100" reflects a 99.97% reduction to the same exposure including oily contaminants. While the standard specifies 0.3 µm as the minimum particle size for testing, these respirators filter smaller and larger particles more efficiently (0.3 µm is used as the "most penetrating particle size" for filtration) (129).

Certified respirators are also distinguished from uncertified face coverings by the assigned protection factor and achievable fit factor.

The certification of surgical masks for particle/bacterial filtering efficiency (P/BFE) does not reflect equivalence to respirators as the filtration is typically compromised by poor face seal (77, 103). The ASTM F2100-21 P/BFE certification, for example, requires at least 95% filtration against 0.1-µm particles and at least 98% against aerosolized *Staphylococcus aureus*, but this is on a sample of the mask clamped in a fixture, not on a representative face. In terms of filtering aerosols, N95 respirators outperform surgical masks between 8- and 12-fold (77). The effectiveness of certified surgical mask

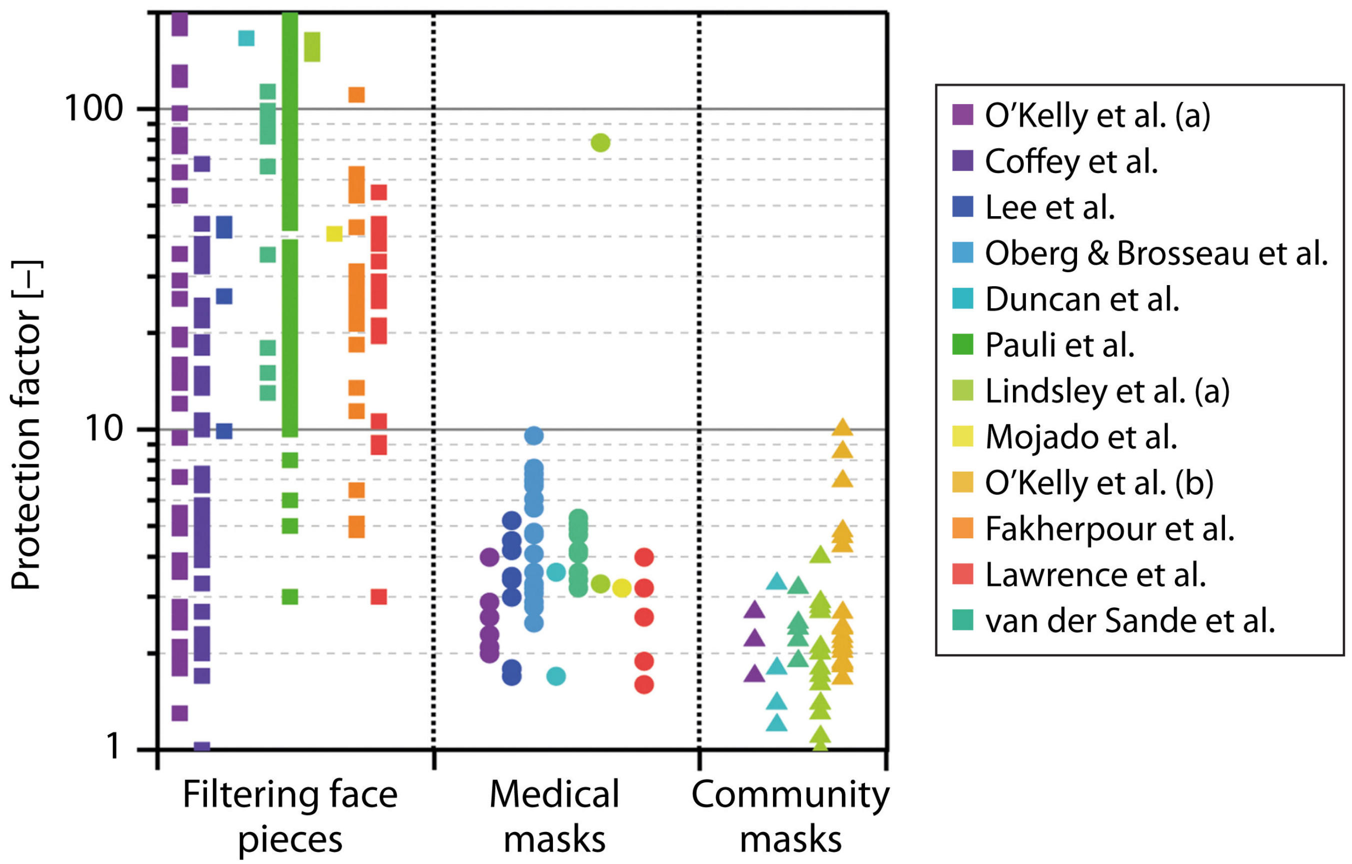

FIG 1 Synthesis of the measured fit factors and protection factors for various types of face coverings, based on the 12 primary studies shown in the key. Reproduced under Creative Commons license from Schmitt and Wang (118). "Protection factor" and "fit factor" are similar constructs. Both provide quantitative estimates of protection based on objective testing (fit factor takes more account of real conditions of use). Studies shown used one or the other. References: O'Kelly et al. (a) (119), Coffey et al. (120), Lee et al. (121), Oberg and Brosseau (77), Duncan et al. (122), Pauli et al. (123), Lindsley et al. (124), De-Yñigo-Mojado et al. (114), O'Kelly et al. (b) (125), Fakherpour et al. (126), Lawrence et al. (127), and van der Sande (128).

material against transmission when used as a filter was demonstrated in a hamster SARS-CoV-2 model (130). Infected hamsters were separated from non-infected ones by a partition made of surgical mask material; when the partition was in place, transmission of SARS-CoV-2 was reduced by 75%.

In addition to protecting the wearer, respirators provide very effective source control by dramatically limiting the amount of respiratory aerosols emitted by infectious individuals (131). In one study, risk of infection was reduced approximately 74-fold when infected, and susceptible individuals both wore well-fitting FFP respirators compared to when both wore surgical masks (132). Figure 2 reproduces Bagheri et al.'s demonstration of the dramatic decrease in total inward leakage for different types of respirators and surgical masks.

Effective selection of respiratory protection requires knowledge of the hazard and what level of exposure is acceptable. Cheng et al. modeled the critical concept of dose-exposure, with selection of respiratory protection based on the pathogen load of a space (133). In pathogen-rich spaces such as medical centers, respirators and enhanced ventilation are particularly crucial to reduce the high-transmission risk. Cheng et al. acknowledged that control of viral load using ventilation reduces the challenge load faced by any type of face covering. This use of engineering controls to reduce exposure is well established in industrial hygiene.

The design of masks and respirators continues to evolve; it is discussed further in section 8.3.

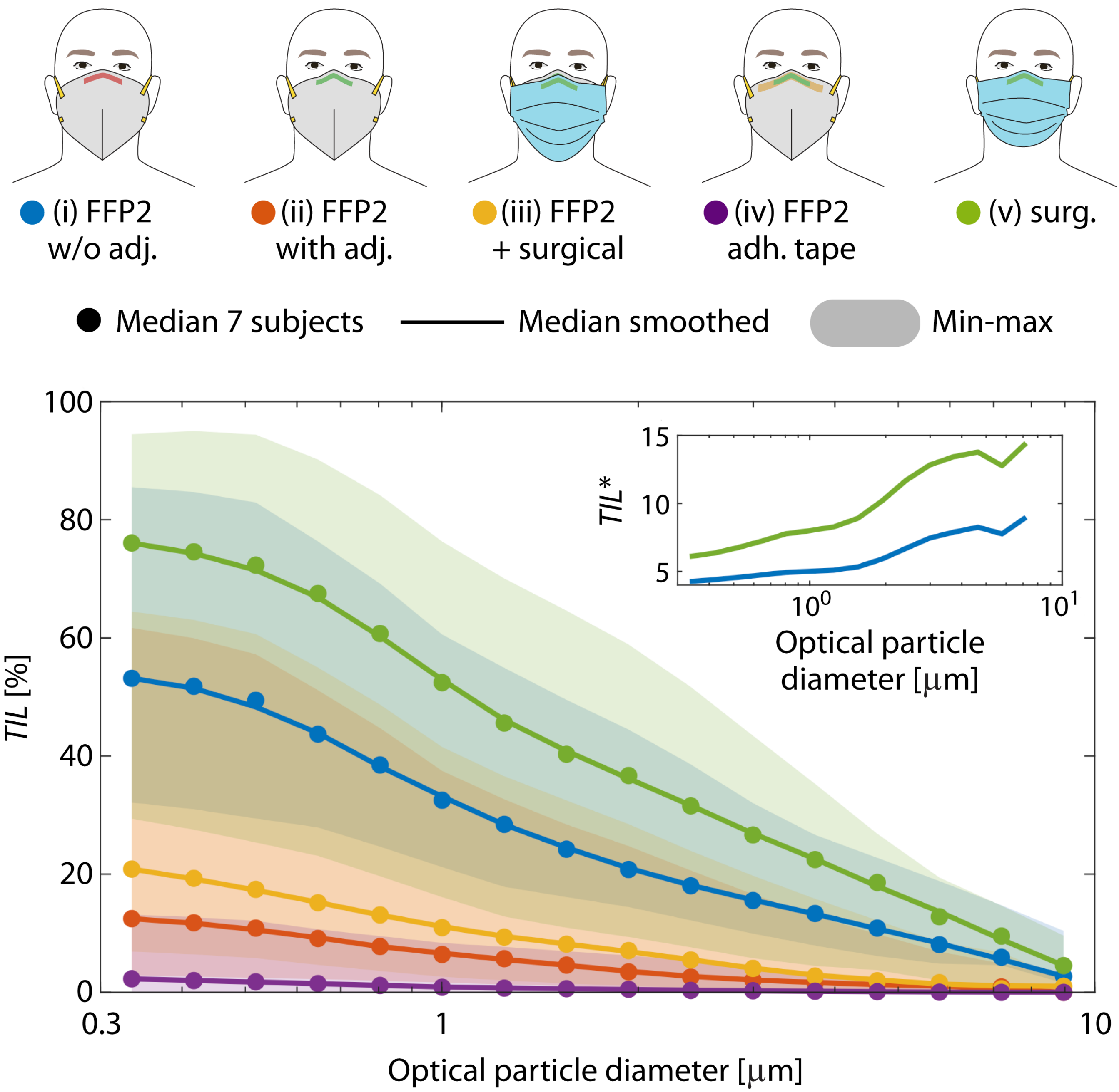

FIG 2 Median of the total inward leakage over all participants for different cases. Adapted under Creative Commons license from Bagheri et al. (132). Further details are given in the original source. FFP2 w/o adj., participant wears FFP2 respirator without adjustment; FFP2 with adj., FFP2 with adjustment to fit; FFP2 + surgical, FFP2 with additional surgical mask over it; FFP2 adh. tape, adhesive tape applied to increase fit of FFP2; surg., surgical mask.

CLINICAL TRIALS OF MASKS AND RESPIRATORS

Methodological challenges in trials and meta-analyses of masks

There are numerous methodological challenges when designing high-quality RCTs of masks vs a control intervention and in combining such studies in meta-analyses. General quality criteria for RCTs of complex interventions relate to issues such as sampling strategy and size, setting, optimization and piloting of the intervention, concealment of allocation, compliance (and intention-to-treat vs per-protocol analyses), primary and secondary outcome measures, follow-up, and assessing adverse effects and harms (134–

136). These criteria are extremely difficult to meet in trials of masking. Some scholars have argued that RCTs have major limitations in answering questions about the efficacy of masking (137). For example, real-world effects (such as poor compliance) in an intention-to-treat analysis of a trial conducted in a non-pandemic context may not reflect effectiveness in a pandemic, where it is more likely that masks would be worn as intended, such as during an emerging pandemic where risk perception and compliance are high and no other mitigation is available.

Below, we list key challenges in interpreting the results of RCTs and meta-analyses.

Nature of the outcome

The outcome in mask trials is an infectious disease which can transmit from person to person; risk of transmission is higher in hospitals and other closed settings. In RCTs of interventions against non-communicable diseases (e.g., hypertension), the intervention affects only the person receiving it. In trials involving a contagious infection, the intervention may affect people other than those receiving it by preventing onward transmission. This “herd protection effect” of N95 respirators has been described in health-care settings (138). It means prevention of infection in one individual can prevent a chain of subsequent transmission. To account for this, any clinical trial of respiratory protection in health-care and other closed settings should ideally be cluster randomized without appreciable contact between clusters. We acknowledge that this ideal design may not always be feasible, but findings from less optimal designs should be interpreted accordingly.

Seasonal and year-on-year variation

Respiratory virus activity (especially influenza) is highly variable by season and from year to year (139). In contrast, SARS-COV-2 is not clearly seasonal. A trial of masking that is conducted when the prevalence of the disease under investigation is extremely low (see, e.g., reference 140) may falsely conclude that masking is ineffective because few people in either arm develop the disease (hence, the study is likely to be underpowered). Ideally, any trial of prevention of influenza should be run over more than 1 year to overcome the risk of low seasonal influenza activity in a single year.

Variable primary outcomes

Mask trials may use clinical, laboratory-confirmed, or a combination of outcomes. Using “influenza-like illness” (ILI) (141) as a clinical outcome is problematic, particularly in studies that rely on self-reporting (with or without subsequent laboratory confirmation) because this relatively insensitive definition requires a fever of at least 38ºC in addition to one respiratory symptom such as cough or sore throat, and most adults do not have documented fever in the presence of a confirmed respiratory viral infection (142). Using ILI as the primary outcome measure may reduce the statistical power of a study. Some RCTs have used a definition of “clinical respiratory illness” (CRI), generally defined as two or more respiratory symptoms (cough, nasal congestion, runny nose, sore throat or sneezes) or one respiratory symptom and a systemic symptom (chill, lethargy, loss of appetite, abdominal pain, muscle or joint aches), which appears more sensitive (115).

Another limitation of these RCTs is including only influenza and/or COVID-19 as the primary outcome. Trial power may be reduced if tests are not conducted at the peak of viral shedding or are done incorrectly. Not accounting for influenza vaccination may also result in misclassification of people testing positive on serology as infected. In most mask trials, laboratory confirmation was through PCR, but some studies used serology as well. Influenza and SARS-CoV-2 have a higher risk of morbidity and mortality than other seasonal respiratory viruses measured in some RCTs. However, in reality, a wide range of pathogens cause respiratory illnesses and are transmitted in a similar way regardless of how severe the illness is. Although several RCTs report “other respiratory viruses” as an outcome, separate analysis is typically provided for influenza and, more recently, for COVID-19. A pooled analysis of two large RCTs reported significantly lower rates of laboratory-confirmed viral respiratory infections, even those assumed to be spread predominantly by large droplets, among participants who used a continuous N95 respirator (143).

Combining dissimilar interventions

Meta-analyses commonly and erroneously combine dissimilar interventions, such as a trial of advice to wear a mask when going out of the home combined with a trial of advice to wear a mask inside the home in the presence of a sick family member (144). Some community trials examined masks only in combination with another intervention such as hand hygiene. Such trials do not allow estimation of the efficacy of masks alone, though the rationale for such designs is pragmatic (hand hygiene should accompany mask use to prevent self-contamination) (145). Almost all meta-analyses of N95 use in health-care combine trials on intermittent and continuous use of the device. However, crucially, intermittent use of an N95 respirator by health-care staff when caring for infected or potentially infected patients or conducting an AGMP is a different intervention to wearing a respirator continuously during an entire work shift. In some RCTs, participants used masks and respirators only when they worked within 1-2m of patients with suspected or confirmed respiratory illness or when doing an AGMP, but not at other times (25, 146). This assumes health workers can accurately self-identify situations of exposure risk and fails to consider wider airborne exposure (including to asymptomatic or presymptomatically infected staff or patients) in health-care settings (48). The only trial to compare continuous and intermittent N95 use showed that continuous wearing of an N95 is protective, but intermittent use is not, and that intermittent N95 use and surgical masks were equally inefficient (147). This is consistent with trials that compared intermittent N95 use with surgical masks and found no difference (25, 146). Other examples of combining dissimilar interventions include combining masking to protect the uninfected wearer with masking of sick people ("source control") to protect their contacts and combining studies of masking with studies of masking plus handwashing (9).

Combining different settings

Meta-analysis should combine only studies that were done in similar settings, but widely cited meta-analyses of mask trials combined dissimilar settings such as health-care and community settings (9). Even among community settings, there is heterogeneity. Households with an infected member are the highest-risk community setting, but a wide range of non-household community settings are commonly combined with household studies in meta-analyses (9). Moreover, in health-care settings, masks are used for occupational protection, and it is a responsibility of the employer to protect the health of employees (148). Masks may also provide source control to protect patients from asymptomatically infected health workers, but to our knowledge no study has investigated this. A meta-analysis of aged care outbreaks did show that universal masking of staff was protective and resulted in smaller outbreak attack rates (149).

Combining heterogeneous outcomes

When combining studies in a meta-analysis, the outcome being combined should be homogeneous. Mask trials may use clinical, laboratory-confirmed, or a combination of outcomes. Widely cited meta-analyses of mask trials combined dissimilar outcomes (9). The use of a definition of ILI (141) as a clinical outcome is problematic because most adults do not have fever (a prerequisite for the ILI definition) in the presence of a confirmed respiratory viral infection (142). Some RCTs have used a definition of CRI, which does not mandate fever and is more sensitive (115). A common mistake in meta-analyses is combining studies with dissimilar laboratory outcomes, such as RCTs whose outcomes were influenza confirmed by PCR plus serology with other RCTs that used only PCR (9). For influenza, serology may be positive following *either* infection *or* vaccination, and seropositivity is far more common than PCR positivity in such trials (25, 146). This flaw in the review process gives disproportionate weight to trials that used a less specific outcome (serology) than those that use PCR only. This can substantially distort findings because positive serology is numerically far greater than positive PCR results (9, 146). Furthermore, the interpretation of a single high titer compared to rising titers with paired sera may lead to misclassification. If participants are being vaccinated against the pathogen being tested, analysis should account for this (including the timing of vaccination relative to the positive test) to avoid misclassification bias.

A new meta-analysis: justification of approach

To address our methodological concerns about previous studies (notably, the mask section of the 2023 Cochrane review [9]), we separated dissimilar settings, interventions, and outcome measures for a new meta-analysis of published RCTs. Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) guidelines were followed (PRISMA flowchart is available on request from CRM). Meta-analysis of single proportions was performed using R 4.1.3, using the 'metafor' and 'meta' packages. A random effects model was used throughout. Heterogeneity was assessed using I^2 and Q statistics. The restricted maximum-likelihood estimator method was used to estimate between-study variance (τ^2). Statistical significance was defined as a two-sided P-value of <0.05. To examine the efficacy of masks and respirators in community and health-care settings, we searched PubMed and Embase for RCTs in these settings. We grouped community RCTs into "primary prevention" (masking to protect the wearer) (27, 144, 150–156) and source control (masking to protect others in the community) (157–159). Because health-care settings present different risks and issues, we examined the effectiveness of masks and respirators in community and health-care settings separately. For the meta-analyses reported here, we excluded RCTs of source control and analyzed only primary prevention RCTs. In community RCTs, we separately analyzed RCTs of mask and RCTs of masks plus hand hygiene. We analyzed outcomes of CRI, ILI, and laboratory (PCR)-confirmed influenza and other respiratory viruses (including influenza and COVID-19). Serological data were excluded to remove heterogeneity of outcome. We found six RCTs in health-care settings comparing various types of masks and respirators (24, 25, 115, 146, 147, 160). We analyzed data on targeted (intermittent) and continuous use of respirators separately.

For all trials, we extracted the following data: study design, year, type of intervention, primary and secondary outcomes, total number of participants, participants with each outcome, main results, and limitations as reported by authors. We tabulated study characteristics and performed meta-analyses using the subgroup analysis approach by outcome measures (161). We used the random effects model to estimate the respective pooled risk ratios (RRs) and 95% confidence intervals (CIs). We prepared forest plots to show pooled estimates and corresponding 95% CIs. Reanalysis of RCTs of Masks in Community Settings reports the findings of this reanalysis for community settings, and Reanalysis of RCTs of Masks and Respirators in Health-care Settings reports findings for health-care settings.

Reanalysis of RCTs of masks in community settings

Table 3 summarizes published RCTs conducted in community settings, noting that in some, the intervention being tested was "policy or guidance" to wear a mask.

Figure 3 shows the forest plot comparing medical masks with controls in community settings. There was a significant difference between arms for ILI (influenza-like illness or COVID-like illness), which was significantly lower in the mask arm compared to the control arm (RR 0.89, 95% CI 0.87–0.91). There was no significant difference in any other outcome between these two arms. Figure 4 shows the forest plot comparing medical masks plus hand hygiene with no-mask control. Incidence of PCR-confirmed influenza was significantly lower in the masks plus hand hygiene arm (RR 0.63, 95% CI 0.42–0.92).

TABLE 3 RCTs of masks and respirators in community settings[b]

Author, year	Design, methods	Population, intervention, comparison	Outcomes	Results	Comments, limitations
Cowling et al., 2008 (153)	Cluster RCT (by household) in Hong Kong	Households where one member had ILI were randomized to three arms: medical masks, hand hygiene, and control (n = 350); masking by index case and household contacts	Self-reported influenza symptoms, laboratory-confirmed influenza (by culture or RT-PCR) in household; nose and throat swabs taken from each household contact, except for asymptomatic children under the age of 2, at baseline and days 3 and 6	Rates of laboratory-confirmed influenza (OR 1.16, 95% CI 0.31–4.34) and ILI (OR 0.88, 95% CI 0.34–2.27) were not significantly different in masks vs control arm.	Pilot study which informed Cowling et al. (2009), underpowered, compliance 45% in index cases and 21% in household contacts; compliance data showed that some index cases in control and hand hygiene arms used medical masks
Cowling et al., 2009 (145)	Cluster RCT (by household) in Hong Kong	Households where one member had ILI were randomized to three arms: medical masks plus hand hygiene, hand hygiene, and control (education). Both index cases and household contacts used masks (n = 794); masking by index case and household contacts.	Self-reported influenza symptoms, laboratory-confirmed influenza (by RT-PCR) in household; all household members tested with throat swab regardless of symptoms at baseline, days 3 and 6	Rates of laboratory-confirmed influenza not significantly different in three arms. Significant difference if masks + hand hygiene within 36 hours of illness onset (OR 0.33 and 95% CI 0.13–0.87). Hand hygiene alone was not significant.	No separate medical mask arm, making it difficult to estimate efficacy of masks alone; pragmatic trial design, as hand hygiene should accompany mask use; compliance 49% in index cases and 26% in household contacts. Compliance data showed that some index cases in the control and hand hygiene arms used medical masks
MacIntyre et al., 2009 (144)	Cluster RCT (by household) from 2006 to 2007 in Sydney, Australia	Households where a child had ILI were randomized to three arms: medical masks, P2 respirators (equivalent to N95), and control (n = 286); masking (medical masks and P2 respirators) by household contacts.	Self-reported ILI, laboratory-confirmed respiratory infection by multiplex respiratory PCR; index case and contacts tested at baseline. Household contacts tested if symptoms developed over 2 weeks of daily follow up.	In the intention-to-treat analysis, no significant difference in any outcome; adherent use of respirators or medical masks significantly reduced risk of ILI (HR 0.26, 95% CI 0.09–0.77).	Low compliance: 21% of household contacts wore masks often/always. Adherence with mask wearing was low and unsustained (25%–30% by day 5).
Aiello et al., 2010 (150)	Cluster RCT of college students (by university residence house) in Ann Arbor, USA, during 2006–2007 influenza season	Three arms: medical masks, medical masks + hand hygiene, control (n = 1297). Intervention arms started after lab confirmation of influenza infection on the university campus. On the basis of the size and demographic similarity of residential halls, seven halls were included as intervention or control units. No index cases or contacts were specified for mask intervention.	Self-reported ILI, laboratory-confirmed influenza (by culture or RT-PCR). Study nurses collected throat specimens from students with ILI for laboratory examinations.	Intention-to-treat analysis found no significant difference in ILI in the three arms. Significant reduction in ILI in the medical masks plus hand hygiene arm in weeks 4–6 ($P < 0.05$)	Not all ILI cases (n = 368) were laboratory tested (n = 94); no data on compliance. Week 4–6 data reflects a period of higher influenza circulation.
[a]Larson et al (154)	Block-randomized household RCT in Manhattan, USA	Three arms: HE, HE + hand sanitizer, HE + hand sanitizer + medical masks (n = 2,788) Households where an ILI occurred in any household members, inclusive of ill person and caretaker (if the index case was a child younger than 18 years of age). Masking after the household contact or caretaker was within 3 ft of a person with an ILI for 7 days or until	Self-reported ILI, self-reported upper respiratory infection (URI), laboratory-confirmed influenza (by culture or PCR). Project staff made a home visit within 24–48 hours to the household of a reported ILI case to collect a sample for laboratory testing for influenza.	No significant difference in rates of URI, ILI, or laboratory-confirmed influenza between the three arms; significantly lower secondary attack rates of URI/ILI/influenza in HE + hand sanitizer + medical mask arm (OR 0.82, 95% CI 0.70–0.97).	No separate medical mask arm, making it difficult to evaluate efficacy of masks alone; pragmatic trial design, as hand hygiene should accompany mask use. Low compliance and around half of households in the masks arm used masks within 48 hours. Unlike other trials, there was no index case at home,

(*Continued on next page*)

TABLE 3 RCTs of masks and respirators in community settings[b] (*Continued*)

Author, year	Design, methods	Population, intervention, comparison	Outcomes	Results	Comments, limitations
		symptoms disappeared. The ill person was also advised to wear a mask within 3 ft of other household members, if possible.			so exposure was less likely, resulting in lower statistical power.
Simmerman et al., 2011 (155)[a]	Cluster RCT (by household) in Bangkok, Thailand, from 2008 to 2009. Index case was a child with influenza, and subjects were their household members.	Households where a child had ILI were randomized to three arms: hand hygiene, hand hygiene + medical masks, control (n = 885); masking by index case and household contacts	Self-reported ILI, laboratory confirmed influenza (by PCR or serology) in family members. Index cases in the outpatient department were identified by a nasal swab rapid test. If the test was positive, one additional nasal swab and one throat swab were collected from the index case. During home visits, one nasal swab and one throat swab were collected from the index case and from all household contacts. For serology, blood samples were collected on days 1 and 21.	No significant difference in secondary influenza infection rates in hand hygiene arm (OR 1.20, 95% CI 0.76–1.88) and hand hygiene plus medial masks arm (OR1.16, 95% CI 0.74–1.82).	No separate medical mask arm, making it difficult to evaluate efficacy of masks alone; pragmatic trial design, as hand hygiene should accompany mask use. The influenza A (H1N1) pandemic occurred during the study, resulting in mask use substantially increasing among the index cases (4%–52%) and families (17.6%–67.7%) in control arm.
Aiello et al., 2012 (151)	Cluster RCT of college students (by university residence house) in Michigan, USA, during the 2007–2008 influenza season	Three arms: medical masks, medical masks + hand hygiene, control (n = 1,111). Masking in the intervention arms started, following laboratory confirmation of influenza on campus. All residents used the intervention.	Clinically diagnosed and laboratory confirmed influenza (by RT-PCR) College students responded to questions on ILI symptoms via weekly surveys. Throat swabs were collected from students who reported ILI, and the swabs were tested for influenza.	No overall difference in ILI and laboratory-confirmed influenza in three arms. A significant reduction was observed in ILL in medical masks + hand hygiene arm in weeks 3–6 ($P < 0.05$). Masks alone were not protective.	Compliance was good. Masks were worn for approximately 5 hours/day. ILI was self-reported. Authors concluded that effect in masks + hand hygiene arm may have been due to hand hygiene, as medical masks alone were not significant.
Suess et al., 2012 (156)	Cluster RCT (by household) in Berlin, Germany, during 2009/2010 pandemic influenza season and 2010/2011 influenza season	Household members of influenza-positive cases were randomized to three arms: medical masks, medical masks + hand hygiene, control (n = 218). Participants in both mask arms were asked to wear masks at all times when the index patient was in the room. Masking by index case and household contacts	Laboratory-confirmed influenza infection and ILI. Nasal wash, using isotonic saline into one nostril of the participants, was conducted. Nasal swabs were collected by using virus transport swabs. Specimens were analyzed by RT-PCR.	Intention-to-treat analysis showed no significant difference in rates of laboratory-confirmed influenza and ILI in all arms. Risk of influenza was significantly lower if data from two intervention arms (masks and masks plus hand hygiene) were pooled and intervention was applied within 36 hours of onset of symptoms (OR 0.16 and 95% CI 0.03–0.92).	Compliance with masks was low (approximately 50% of the participants wore masks "mostly" or "always"). Monetary benefits provided. Only household contacts used a mask (index case did not mask). The short incubation period of influenza (2–3 days) means applying an intervention after a household member has influenza may not have efficacy.
Alfelali et al., 2020 (152)	Cluster RCT (by pilgrim tent) over three consecutive Hajj seasons (2013, 2014, and	Two arms: masks, no masks (n = 6,388); masking randomized by tents that accommodated up to 150 pilgrims for up to 5 days during Hajj in	Laboratory-confirmed viral respiratory infections and clinical respiratory infections. Study tents were visited	In both intention-to-treat and per-protocol analyses, masks were not effective	Compliance was low in both arms - overall (24.7% participants used masks daily, while 47.7% used masks

(*Continued on next page*)

TABLE 3 RCTs of masks and respirators in community settings[b] (*Continued*)

Author, year	Design, methods	Population, intervention, comparison	Outcomes	Results	Comments, limitations
	2015) in Makkah, Saudi Arabia	2013, 2014, and 2015. Pilgrims were supplied with masks (per protocol: to be worn for 24 hours daily for 4 days during Hajj, if possible).	twice daily. Nasal swabs were obtained from those who had flu-like symptoms. Respiratory viruses were detected using a real-time PCR test. For the analysis, pilgrims who used at least one facemask daily during Hajj were considered to have masked that day.	against laboratory-confirmed viral respiratory infections or clinical respiratory infection	intermittently). Moreover, in control arms a few participants also used masks daily (14.3%) or intermittently (34.9%).
Bundgaard et al., 2021 (140)	RCT in Denmark, from April to May 2020	Two arms: recommendation to wear masks when outside the home, no recommendation (*n* = 4,862) Community-based study, no prerequisite for exposure to infection Conducted in a low-incidence period of COVID-19 (3 April–2 June 2020) when Danish authorities did not recommend mask use in the community	SARS-CoV-2 infection by antibody testing, PCR, or hospital diagnosis; PCR positivity for other respiratory viruses. Participants received materials and instructions for antibody testing and for collecting an oropharyngeal/nasal swab sample for PCR testing at 1 month and whenever they had COVID-19 like symptoms. Participants registered symptoms and results of tests in the online REDCap system.	No significant difference in any outcome	Primary outcome includes both PCR-positive SARS-CoV-2 infection and antibody-positive SARS-CoV-2 (IgM or IgG). Sample size powered to detect a 50% reduction of infection, so was underpowered to detect smaller differences. Fewer than 50% used masks as recommended. Study funded by Salling Foundation, with Salling being the largest retailer in Denmark. Antibody testing was done by participants themselves. No ethics approval was sought.
Abaluck et al., 2022 (27)	Cluster RCT (by village), in rural Bangladesh from November 2020 to April 2021	Three arms: surgical masks, cloth masks, and no masks (*n* = 336,010). Household members in the intervention villages were asked to use masks (surgical masks and cloth masks) when they are outside and around other people, during the study period, which was a COVID-19 pandemic period. Community-based study, no prerequisite for exposure to infection.	Symptomatic SARS-CoV-2 seroprevalence and symptoms consistent with COVID-19 illness. Participants reported COVID-19 like symptoms that were experienced by any household member in the previous week and previous month. Blood samples from participants with COVID-19-like symptoms were collected and tested for IgG antibodies against SARS-CoV-2.	Mask use was efficacious in reducing COVID symptoms and symptomatic seroprevalence of SARS-CoV-2; benefits were greater in older people (35% reduction in symptomatic seroprevalence). Effect size 30%–80% larger for surgical masks compared to cloth masks	Large, community-wide study; geographically contiguous villages used as intervention vs control to reduce bias caused by different rates of transmission by location. Only serologically positive cases of SARS-CoV-2 were included. Surgical masks were reused, and cloth masks could be washed and reused. Mask wearing increased from 13% to 43% in intervention villages; results reflect protective effects despite low compliance. Social distancing was unchanged by interventions. Only symptomatic people tested, so infection rate underestimated and may have biased results toward the null.

[a]Larson et al., 2010, was not included in the forest plot as it did not have a separate mask arm. Simmerman 2011 was not included in the forest plot as serology results could not be separated from PCR in the laboratory-confirmed results.
[b]HE, health education; OR, odds ratio; RT-PCR, reverse transcription PCR.

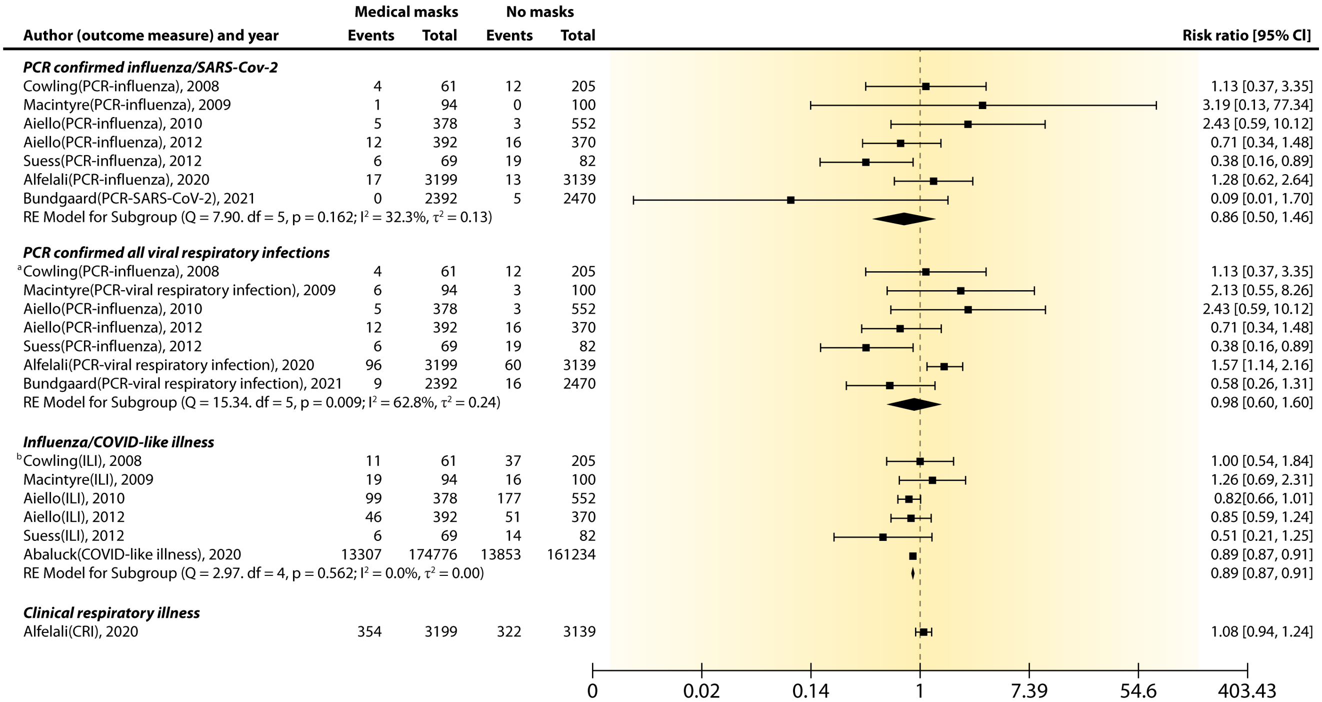

FIG 3 Forest plot of community trials: medical masks vs control (no masks). For references, see Table 3. There is some heterogeneity between studies. In some trials, infection or ILI symptoms in an index case was a pre-requisite for recruitment of family members (e.g., Cowling 2008, Suess 2012 and MacIntyre 2009) while in other trials, the intervention was triggered when a first case was confirmed in a non-household setting (Aiello 1 2010, Aiello 2 2012). In others (Abaluck 2022, Bundgaard 2021) there was no pre-requisite for exposure and the intervention was applied to general community (Abaluck 2022). The rate of infection is expected to be higher in settings such as households with an index case. Two primary prevention trials (Cowling 2008 and Suess 2012) also included "source control" – i.e., the index case wearing a mask in addition to their contacts). This was a mixed intervention, but we included them in the analysis because they also included primary prevention in contacts. a. Cowling 2008, PCR positive case numbers are calculated from rates provided in the paper in Table 2 and approximated to nearest whole number (e.g., Medical/surgical mask arm: 0.07*61 = 4 cases, Control arm: 0.06*205 = 12 cases). b. Cowling 2008, Clinical definition 1 in the paper included fever ≥ 38°C, hence placed under Influenza-like illness; case numbers are calculated from rates provided in the paper in Table 2 and approximated to nearest whole number (e.g., Medical/surgical mask arm: 0.18*61 = 11 cases; Control arm: 0.18*205 = 37 cases).

These results suggest that masks plus hand hygiene is probably a more effective infection prevention intervention than masks alone in community settings, but masks do appear to give some protection against ILI. Hand hygiene may protect against direct

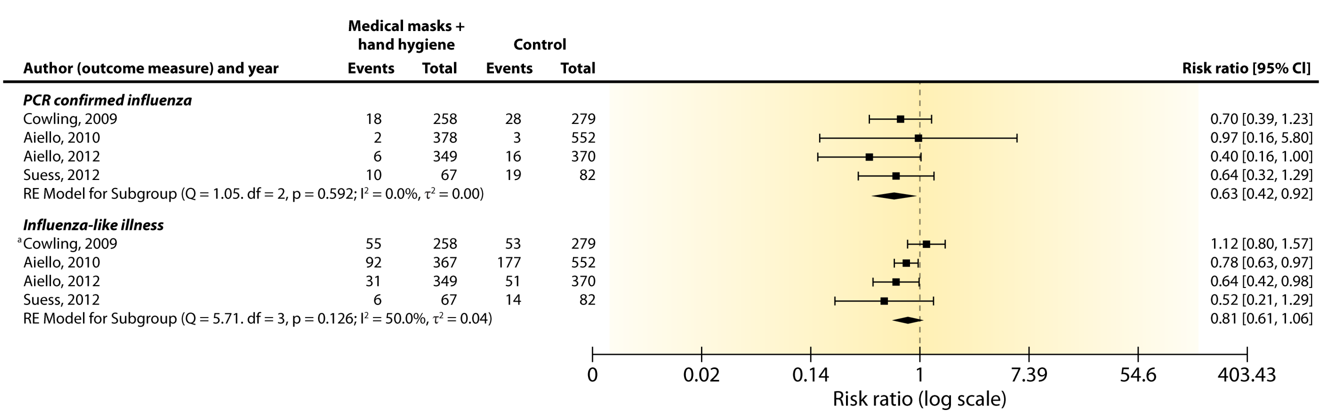

FIG 4 Forest plot of community trials: hand hygiene + medical masks vs control. For references, see Table 3. Among the community trials there is some heterogeneity between studies. In some trials, infection or ILI symptoms in an index case was a pre-requisite for recruitment of family members (e.g., Cowling 2009, Suess 2012), while in other trials, the intervention was triggered when a first case was confirmed in a non-household setting (Aiello 1 2010, Aiello 2 2012). a. Cowling 2009, Clinical definition 1 in the paper included fever ≥ 38°C, hence placed under Influenza-like illness.

TABLE 4 RCTs of masks and respirators in health-care settings

Author, year	Design and methods	Population, intervention, and comparison	Outcomes	Results	Comments and limitations
Loeb et al., 2009 (25)	Non-inferiority RCT conducted in eight tertiary care hospitals in Ontario, Canada, from 2008 to 2009	Nurses: targeted use (selected circumstances such as conducting an aerosol-generating medical procedure) of fit-tested N95 respirators compared to medical masks (n = 422)	Laboratory-confirmed influenza infection by PCR or seroconversion (fourfold rise in hemagglutinin titers) Participants were assessed for flu-like symptoms twice weekly. If a symptom was reported, the study nurse was notified, and a nasal specimen was collected.	No significant difference in outcomes. Influenza cases in medical masks arm 23.6% vs 22.9% in respirator arm (absolute risk difference −0.73%; 95% CI −8.8%-7.3%).	No control arm, hence lack of difference between arms could indicate equal efficacy or equal inefficacy. Nurses who could not pass a fit test were excluded. No data on compliance. Trial was terminated early due to influenza A(H1N1)pdm09, as respirator use became mandatory. Trial was "non-inferiority", but there was no gold standard of efficacy prior to this for comparison, because the superiority of any tested intervention was not previously demonstrated in any RCT (and could not be demonstrated in this RCT without a control arm).
MacIntyre et al., 2011 (115)	Cluster RCT in 15 hospitals in Beijing, China, from 2008 to 2009.	Three arms: medical mask, fit-tested N95 respirator, and non-fit tested N95 respirator. All interventions were used continuously. A convenience control group was also included (n = 1,441)	Self-reported CRI, self-reported ILI, laboratory-confirmed respiratory viral infection including influenza, by multiplex respiratory PCR Trained nurses and doctors collected two pharyngeal swabs from participants with ILI or CRI. Pharyngeal swabs tested by PCR for respiratory viruses	In intention-to-treat analysis, rate of CRI was significantly lower in non-fit-tested N95 respirators compared to medical masks (OR 0.48 (0.24–0.98). The medical mask and fit-tested N95 arms were non-significant. Both N95 arms combined were significantly protective.	Self-reported compliance 68-86%. Lack of power for PCR-confirmed influenza. The convenience control group was selected from hospitals which do not routinely use masks, as the ethics committee deemed it unethical to allocate subjects to no mask. The study often cited on the need for fit testing, but the low fit test failure rate in this study is specific to the N95 used in the study, and cannot be generalized to other N95s.
MacIntyre et al., 2013 (147)	Cluster RCT in 68 wards (19 hospitals) in Beijing, China, from 2010 to 2011	Three arms: continuous use of N95 respirators, targeted use of N95 respirators for high-risk situations, continuous use of medical masks (n = 1,669)	Self-reported CRI, self-reported ILI, laboratory-confirmed viral infection, including influenza by multiplex respiratory PCR Swabs of tonsils and posterior pharyngeal wall collected from participant(s) who had ILI or CRI symptoms. Swabs tested by PCR for respiratory viruses	Rates of CRI (HR[a] 0.39, 95% CI 0.21–0.71) and bacterial colonization (HR 0.40, 95% CI 0.21–0.73) were significantly lower in continuous use of N95 respirator arm.	Self-reported compliance 57%–82%. Lack of power for PCR-confirmed influenza. Results consistent with references (25) and (146), showing equal inefficacy of masks and targeted (i.e., non-continuous) N95, but adds to the evidence base because the latter two trials did not have a control or other arm for comparison.
MacIntyre et al., 2015 (160)	Cluster RCT in 14 secondary- and tertiary-level hospitals in Hanoi, Vietnam, in 2011	Three arms: medical masks, cloth masks, and no-mask control (n = 1,607)	CRI, ILI, and laboratory-confirmed viral respiratory infection, including influenza, by multiplex respiratory PCR. Swabs from tonsils and posterior pharyngeal wall	In Intention-to-treat analysis, ILI rate significantly higher in cloth mask arm (RR 13.00, 95% CI 1.69–100.07) vs medical mask arm. Post-hoc analysis by actual	Mask use was high in the control group, so a post hoc analysis was done comparing all participants who used only a medical mask (from the control arm and the

(Continued on next page)

TABLE 4 RCTs of masks and respirators in health-care settings (*Continued*)

Author, year	Design and methods	Population, intervention, and comparison	Outcomes	Results	Comments and limitations
			taken from participants who had CRI or ILI symptoms. Swabs tested by RT-PCR for respiratory viruses.	mask use showed significantly higher ILI rates (RR = 6.64, 95% CI 1.45–28.65) and laboratory-confirmed virus (RR = 1.72, 95% CI 1.01–2.94) in those using cloth masks vs medical masks.	medical masks arm) with all participants who used only a cloth mask (from the control arm and the cloth masks arm). Self-reported compliance with mask use and hand hygiene was reported. There was a lack of influenza circulation during the study period. A subsequent study using data collected from this trial showed that poor washing of the cloth masks contributed to poor outcomes and that, if machine washed, they performed equally to a medical mask (164).
Radonovich et al., 2019 (146)	Cluster RCT at 137 outpatient sites at 7 US medical centers from 2011 to 2015	Two arms: targeted use of medical masks and targeted use of N95s (n = 5,180)	Laboratory-confirmed influenza (PCR or serology), acute respiratory illness, laboratory-detected respiratory infection, ILI Swabs of the anterior nares and oropharynx were obtained from participants. who reported respiratory symptoms. During each 12-week intervention period, two random swabs were obtained from all participants, typically while asymptomatic. Swabs were tested for influenza A or B using PCR. Serum samples obtained each year from all participants for influenza hemagglutinin levels before and after peak viral respiratory season	No significant difference in any outcome between medical masks and targeted N95	Outpatient study with no control arm. Intervention comprised wearing the mask or respirator when within 6 ft (1.83 m) of patients with suspected or confirmed respiratory infection. Approximately 65% of participants in respirator and mask arms reported wearing their device "always." A post hoc analysis found that the presence of preschool-aged children in the home was associated with a higher risk of respiratory infections among participating health-care workers (165).
Loeb et al., 2022 (24)	Non-inferiority RCT in 29 health-care facilities in Canada, Israel, Pakistan, and Egypt (n = 1,004)	Two arms: medical masks, fit-tested N95 respirators	SARS-CoV-2 tested by reverse transcriptase PCR. Nasopharyngeal swabs were obtained from symptomatic participants. Blood tests at baseline and end of follow-up for IgG antibodies. Other outcomes: acute respiratory illness, lower respiratory infection or pneumonia, and work-related absence.	In the intention-to-treat analysis, there was no difference in RT-PCR–confirmed SARS-COV-2 in the medical mask arm compared to the N95 respirator arm (HR 1.14 ,95% CI 0.77 to 1.69). Other outcomes were also non-significant. Combined data from Canada and Israel reported lower rates of COVID-19 in	Prespecified analyses (which do not support the published conclusion of non-inferiority) were omitted (166). Non-inferiority was redefined during the Omicron wave, after 95% of the study period was complete, to accept a hazard ratio of up to 2 (approximately doubling the prespecified margin) as constituting clinically important

(*Continued on next page*)

TABLE 4 RCTs of masks and respirators in health-care settings (*Continued*)

Author, year	Design and methods	Population, intervention, and comparison	Outcomes	Results	Comments and limitations
			Participants were assessed for COVID-19-like symptoms twice weekly.	N95 arm, compared to medical mask arm (4.6% vs 9.5%), but difference was not statistically significant. Corresponding rates of COVID-19 in combined data of Pakistan and Egypt were 11.3% and 10.9%.	inferiority in the medical mask arm. This means anything up to a 99% increase in relative risk associated with a medical mask was considered unimportant. The study's sample size (1,004) was too low to identify clinically important differences in risk and likely to generate a null result. Over 4,200 participants would have been necessary to identify a hazard ratio of 1.5 with 90% power and a one-sided alpha of 0.025 (164). Rolling recruitment with addition of Pakistan and Egypt almost a year later (not included in initial trial registration) and during the Omicron period, compared to Canada and Israel (pre-Omicron). Most trial outcomes were from the Egypt site. Trial registration specifies N95 was intermittent (targeted) use, but authors later stated it was continuous. Therefore, intervention fidelity and consistency is unclear. Substantial changes to protocol were made on multiple occasions as the study unfolded. Other criticisms have been summarized in a preprint (166).

[a]HR, hazard ratio.

Author (outcome measure) and year	N95 respirators Events	N95 respirators Total	Medical masks Events	Medical masks Total	Risk ratio [95% CI]
PCR confirmed influenza					
Loeb, 2009	4	210	6	212	0.67 [0.19, 2.35]
[a]Macintyre, 2011	3	949	5	492	0.31 [0.07, 1.30]
[b]Macintyre (targeted), 2013	2	516	1	572	2.22 [0.20, 24.38]
Macintyre (continuous), 2013	3	581	1	572	2.95 [0.31, 28.31]
Radonovich, 2019	77	2512	81	2668	1.01 [0.74, 1.37]
RE Model for Subgroup (Q = 4.22. df = 4, p = 0.377; I^2 = 0.0%, τ^2 = 0.00)					0.97 [0.73, 1.29]
PCR confirmed all viral respiratory infections					
Loeb, 2009	26	210	26	212	1.01 [0.61, 1.68]
[a]Macintyre, 2011	13	949	13	492	0.52 [0.24, 1.11]
[b]Macintyre (targeted), 2013	17	516	19	572	0.99 [0.52, 1.89]
Macintyre (continuous), 2013	13	581	19	572	0.67 [0.34, 1.35]
Radonovich, 2019	371	2512	417	2668	0.94 [0.83, 1.07]
Loeb (PCR-confirmed SARS-CoV-2), 2022	47	507	52	497	0.89 [0.61, 1.29]
RE Model for Subgroup (Q = 3.33. df = 5, p = 0.649; I^2 = 0.0%, τ^2 = 0.00)					0.92 [0.82, 1.03]
Influenza-like illness					
Loeb, 2009	2	210	9	212	0.22 [0.05, 1.03]
[a]Macintyre, 2011	3	949	3	492	0.52 [0.11, 2.56]
[b]Macintyre (targeted), 2013	2	516	4	572	0.55 [0.10, 3.01]
Macintyre (continuous), 2013	6	581	4	572	1.48 [0.42, 5.21]
Radonovich, 2019	128	2512	166	2668	0.82 [0.65, 1.02]
RE Model for Subgroup (Q = 4.10. df = 4, p = 0.392; I^2 = 0.0%, τ^2 = 0.00)					0.80 [0.65, 0.99]
Clinical respiratory illness					
Loeb, 2009	13	210	13	212	1.01 [0.48, 2.13]
[a]Macintyre, 2011	37	949	33	492	0.58 [0.37, 0.92]
[b]Macintyre (targeted), 2013	61	516	98	572	0.69 [0.51, 0.93]
Macintyre (continuous), 2013	42	581	98	572	0.42 [0.30, 0.59]
Radonovich, 2019	1556	2512	1711	2668	0.97 [0.93, 1.01]
Loeb, 2022	31	507	27	497	1.13 [0.68, 1.86]
RE Model for Subgroup (Q = 31.51. df = 5, p < 0.001; I^2 = 82.7%, τ^2 = 0.11)					0.74 [0.54, 1.01]

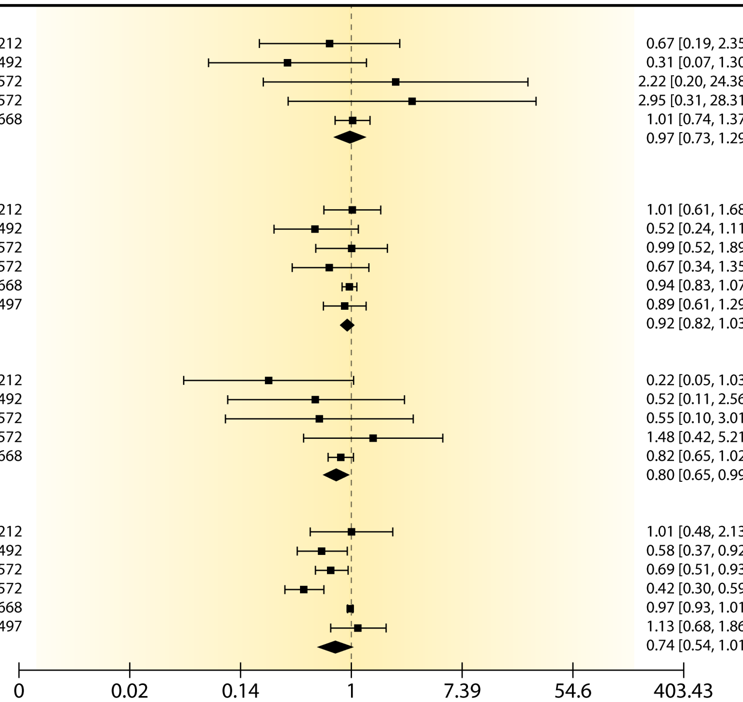

FIG 5 Forest plot of trials in health-care workers: any use of N95 vs medical masks. For references, see Table 4. a. MacIntyre 2011 combined values for fit-tested and not-fit tested arms = All N95 arm. b. MacIntyre 2013 (targeted N95 arm) vs control arm was continuous use of medical masks.

contact transmission and transmission through contaminated masks. Pathogens may be present on the outer surface of masks, resulting in self-contamination (162). Guidance for the public recommends hand hygiene before and after mask use (163).

Author (outcome measure) and year	N95 respirators (continuous) Events	N95 respirators (continuous) Total	Medical masks Events	Medical masks Total	Risk ratio [95% CI]
PCR confirmed influenza					
[a]Macintyre, 2011	3	949	5	492	0.31 [0.07, 1.30]
Macintyre, 2013	3	581	1	572	2.95 [0.31, 28.31]
RE Model for Subgroup (Q = 2.72. df = 1, p = 0.099; I^2 = 63.3%, τ^2 = 1.60)					0.80 [0.09, 7.09]
PCR confirmed all viral respiratory infections					
[a]Macintyre, 2011	13	949	13	492	0.52 [0.24, 1.11]
Macintyre, 2013	13	581	19	572	0.67 [0.34, 1.35]
RE Model for Subgroup (Q = 0.25. df = 1, p = 0.619; I^2 = 0.0%, τ^2 = 0.00)					0.60 [0.36, 1.00]
Influenza/COVID-like illness					
[a]Macintyre, 2011	3	949	3	492	0.52 [0.11, 2.56]
Macintyre, 2013	6	581	4	572	1.48 [0.42, 5.21]
RE Model for Subgroup (Q = 1.02. df = 1, p = 0.313; I^2 = 1.7%, τ^2 = 0.01)					0.99 [0.36, 2.68]
Clinical respiratory illness					
[a]Macintyre, 2011	37	949	33	492	0.58 [0.37, 0.92]
Macintyre, 2013	42	581	98	572	0.42 [0.30, 0.59]
RE Model for Subgroup (Q = 1.21. df = 1, p = 0.271; I^2 = 17.4%, τ^2 = 0.01)					0.48 [0.35, 0.65]

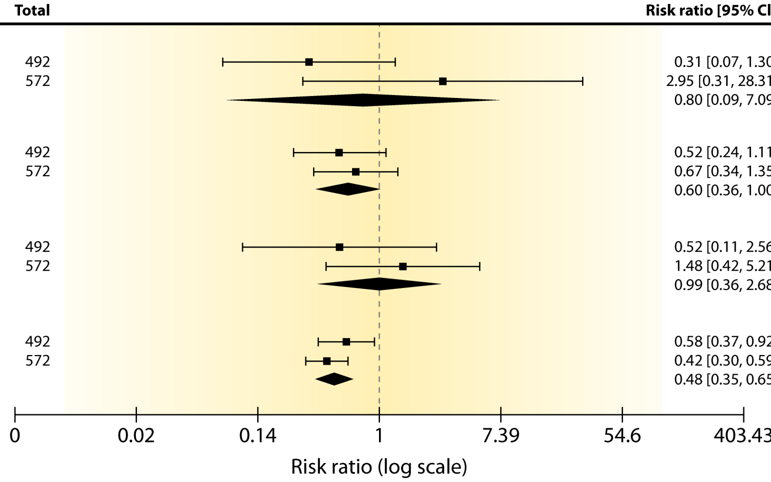

FIG 6 Forest plot of trials in health-care workers: continuous use of N95 vs medical masks. For references, see Table 4. a. MacIntyre 2011 combined values for fit-tested and not-fit tested arms = All N95 arm.

Reanalysis of RCTs of masks and respirators in health-care settings

Table 4 lists the included studies in our reanalysis of RCTs of masks and respirators in health-care settings. Figure 5 and 6 show the results of our meta-analysis on these studies.

The forest plot in Fig. 5 includes all RCTs which compared N95s (regardless of whether they were used intermittently or continuously) with medical masks in health-care settings. Incidence of ILI was significantly lower in the N95 arm (RR 0.80, 95% CI 0.65–0.99).

Figure 6 shows the same primary studies as Fig. 5, differently analyzed to separate continuous from intermittent use of N95s. This important reanalysis shows that continuous use of N95 respirators compared to medical masks in health-care settings was significantly protective against CRI (RR 0.48, 95%CI 0.35–0.65). Rates of ILI, laboratory (PCR)-confirmed respiratory viruses, and laboratory (PCR)-confirmed influenza were also lower in the continuous N95 arm, but differences were not statistically significant.

Comment

The findings presented in Reanalysis of RCTs of Masks in Community Settings and Reanalysis of RCTs of Masks and Respirators in Health-care Settings differ from those of some previous systematic reviews and meta-analyses, which did not acknowledge or fully take account of the heterogeneities listed in Methodological Challenges in Trials and Meta-Analyses of Masks and gave greater weight to trials with a large number of seropositive subjects (9, 167–170); those analyses generally concluded that the evidence for masking was weak. However, our findings broadly align with other reviews which did attempt to address the methodological issues listed in Methodological Challenges in Trials and Meta-Analyses of Masks. Kim et al., for example, found that in studies where adherence to masking was measured, high adherence conferred significantly greater protection against respiratory viruses [odds ratio (OR) 0.43, 95% CI 0.23–0.82] (171). Kollepara et al. noted that almost all published RCTs of mask efficacy were underpowered; they too found a dose-response effect with adherence and concluded that "The studies [of mask efficacy] that did not find statistically significant effects prove only that masks cannot offer protection if they are not worn" (172).

We did not perform a meta-analysis of RCTs of source control, some of which looked at efficacy endpoints and one of which looked at the amount of virus in exhaled breath with and without masks, due to the small number of trials and our focus in this review on primary prevention (173, 174). Leung et al. found that surgical masks had a limited effect on rhinovirus compared to other viruses, highlighting specific differences in respiratory viruses (174). The policy implications of masks are most relevant for potential pandemic pathogens such as influenza or novel coronaviruses, but data on other respiratory viruses transmitted through respiratory aerosols are informative, regardless of the severity of the infection and varying degrees of airborne transmission.

NON-EXPERIMENTAL EVIDENCE ON EFFICACY

Observational studies

Early in the COVID-19 pandemic, when there were no RCTs of masks for SARS-COV-2, Chu et al. conducted a systematic review and meta-analysis of 44 observational studies involving SARS-1, MERS, and SARS-CoV-2. (175) They found that masks and respirators reduced the risk of infection by 85% (adjusted odds ratio [aOR] 0.15, 95% CI 0.07–0.34), more in health-care settings (RR 0.30, 95% CI 0.22–0.41) but also in the community (RR 0.56, 95% CI 0.40–0.79; $p_{\text{interaction}} = 0.049$). They attributed this greater effect in health-care settings to the predominant use of N95 respirators in those settings. In a subanalysis, they showed that respirators were, overall, 96% effective (aOR 0.04, 95% CI 0.004–0.30) compared with masks, which were 67% effective (aOR 0.33, 95% CI 0.17–0.61; $p_{\text{interaction}} = 0.090$) (175). Chu et al. concluded in 2020 that use of face masks "could result in a large reduction in risk of infection … with stronger associations with N95 or similar respirators compared with single-use surgical masks or similar," though they described the evidence base at the time as "low certainty" (175). Li et al., who included a sensitivity analysis, concluded that masking was likely to be effective in the community and highly effective in the protection of health-care workers during outbreaks; they called for further RCTs to confirm these findings (176).

To update and extend this early review of observational studies, we supplemented key studies of which we were aware through a Medline search using terms (mask OR respirator) AND (COVID-19 OR SARS-CoV-2 OR pandemic) AND epidemiology AND year of publication >2019, a strategy which identified 199 unique publications. Abstracts were reviewed to identify relevant studies for inclusion, which were supplemented with studies of which we were previously aware, including three reviews (14, 175, 177). Masking was often one component of bundled prevention strategies (178), so we sought to focus on studies in which mask and respirator effects could be isolated from other contemporaneous interventions.

Evidence which consistently demonstrated the efficacy of cloth masks, medical masks, and respirators against infection with SARS-CoV-2 emerged early in the pandemic, from classical epidemiological (cohort and case-control) studies (179–186), database-derived real-world evidence (187, 188), and ecological studies and quasi-experiments related to policy change (189–198). A community-based case-control study performed in California found a dose-response relationship between both mask or respirator quality and frequency of use and reduction in SARS-CoV-2 risk: the aOR for SARS-CoV-2 infection associated with mask use was 0.44 (95% CI 0.24–0.82); surgical mask aOR was 0.34 (95% CI 0.13–0.90), and respirator use aOR was 0.17 (95% CI 0.05–0.64) (179).

In cohort studies in schools, COVID-19 risk in students' family members and confirmed SARS-CoV-2 risk among elementary school attendees were reduced by 30%–40% when teachers wore masks (180, 181), supporting the hypothesis that masks have some efficacy as source control. Mask effects were multiplicative with the 30%–50% reduction in risk that was achieved through ventilation improvement in schools (180). A university-based cohort study that evaluated transmission probability between identified SARS-CoV-2 cases and their contacts found that the risk of transmission to contacts when neither individual used a mask was fivefold higher (aOR 4.9, 95% CI 1.4–31.1) than when both were masked, implying an effectiveness of around 80% for infection prevention (95% CI 29%–97%) (182).

Cohort and case-control studies in health-care workers provided early evidence of a substantial reduction in SARS-CoV-2 risk associated with consistent and continuous use of respirators for prevention. Wang et al. noted early in 2020 that the adjusted odds of occupational acquisition of SARS-CoV-2 was over 400 times lower (lower-bound CI 98) among hospital staff who wore N95 respirators while on duty in respiratory, ICU and infectious diseases departments than among those working in other departments (who did not wear any kind of face covering continuously), notwithstanding the higher risk of SARS-CoV-2 exposure in the former (183). In a case-control study from Thailand completed and published in 2020, Duong-Ngern and colleagues found that consistent use of even cloth or surgical masks by health-care workers reduced SARS-CoV-2 infection risk by 77% (95% CI 40%–91%) after adjusting for other risk factors (184). In a longitudinal cohort study, Dörr et al. found that risk of infection with SARS-CoV-2 was reduced by use of a respirator compared to a mask when in contact with COVID-19 patients, after adjustment for both frequency of exposure and vaccination status (adjusted effectiveness 44%, 95% CI 26%–57%) (185). Hutchinson and colleagues evaluated clusters of hospital-acquired SARS-CoV-2 infections during the emergence of the Delta variant (June–October 2021) in Sydney, Australia, and found that all four documented health-care worker clusters and all workplace-acquired SARS-CoV-2 infections during this period occurred on general wards where surgical masks were used as PPE. By contrast, no clusters and no workplace-acquired infections occurred in critical care areas where respirators were used as PPE (186).

As with the above (and other) classical epidemiological studies, database-driven real-world evidence strongly supports efficacy of masks at the population level, especially but not exclusively when mandated (199). Rader et al., using online survey data from approximately 380,000 individuals in the United States in 2020, found that a 10% increase in likelihood of self-reported mask use was associated with a 3.5-fold increase (95% CI 2.0–6.4) in the probability of the local reproduction number being reduced below 1 (187). Leech and colleagues noted that in European jurisdictions during the first year of the COVID-19 pandemic, spontaneous mask wearing was common and was only moderately increased by government mandates (188). They performed a Bayesian analysis to estimate actual mask (as opposed to mandate) effect, independent of other public health measures such as restrictions on mobility and public gatherings, using multi-jurisdictional survey data. They found that universal masking appeared to independently reduce transmission by 25% (95% CI 6%–43%), with this estimate proving robust in numerous sensitivity analyses.

Ecological studies and quasi-experiments have demonstrated the impact of changes in mask policy at the level of health-care institutions, schools, and jurisdictions. The first such analysis evaluated the impact of jurisdictional mask mandates in the United States using a difference-in-differences approach and found a progressive decline in epidemic growth rates (to −2% per day 21 days after mandate introduction) when compared to a referent period of 1–5 days prior to mandate introduction (189). Bollyky et al. found that mask use in US states was a predictor of lower infection incidence during the COVID-19 pandemic but was not independently associated with decreased mortality (196). In this study, vaccine mandates were associated with decreased risk of death, but mask mandates were not (196). A study by Krishnamachari and colleagues found that earlier implementation of mask mandates in US states was associated with lower COVID-19 incidence than later implementation (197). Using a structural equation modeling approach, Chernozhukov et al. (198) estimated the impact of workplace mask mandates in the United States and also simulated counterfactuals in which national mask mandates were promptly instituted early in the pandemic (March 2020). They estimated that cumulative cases and deaths during the first pandemic wave (to June 2020) could have been reduced by 21% (9%–32%) and 34% (19%–47%), respectively, which would have been equivalent to 34,000 deaths prevented during that time period (198). A difference-in-differences analysis performed in Boston following the February 2022 lifting of school mask mandates found that removal of mandates was associated with a surge in SARS-CoV-2 incidence of 45 cases per 1,000 students and staff. The study was likely subject to negative confounding, as higher-risk school districts maintained mask mandates longer, suggesting that true mask effects may be even greater (190).

Ferris and colleagues used a quasi-experiment resulting from a change in mask and respirator policy at a teaching hospital in the United Kingdom to demonstrate the effectiveness of respirator use for prevention of health-care associated COVID-19 (191). The hospital in question was divided into "red" wards, which accepted infected patients, and "green" wards, which did not. At baseline, both red and green wards used surgical masks for worker protection. COVID-19 incidence on green wards correlated well with local community incidence, implying that infections were less likely to be occupationally acquired. By contrast, incidence on red wards was initially 31-fold higher (95% CI 5.9 to infinity), implying an occupationally acquired attributable fraction of 97% (83%–100%). With a switch to FFP3 respirators on red wards, incidence fell to below that seen on green wards; model fitting via maximum likelihood estimation provided estimates of FFP3 respirator effectiveness of 52%–100% against occupationally acquired COVID-19 infection.

In Ontario, Canada, a quasi-experiment on mask mandates was created when each of 34 health regions introduced mask mandates in a staggered fashion in the summer of 2020. Karavainov and colleagues used statistical modeling and found that mask mandates were likely to have reduced transmission by approximately 24% when adjusted for other public health control measures as well as population mobility (192).

The publicly reported case counts used by Karavainov et al. are likely to be strongly influenced by high rates of testing in older adults (those aged over 70) and by outbreaks in long-term care institutions (193). We developed an approach to adjusting case counts for undertesting in younger individuals (194) and found that when we repeated Karavainov et al.'s analysis using test-adjusted case counts, mask mandate effects were far stronger (effectiveness, depending on the modeling approach used, ranged from 44% to 86%) (195).

The protective effects of masks and respirators consistently demonstrated against SARS-CoV-2 transmission across observational studies were summarized in a 2021 systematic review by Talic et al. (177). This evidence is all the more remarkable as there are several reasons to expect that the direction of biases in observational epidemiological studies of masks and respirators would be toward the null (i.e., published estimates are likely to underestimate actual effectiveness). Social desirability bias may lead to overreporting of mask use, resulting in non-differential misclassification of exposures (200). Mask mandates may occur in conjunction with enhanced surveillance activities and case finding (195). The indirect effects of masks as source control, which diminishes risk for the population as a whole, would also result in diminished effectiveness estimates due to protection of unmasked individuals. Kollepara and colleagues have also demonstrated that variability in mask adherence is an important determinant of mask effectiveness but is seldom considered when calculating sample size. The result is underpowered observational studies, which are unlikely to demonstrate statistically significant protection by masks even if a strong protective effect exists (172).

Modeling masking

Mathematical models of communicable diseases are used to describe and simulate epidemic processes, either by describing observed disease patterns in populations as non-specific logistic growth processes (201, 202) or by representing underlying mechanisms affecting these patterns such as transmission probability, duration of infectivity, effectiveness of immunity, and effectiveness of interventions designed to prevent transmission (203). They should be distinguished from statistical models (such as regression models), which make simplifying assumptions about the statistical form and relationships between data elements to draw probabilistic conclusions about gaps between observed and expected findings.

In the context of masks for communicable disease control, mathematical models can be applied in several different ways, including (i) "what if" scenarios, which explore the expected impact of masks and mask directives in specific populations; (ii) model-fitting studies, in which mask effects are inferred at a population level by fitting mechanistic models to empirical data; (iii) exploring multiple influences, for example, masks' bidirectional impact on transmission (i.e., disrupting both transmission and acquisition of infection), in a context that also considers other influences such as population behavior and mixing; these studies typically include sensitivity analyses, which vary the input parameters to produce best-case and worst-case estimates, thereby taking account of uncertainty; and (iv) integrative models, that is, mathematical platforms designed to integrate data on communicable disease dynamics with data from other disciplines such as the physics of aerosol behavior. We consider examples of each category in turn below.

We identified recent mathematical models of SARS-CoV-2 or influenza and community-level mask effect using a targeted PubMed search with terms "mathematical model," ("mask" or "respirator"), ("SARS-CoV-2" or "novel coronavirus" or "influenza"), and ("pandemic" or "epidemic" or "outbreak"). This search identified 30 citations that were reviewed for relevance. We supplemented these with other relevant papers known to the authors, producing a final sample of 28 studies (23, 39, 45, 204–228).

The largest category in our dataset was "what if" analyses—studies which used mathematical models to project the impact of masking on the contours of pandemics, epidemics, and outbreaks (204–212, 222, 223, 225–228). Such studies depend heavily on input parameters derived from mechanistic, observational, and experimental research.

Results are somewhat predictable, since when masks and respirators are parameterized as being sufficiently effective to bring the reproduction number below 1 (either by themselves (204, 212) or in combination with vaccination (207)), it is a mathematical tautology that they will be effective. While "what if" models can serve as a tool for management and communication of uncertainty, they are not crystal balls that can predict outcomes or determine policy.

"What if" models can also be used as platforms to estimate the expected economic attractiveness of mask or respirator use under uncertainty. Mukerji and colleagues (226) reviewed the available literature on model-based health economic analyses of masks and respirators for prevention of infection. However, of the seven studies they identified, four used either simple back-of-the-envelope calculations or fixed-risk models to estimate economic attractiveness. Such approaches are inappropriate when evaluating the economic attractiveness of communicable disease control interventions (229), as the knock-on effects of reduced transmission cannot be estimated. Interestingly, modeling by Tracht et al. that did incorporate dynamic transmission projected mask use during a pandemic to be broadly cost-saving across a range of mask effectiveness estimates (225). Two additional studies that used transmission models presented results in a manner that prevented estimation of mask cost-effectiveness (227, 228).

Few studies identified for this review used model fitting to estimate mask effectiveness. Mohammadi and colleagues used modeling to estimate the reduction in SARS-CoV-2 transmission associated with masking to be between 39% and 100% (213). Other work, such as that by Yang and colleagues, did not attempt to disentangle mask effects from the impact of other contemporaneous public health interventions (214), highlighting a limitation of mathematical model-based parameter estimation, which mathematical models may share with statistical models of observational data.

We identified three modeling studies looking at the effect of multiple influences under conditions of uncertainty using sensitivity analysis (23, 215, 216). Iboi et al. evaluated the interplay between mask efficacy, mask compliance, and control of a SARS-CoV-2 outbreak in Nigeria, and identified parameter combinations for which masking would drive the reproduction number below 1 (215).

Fisman et al. explored the relationship between bidirectional mask effects and the tendency of populations to self-assort based on behaviors (such as masking), such that masked and unmasked individuals are more likely to interact with one another than with individuals from the other group (23). These authors found that for realistic values of mask efficacy, masks could drive epidemic reproduction numbers below one in combination with other disease control measures, but the tendency of unmasked people to assort with one another made disease control more challenging (Fig. 7) (23).

Watanabe and Hasegawa, using network-based modeling (a mathematical model that explicitly incorporates the structure of contact networks, with infection moving along "edges" or connections between individuals), came to similar conclusions (216).

We identified a small empirical literature which combined communicable disease modeling (including effects of masks and other interventions aimed at disrupting transmission of airborne respiratory pathogens) with data from aerosol science, which has a long tradition of using mathematical models to predict the effects of an infective individual on risk among others sharing air in an indoor space (45, 217–221). Aerosol scientists conventionally use the Wells-Riley equation (or variants of it) to simulate the infective "quanta" produced by an infective individual (217–219), such that infectivity is proportional to Q/V, where Q is quantum production and V is the ventilation rate in a given indoor space; Q can be further decomposed into component parameters based on the known natural history of a given infectious disease (217). By contrast, infectious disease dynamic models typically represent airborne infectious diseases by modeling "mass action," where the rate of infection among susceptible individuals is a function of $\beta \times I$, where I is the number of infectives in the population and β is an infectivity constant (220). The Wells-Riley expression for infectious quanta can be used as a stand-in for β in infectious disease models, in a manner that allows infectious aerosols to be represented

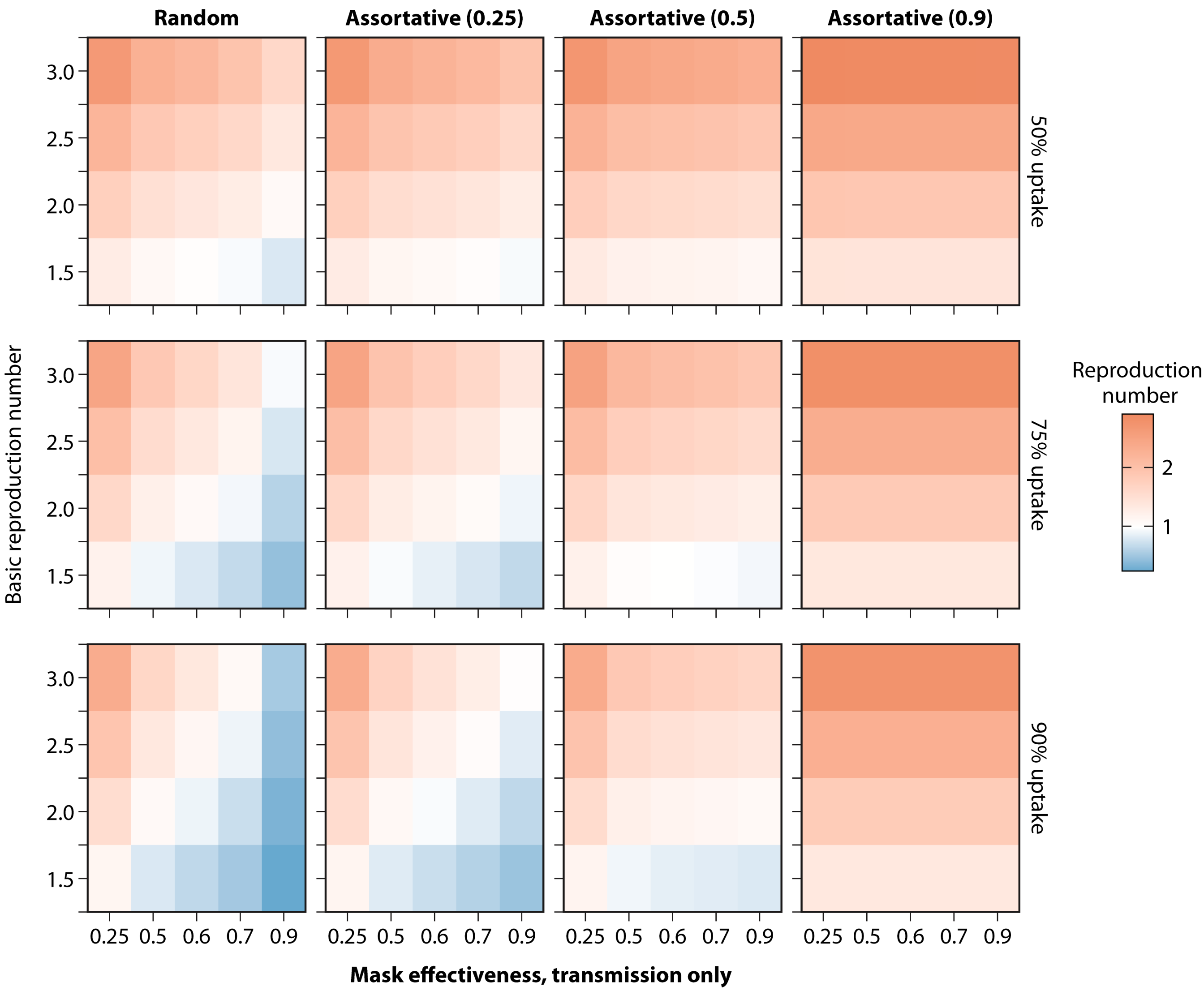

FIG 7 Model of mask effectiveness in different levels of population assortativity. Reproduced under Creative Commons license from Fisman et al. (23). Assortativity is the tendency of individuals to interact preferentially with those who are most like themselves. The basic reproduction number (number of secondary cases produced by a primary case in the absence of immunity or control interventions) is on the left-side vertical axis; mask uptake in the population is on the right-side vertical axis with lower uptake at the top of the figure, high uptake at the bottom of the figure, and intermediate uptake in the middle of the figure. Mask effectiveness in reducing transmission from masked, infectious individuals is on the bottom horizontal axis with the highest effectiveness to the right and lower effectiveness to the left. Assortativity (the tendency of like to mix with like) is on the top horizontal axis and ranges from random (non-assortative) mixing on the left to highly assortative mixing (with individuals strongly preferring to interact with people like them) at the right. Pink-shaded areas indicate expected effective reproduction numbers above 1, where epidemic growth will continue. Blue-shaded areas represent combinations of parameter values where the reproduction number is reduced below 1 (the threshold where an epidemic will continue to grow). This is easier to achieve with higher mask effectiveness, a lower baseline reproduction number, higher mask uptake, and lower assortativity. The more unmasked people preferentially associate with other unmasked people, the less likely epidemic control is to occur.

mechanistically in models and which would permit incorporation of available data from aerosol science into models of infectious disease dynamics at the population level. Noakes and her colleagues have pioneered integration of these model types (218, 219, 221), with application to relatively small indoor spaces such as hospital wards. Expanding such models to incorporate heterogeneity, population behavior, and larger population sizes represents an exciting frontier for infectious disease modeling.

ADVERSE EFFECTS AND HARMS OF MASKS

Introduction and general adverse effects

Adverse effects of infection control measures must always be compared with the counterfactual scenario of potential increased infections. The existence of adverse effects is not an absolute contraindication to mask wearing, just as adverse effects are not necessarily a contraindication to taking a medication for a health condition, but these effects need to be understood, weighed up and addressed. They can be divided into generic adverse effects of masks on all wearers, which need mitigation at a universal level such as better mask design (this section); effects on wearers in particular risk groups, which need targeted exemptions and mitigations (see Adverse Effects of Masks in People in Particular Risk Groups); effects experienced by some people when those around them are masked, which may need individualized solutions (see Masks and Communication); and harms to the environment (see Single-Use Masks and Respirators: Environmental Impact). It is important to distinguish speculative harms (which, if not refuted by evidence, should be taken into account by a precautionary approach to policy) and empirically demonstrated harms, which should generally carry more weight in policy.

Systematic and comprehensive narrative reviews did not identify serious adverse effects from mask wearing at a whole-of-population level (230–234). These reviews found minor side effects (discussed below) and other more speculative harms including documented viral contamination of masks (but no studies demonstrating transmission of infection from such masks). We consider the documented adverse effects below.

Discomfort and local irritation

Mask wearers commonly experience local irritation of the skin and eyes, pressure effects, and a mechanical acne ("maskne") resulting from contact dermatitis and disruption of skin microbiota (235). Risk of all these increases with duration of use (235) and appears to be high in health-care workers (230, 235). Headache is also common, particularly among those with a history of headache, and increases with duration of mask use (236). Thermal discomfort may occur, particularly in health-care workers wearing full PPE (237–239). Potential mitigations include local measures (topical treatment, cushioning tapes, and moving mask straps away from the ears) and workplace measures such as regular and timely "air breaks" (235, 240, 241). In the longer term, there is a need for improved designs that meet safety standards while ensuring that masks are comfortable to wear for extended periods (241), a topic that is discussed further in Toward Better Masks.

Effects during exercise

The effect of mask wearing on respiratory function has been extensively researched. Statistically significant but transient and clinically insignificant changes in gas exchange and pulmonary function have been detected in healthy individuals wearing masks or respirators during strenuous exercise (234, 242, 243) and during manual work (244). Many though not all primary studies found modest reductions in exercise performance, but participants often reported discomfort and subjective increase in breathing resistance. Accurate measurement of the physiological effects of mask wearing is challenging in several respects (245). Wearing spirometry apparatus over a face mask (242) can generate artifactual errors in estimates of breathing pressure and perceived respiratory effort that may exaggerate the impacts of masking on pulmonary function (246, 247). Overall, these findings suggest that individuals may choose to avoid high-intensity exercise while wearing a tightly fitting respirator. A concern raised early in the pandemic about the risk of cardiac dysrhythmias during exercise (248) was not confirmed in subsequent systematic reviews (240).

Speculated but unconfirmed harms in anti-mask discourse

Although speculative claims have been made for widespread serious harms (especially to cardiorespiratory and metabolic health from masking), consistent findings across what is now a large body of research have shown a reassuring absence of clinically meaningful serious harms (230, 232, 240). Furthermore, no serious safety incidents have been documented despite periods of high community uptake of masking during pandemic waves (31, 249). Risk compensation behaviors (paying less attention to other protective measures when masked) have been proposed as an adverse effect of masking, but studies which looked for such behaviors did not find them, and indeed masking may lead to wearers adopting more protective behaviors (250). An exception is the work of Wadud et al., who found that community mobility increased after implementation of mask mandates (251) and characterized this change as risk compensation. However, as noted by Cooper et al. (252), trade-offs between (effective) mask mandates, on the one hand, and mobility and in-person work hours, on the other hand, mean that rather than being regarded as a negative consequence of population masking, mask effects could be framed as the potentiation of normal activities, be they economic (e.g., work), social (e.g., family visits), or educational (e.g., school attendance) without the worsening in population health status that would occur in their absence.

It is worth noting that the scientific literature contains peer-reviewed articles which selectively cite flawed empirical studies to support the argument that masks are universally harmful. In 2021, for example, a research letter in *JAMA Pediatrics* claimed that masks increased the carbon dioxide content of inhaled air in children aged 6–17 years (253). Shortly after publication, this letter was retracted by the journal following complaints by scientists, citing "fundamental concerns" with the study methodology and uncertainty regarding the validity of the findings and conclusions (254), but it has attracted over a million views. That evidently flawed study was later republished in a different journal (255). Similarly, a recent systematic review of harmful effects of masking on breathing (256) was quickly retracted by the journal because of concerns with scientific validity (257), but it continues to be circulated on social media.

Adverse effects of masks in people in particular risk groups

Masking can be particularly challenging and even contraindicated in certain groups. We consider some of these groups here and acknowledge that there may be others.

Children

"Children" range in age from 0 to 17 years. Infants are a special case: they have narrower airways, which may exacerbate the increased work of breathing during mask wearing, and they are less able to remove a mask if experiencing discomfort or obstruction. Masks are therefore not recommended for children under 2 years (258). Empirical studies are occasionally cited selectively in narrative reviews to support a strongly held view that masks are dangerous in older children. In some cases, the primary studies cited did not show the adverse effects claimed or did not include children. A 2021 narrative review examining the impacts of masking on respiratory infections in children aged 7–14 years did not identify any adverse effects, but only two randomized trials on children (124 participants) were included (259). Additional trials on school-aged children published since that review have shown no adverse impact of masking on cognitive performance (n = 133) (260).

While the absence of serious adverse effects in RCTs of masks in children is reassuring up to a point, the studies were small and had methodological limitations. However, despite widespread uptake of mask wearing in school-aged children around the world (e.g., masking of children was widespread in Asia in some settings and situations before the COVID-19 pandemic), there have, to our knowledge, been no formal reports of incidents of harm. An observational study of cloth masks in US primary schools (261) (n = 1,000 students in pre-K, kindergarten, first, or second grades) reported appropriate mask usage for an average of 77% of the school day over a 4-week period. No serious harms were reported, and there were fewer than 15 reports each of stress, ears hurting/headaches, communication difficulties, feeling hot, and difficulty breathing (the last resolved after a short break from the mask).

Several commentators have speculated that wearing a mask would increase hand-to-face contact among children. Empirical evidence has shown the opposite: either no difference or a decrease in hand-to-face contact among children wearing masks (262, 263).

Children's own opinions on masks are highly relevant and rarely elicited. When they are, the responses tend to be positive. In a survey of 42,767 Canadian adolescents during the 2020/2021 school year, 81.9% supported wearing masks in indoor public spaces; 67.8% supported wearing them in school (23.1% were neutral and 9.1% opposed) (264). Coelho et al. conducted a survey and held focus groups to understand children's experience of masking (265); acceptability appeared high, but some children reported barriers to communication, learning, and socialization. The authors recommended strategies to address these barriers, including the use of clear face masks. A recent systematic review of children's views on masks covered 30 primary studies and concluded that acceptability appeared high, but comfort, fit, style (including age-appropriate designs), communication, and environmental issues were of high priority for children; the review also found that parents were sometimes more opposed to masks for their children than the children themselves were (266). These findings challenge statements by people speaking on behalf of children and claiming that masks are unacceptable to them (267, 268).

Adults with medical conditions

Table 5 summarizes empirical evidence on particular medical conditions, based mainly on previous reviews, along with suggested mitigations (230, 232, 233, 240). While primary studies were small, few in number and of variable scientific quality, common sense suggests a need for flexibility and precaution. Note that some of the conditions listed in Table 5 substantially increase vulnerability to respiratory infections, underscoring the point that the risks of masking should be balanced against the benefits.

During mask mandates, people who cannot wear a mask may opt to wear a distinctive lanyard in public or use a flashcard to communicate their exemption status. We found no research studies on the use or acceptability of such interventions.

Masks and communication

Masks reduce the intelligibility of verbal communication because they attenuate speech sounds, particularly in the high-frequency range (283, 284), and present a barrier to lipreading. They also affect non-verbal communication by reducing the visibility of social cues and emotions (285), which can increase the stress of social interactions. Masks are challenging for sign language users because they impede access to essential components of grammar and meaning that are conveyed by facial expressions and lip movements. These disruptive impacts on social connection and information sharing have been most frequently investigated in health-care settings (286), but they are relevant to many other situations including in-person education (287, 288). While most adverse effects of masks affect the wearer, communication difficulties mainly affect other people.

Communication difficulties arising from masking can be a cause of frustration in everyone, but some groups may experience significant disadvantage and distress when others are masked. They include

- D/deaf people and others who need to see full faces to access communication; this group includes but is not limited to people who identify as disabled (286, 289).

TABLE 5 Medical conditions requiring caution with masking

Condition	Possible adverse impact of masking and relevant studies	Suggested mitigation
Allergic rhinitis	Mask-induced worsening of rhinorrhea (269), though masks may also reduce exposure to environmental allergens (e.g., pollen) (270)	Experiment with different designs and situations. Exemption may be needed when mandates are in place.
Alzheimer's disease	Impossible to achieve consistent fit and adherence [people with severe Alzheimer's did not wear masks properly or at all during pandemic peaks (271, 272)]	Focus on other preventive measures, including indoor air quality, reduced mixing, and masking of staff and visitors
Chronic lung disease	Subjective difficulty in breathing because of increased breathing resistance, especially during exercise (234); in severe lung disease, theoretical (but not empirically demonstrated) risk of compromised gas exchange.	People with mild and well-controlled asthma can usually mask normally; those with more severe respiratory conditions should be assessed individually. If necessary, avoid indoor crowded situations. Low-breathing resistance respirators may be better tolerated. Exemption may be needed.
End-stage kidney disease	Decrease in oxygenation and increased respiratory effort, of uncertain clinical significance (based on a single small study conducted during the 2003 SARS-1 outbreak) (273)	Assess individually, taking account that such people may be vulnerable to severe complications if infected. Avoid indoor crowded situations.
Epilepsy	Risk of hyperventilation, which could theoretically trigger a seizure (based mainly on expert opinion) (274, 275).	Avoid indoor crowded situations. Mask should be removed from anyone having a seizure. Exemption may be needed.
Facial conditions	Facial trauma or surgery and painful conditions of the face (e.g., trigeminal neuralgia) may make masking difficult or painful [no empirical studies but often mentioned in guidance (233)].	Assess individually; exemption may be needed.
Heart failure	Possible deterioration of cardiopulmonary function during exercise (276)	Test to see if mask is tolerated during indoor exercise. If symptomatic in such situations, exercise outdoors.
Laryngeal or tracheal surgery	People with laryngectomy or tracheotomy are at greatly increased risk of respiratory infections, and some are immunocompromised (e.g., during cancer treatment) (277).	Mask should be worn over the tracheotomy.
Mental health conditions (e.g., anxiety, autism, depression, and claustrophobia)	Worsening of anxiety, panic, and sense of suffocation (278–280). People who have experienced trauma may feel profound distress while masking (281).	Experiment with different designs (an elastomeric respirator with high breathability may be less symptom inducing). Take frequent breaks. Grounding techniques can be helpful for trauma-related anxiety. Exemption may be needed.
Pregnancy-related conditions	Pregnancy is a high-risk state for complications of COVID-19 (including miscarriage); empirical evidence on masking in pregnancy is limited (240). A single-challenge study in 20 pregnant health-care workers showed changes in some physiological variables (e.g., tidal volume) with respirator materials (282). That study had major design flaws (e.g., breathing was not through an actual respirator but through a tiny segment of N95 filter material cut from a respirator).	While definitive evidence is lacking, masking during strenuous exercise or demanding physical work when pregnant is not advised. In other situations, advantages of masking while pregnant appear to outweigh disadvantages.

- People who are neurodiverse, have cognitive difficulties, or have experience of trauma, and others who experience distress from seeing or interacting with masked people (290).
- Infants and young children in childcare and early education settings who may experience harms to speech and socialization from interacting with masked adults. However, parents and primary caregivers, the most important source of these developmental skills (291), would not normally be masked in the home. Harms to language outcomes have not been empirically demonstrated, but well-designed trials and longitudinal studies are needed to identify best practice for communication and language learning during periods of high respiratory infection risk (292).

The above impacts are best considered on a case-by-case basis and must be balanced against infection risk and vulnerability of wearers. Even if communication is more difficult, it may not be in a person's best interests for people interacting with them to be unmasked. Instead, better communication strategies and other approaches to support ongoing masking may be more appropriate (285); see Marler and Ditton (293) and Grote and Izgaren (286) for solutions informed by speech and language therapy expertise and lived experience respectively. Amplification by lapel microphones remains effective in the presence of masking (283) and is a readily available technological solution for classrooms and other settings, reducing the need for increased vocal effort and the risk of vocal fatigue (284). Written communication, flashcards, and speech-to-text apps can be helpful, but video relay may be a better option for first-language sign users (294). Some masks have a clear panel which allows the lower half of the face to be seen (295), although this solution may be limited by lack of availability (286) and fogging (296).

When the above strategies are not adequate or appropriate, a decision may be made to suspend a mask requirement (see Masking as Policy).

SOCIAL AND POLITICAL ASPECTS OF MASKING

Why people mask and why they don't

The reasons why people mask (or not) can be broadly divided into psychological, sociocultural, sociomaterial, and socioeconomic.

Psychological research, summarized in a number of reviews (232, 297–299), considers the influence of personality traits, emotions, mental health and well-being, attitudes, and cognition on acceptance and uptake of mask wearing. Uncertainty and other stressors such as grief, anger, social isolation, and exposure to trauma have a significant impact on mental health during epidemics (299). Public health measures such as recommendations or mandates to mask can help alleviate stress and feelings of loss of control by offering positive steps for action, but they can also be experienced as restrictions on autonomy and freedom, leading to psychological reactance and non-adherence (297, 299). The psychological need for autonomy (the ability to have free will and choice over one's actions), relatedness (feeling socially connected to others), and competence (the feeling that we are effective and capable and have mastery over our circumstances) helps explain people's reluctance to mask (232). Psychological reactions may help explain non-compliance and anger toward those who do comply (232), which sometimes manifests as public protests and the formation of groups to push against universal masking policies (300, 301). For those wearing masks, being subjected to racism or other acts of discrimination, social exclusion, and aggression can cause a variety of psychological reactions including fear, rejection, loneliness, and anxiety (302–305).

The psychological phenomenon of pandemic fatigue—feelings of burnout or emotional exhaustion in response to continuing pandemic-related stressors and uncertainties—has been suggested as an explanation for the decreasing willingness of people to engage in COVID-19 protective behaviors, including masking over time (306). Pandemic fatigue is associated with traits such as narcissism, entitlement, perception of greater affluence, pessimism, and apathy, as well as having previously been infected with and successfully recovered from SARS-CoV-2, and being vaccinated (307). These factors are not necessarily fixed, however. Both compliance with and rejection of public health recommendations can change, responding to aspects in pandemic conditions such as the stringency of restrictions, case numbers, and personal experience of infection (308), as well as changes in perception of risk (309). The concept of pandemic fatigue has been invoked by governments and health authorities as a political strategy to delay the introduction of or loosen COVID-19 protections and frame COVID-19 safety as a matter of personal responsibility and choice, though a review of empirical studies suggests that such fatigue is less of an issue than is often claimed (298).

Sociocultural research on masks, summarized in a book (301), has shown how preexisting cultural norms powerfully influence uptake of masking during epidemics and outbreaks. Countries such as Japan, Korea, and China accept universal masking as a community and personal preventive health practice and used this approach long before the COVID-19 pandemic. These countries also accept masking in health-care settings. In contrast, most countries in the Global North and some in Africa depict mask wearing as strange and perhaps suspicious. For social groups and cultures in which mask wearing as a public health practice is unfamiliar or stigmatized, developing social norms to encourage use is particularly important.

Throughout the COVID-19 pandemic, the meanings and practices related to masks have shifted substantially. The sociocultural, economic, geographical, and political contexts in which masks have been produced, promoted, and worn (or not) are crucial to understand these dynamics. The vast consumer culture that sprang up to cater to a universal masking market, involving hand-crafted and mass-produced decorative masks for special occasions as well as increased production and promotion of medical-style masks, is evidence of how quickly the symbolic meanings and practices related to a simple object can change and diversify well beyond its original role in a specific cultural context (301, 310).

As COVID-19 has shifted from a headline-grabbing global crisis to one of many ongoing challenges to human health, masking and support for it have declined, raising societal and ethical questions about whether and for how long the healthy majority should compromise their “freedom” to help protect the clinically vulnerable (for whom a COVID-19 infection could be life-threatening) and prevent the long-term sequelae of the condition (311). Given that health-care facilities remain high-risk settings for both staff and patients (312), masking of health-care workers has become a management-vs-unions issue, especially in relation to whether and when more costly respirator-grade respiratory protection is needed (148, 313).

Support for and adherence to mask-wearing recommendations or mandates are influenced by sociodemographic attributes such as age group, gender, ethnicity/race, and spiritual beliefs and by the stringency of public health policy (mandates achieve higher levels of adherence than recommendations) (31, 314). Masking attitudes and behavior are also strongly influenced by social group membership and identity. In particular, right-wing political views and libertarian identity in the United States are strong predicators of unwillingness to mask (315), and people who place high value on altruism and social solidarity are more supportive of universal masking (316).

Sociomaterial research has explored the role of cultural meaning in supporting people’s efforts to use masks (301, 310, 317). The symbolic meanings of face masks in popular culture, as evidenced in such phenomena as street art portrayals, public health signage, and online shops selling bespoke masks, are major contributors to the public dialogue. For those unaccustomed to mask wearing, habits of use—such as purchasing masks, having them ready to place on the face, learning how to don and doff, what to do with the mask when it is removed from the face—must be learned and incorporated into everyday routines. Some people find the physical sensation of having a mask on the face uncomfortable or confining, as they adjust to becoming more aware of their own breath and learn new ways to respire and to relate to and communicate with others with their noses and mouths obscured; for others, masking and seeing others mask makes them feel safe and protected, part of a community supporting each other.

Research from a socioeconomic and political economy perspective has demonstrated how susceptibility to and outcomes from COVID-19 are strongly patterned by social determinants such as family income, housing, workplace conditions and precarity, all of which influence people’s ability to obtain and consistently use masks (318). When resources are available, and people feel part of communities of practice in which the majority of their fellow citizens are following public health advice, adherence to rules and recommendations for mask wearing are high, but when this is not the case, unwillingness to mask is socially supported and reinforced (298, 303, 305).

Communicating information and managing misinformation about masks

The COVID-19 pandemic generally has been characterized by misinformation and disinformation (inadvertent and deliberate dissemination of false and misleading information respectively) (319). How public forums are used to convey messages and information about public health preventive practices such as mask wearing are vital to public acceptance or rejection. When government and public health leaders nationally or globally regularly advocate for and model mask wearing in public, this can contribute to developing and promoting strong public support. Conversely, when leaders fail to wear masks or make negative comments about them, these actions also significantly detract from the public health messaging (301).

Since the early months of the COVID-19 pandemic, there have been multiple examples of major health agencies and government leaders (up to and including the World Health Organization) promoting incorrect or misleading narratives about how SARS-CoV-2 is transmitted and the best modes of prevention. These include downplaying the value of universal masking, or even taking a specific position *against* masks, overemphasizing droplet-oriented measures such as hand hygiene, and failing to convey the superior benefits of respirators over cloth or medical masks, leading to public confusion and overreliance on handwashing and hand sanitizing in the community (62).

In recent years, the spreading of anti-science misinformation and disinformation via social media has fomented challenges to public health measures, including conspiracy and apocalyptic theories that actively challenge mask-wearing recommendations or mandates (320–324). The circulation of conspiracy and anti-mask theories damages public health messaging and undermines the trust the public holds in authorities, eroding the social license for regulations and mandates. Exponents of such viewpoints attract high levels of media attention, which amplifies their controversial stance, generating concerns about civil unrest and fostering dissent. In such circumstances, adherence to masking recommendations is increased if public health authorities and other trusted sources provide clear and frequent public communication about the importance of masking in high-risk settings such as crowded indoor spaces (325).

MASKING AS POLICY

Different types of mask policies

Mask policies are stated government and organizational positions on how masks should be used for prevention and control of respiratory infections (and also other hazards such as air pollution (326)). There are four overlapping kinds.

Mask policies for targeted personal protection

These are recommendations for mask use by individuals for whom the consequences of infection are likely to be significantly worse than for others (including people who are elderly, pregnant, immunocompromised, or living with severe long-term conditions (327)) and those for whom avoiding infection is particularly important (e.g., those about to have surgery, travel, or participate in critical activities such as high-stakes sporting events). The scope of mask use would depend on individual risk assessment and management, but would typically be indoors and either intermittently or continuously, depending on the risk assessment. Requirements are likely to be increased in specific settings and during times of elevated infection risk; those at highest risk may be advised to wear respirator-grade protection. These policies may be developed or adapted by various interest groups and could be specified as requirements for some highly regulated activities such as elite competitive sports.

Mask policies for specific settings

These are recommendations and requirements for mask use in workplaces (148) or public places such as health-care settings (328, 329) and long-term care facilities (149, 302) where risk of transmission is elevated or there are vulnerable people. Such policies should be developed and interpreted in the context of existing legal standards (e.g., those that cover protection in workplaces) and respiratory protection policies including formal fit-testing of respirators (110). Mask policies in specific settings are more likely to be effective and sustainable if all interested parties work collaboratively to develop them. In health care, for example, interested parties include IPC clinical teams, employers (responsible for occupational health and safety and maintaining workforce capacity, particularly during peaks of infection (148)), independent worker safety experts, staff unions (who advocate for workers' conditions and safety), and patient advocacy groups (e.g., for the clinically vulnerable). The question of what kind of mask or respirator to provide in health-care settings and whether use should be continuous or intermittent is covered in Reanalysis of RCTs of Masks in Community Settings. Mask policies may also be needed in a range of non-health settings, particularly where staff and visitors are at higher risk of infection, for example, indoor, crowded environments with poor ventilation such as hospitality venues, and public transport (330).

Mask policies for seasonal respiratory infections

An increase in seasonal respiratory infections such as influenza and RSV above a preset threshold locally or nationally could warrant setting-specific or more widespread mask use, along with other measures aimed at reducing infections and disease burden. Masking and physical distancing introduced to control COVID-19 infection were associated with a reduction in seasonal influenza (331), lending support for the benefits of such policies for preventing transmission of respiratory infections more broadly.

Mask policies for pandemics

These policies follow the same principles as for seasonal respiratory infections but may be stricter, introduced earlier, and continued for longer, depending on the risk assessment (see next section). If there is early evidence that a pandemic will be particularly severe (e.g., fatality risk above a defined threshold), the pandemic response should attempt to eliminate, rather than merely reduce, the infectious hazard (332). The use of masks and respirators is particularly important in the early stages of a pandemic, when drugs and vaccines are unavailable and to protect health workers. A proactive elimination response, along with border controls, could exclude the emerging disease from a country for a prolonged period, as was achieved by a few countries in the first 1–2 years of the COVID-19 pandemic (333, 334). In such circumstances, mask requirements could be relaxed within a country while elimination is sustained but would still be required for border, health, and quarantine facility workers having contact with infected people entering the country and for local outbreaks. An effective pandemic mask policy can build on individual, setting-specific, and seasonal policies, all of which help to establish mask use as a familiar form of infection control. However, pandemic management needs additional preparedness, planning, and development during interpandemic periods (335). As this paper went to press, the U.S. Centers for Disease Control and Prevention issued interim guidance recommending respirators for worker protection against the emerging threat of Novel Influenza A Virus ("bird flu"), which is spreading among cattle and has infected humans (336).

Developing and implementing mask policies

Mask policies may be voluntary, based on a recommendation, or mandated, based on an occupational or legal requirement. They must balance the risk of potential harms from the policy, ranging from unpopularity and inconvenience through to possible adverse impacts of masking on individuals or groups. The main rationale for *mandating* mask use for control of respiratory infections, especially major epidemics and pandemics, is that the masking behavior of an infected person has serious consequences for the health of other individuals (132) and will affect the pace of exponential growth in cases, possibly leading to health services becoming overwhelmed. Furthermore, a legal mandate generally increases adherence over and above a mere recommendation (337).

Substantial asymptomatic and presymptomatic transmissions of a pathogen such as SARS-CoV-2 are also a strong rationale for universal masking (40, 338). Pandemic control measures that keep people apart are effective but can be highly disruptive.

Masking enables the continuation of normal activities while reducing the probability of transmission.

Such measures should be based on a thorough risk assessment, be proportionate to the hazard, and be maintained for the minimum period needed to control the outbreak. Key steps include a risk assessment to estimate the level of threat; risk management decisions about who (if anyone) should mask under what circumstances, taking account of contextual factors; and an implementation plan for supporting and enforcing mask use, which may include mandates (Table 6).

New pandemic threats pose the largest challenge for risk assessment as key parameters such as infection fatality risk, reproduction number, and extent of transmission from people who have no symptoms (or mild symptoms which they may not recognize as important) are unknown. Decisions must be made with limited and uncertain information. In such situations, there are strong arguments for applying the precautionary principle (341), which has four elements: taking preventive action in the face of uncertainty (i.e., before definitive evidence is available); shifting the burden of proof to the proponents of a potentially hazardous activity; exploring a wide range of alternatives to possibly harmful actions; and increasing public participation in decision making (355). On the basis of evidence presented in The Basic Science of Masking, Clinical Trials of Masks and Respirators, and Non-Experimental Evidence on Efficacy, universal masking has a particular role in preventing transmission and containing outbreaks caused by predominantly airborne pathogens which may cause asymptomatic infection, have a presymptomatic phase, or cause mild symptoms in some people, especially where people gather in shared indoor environments. It is also a simple and safe intervention that may reduce the need for more invasive interventions such as lockdowns.

SINGLE-USE MASKS AND RESPIRATORS: ENVIRONMENTAL IMPACT

The scale of environmental harm

In previous pandemics, reusable cloth masks (and to a lesser extent, single-use paper masks) predominated (356); cloth masks performed similarly to surgical masks in efficacy tests of the day (357). From the 1970s, these products were steadily supplanted (especially in health-care settings) by single-use synthetic masks, which were seen as more convenient and comfortable and reflected a wider trend to a "disposable" culture in health-care settings (356). The COVID-19 pandemic saw a substantial rise in the manufacture, distribution, use, and improper disposal of environmentally unfriendly surgical masks and single-use respirators (358, 359). A number of reviews published since 2022 have documented the environmental impact of these products (360–370). One estimated that 15 trillion face masks are used globally every year, resulting in 2 megatons of waste (360), though the contribution of masks to plastic waste is small compared to other sources such as food packaging or beverage bottles.

Single-use masks and respirators are typically made from synthetic polymers including polypropylene, polyester, polyurethane, polyacrylonitrile, polycarbonate, polyethylene, polystyrene, and polymeric nanofibers and microfibers, which are not biodegradable. Rather, they break down over a period of up to 20–30 years through photodegradation and thermo-oxidative degradation, producing microplastics (<5 mm), which, under various environmental conditions, accumulate and enter ecosystems (361, 362, 366, 367). This is a particular problem in the marine environment, where microplastic waste ingested by marine animals leads to physical harm, toxic effects, and potential entry into the human food chain through seafood consumption (371, 372). In soil, discarded single-use masks and respirators can generate microfibers and nanofibers, negatively impacting soil biological systems, plant growth and invertebrates (373, 374). They also leach harmful chemicals, including metals (cadmium, antimony, copper), heavy metals (lead), antioxidants, dyes, plasticizers and flame retardants into the environment, harming wildlife and disrupting the balance of ecosystems (375, 376).

TABLE 6 Developing and implementing mask policies for respiratory pathogens[a]

Stage	Details
Stage 1: assess the risk posed by the pathogen	Consider: • Epidemiological pattern: notably endemic, seasonal, or pandemic. • Transmission dynamics: including the proportion of transmission that occurs by the airborne route and the extent of asymptomatic and presymptomatic transmission (40). • Probability of exposure: both generally and in specific settings (330). • Consequences of exposure: which depends on infectivity and pathogenicity of the agent, fatality risk, morbidity risk including long-term health effects and impact of repeated exposure, and wider effects on health-care system and societal functioning (339). • Unequal distribution of risk: with heightened vulnerability for particular demographic or clinical risk groups (340). • The precautionary principle (i.e., the need to take account of risks that are not fully known) (see text) (341).
Stage 2: develop the risk management policy	Consider: • Goal: usually disease control (mitigation or suppression), but may be elimination in specific situations (see text). • Proportionality: mask policies are justified if the risk assessment (see stage 1) shows that the infection is likely to have significant negative impact in terms of mortality, morbidity, hospitalization, long-term illness and disability, and health systems (e.g., overwhelming services), social (e.g., loss of schooling), and economic (e.g., lost productivity) consequences (342, 343), and there is evidence that masking is likely to be effective in this outbreak. • Scope of policy: identify what kind of mask policy (see Different Types of Mask Policies) is justified in the circumstances. Combining protection for the wearer with source control is likely to provide the best levels of protection (see What Are Masks and How Do They Work?). Policy design should include consideration of both individual-level efficacy (high-filtration masks, correctly worn) and population coverage (how widely masks are being worn and by whom). • Costs and cost-effectiveness: Ideally, mask policies should include economic analysis to compare the costs of mask use (including supply, communication, support for use, and monitoring and enforcement) and consequences compared to other alternatives that could achieve similar levels of disease control (though this consideration is less relevant for elimination strategies) (344, 345). • Potential adverse effects and unintended consequences: adverse effects include harm to specific groups (e.g., D/deaf people unable to communicate; see Social and Political Aspects of Masking). Some individuals may be unable to tolerate masks; hence, exemption policies are needed. Unintended consequences include resistance and even civil disobedience (300), which may make the policy difficult or impossible to enforce except in highly controlled environments such as health-care settings or airports.
Stage 3: implement and monitor the policy	Consider: • Likelihood of voluntary adherence: if the society has a history of high voluntary adherence to mask use (346, 347) or higher levels of collectivism (348, 349), policy may be effectively enforced through recommendation. If not, a mandate may be necessary. • Mandates, potentially with legal support: requiring individuals to wear a mask over their mouth and nose may be ethically and legally justified to protect the wearer and those around them in high-risk occupational settings such as hospitals and when exposed to harmful substances. For epidemic and pandemic situations, mask policies need to be based in law, for a formally declared public health emergency, with the aim of limiting spread (343, 350). • Mechanisms to encourage adherence and act on non-compliance: Provide clear and proportionate sanctions for non-compliance (e.g., workplace sanctions for employees, registration requirements for health-care providers, exclusion of un-masked visitors from specified settings, and legal enforcement for mask wearing in defined public places) (343, 350). Criminalization and other punitive measures are a last resort because of potential harms such as undermining trust and disadvantaging marginalized populations (351); • Measures to support mask use: provide clear and consistent information and education about when, where, and how to use masks (352), and emphasize benefit to others as well as self. Role-modeling from political and public health agency leaders is a crucial contributor to encourage mask wearing, as are government social marketing campaigns. These measures not only promote mask wearing but also maintain the social license for masking recommendations and mandates (301). Combine top-down and bottom-up measures (353). Ensure a range of effective masks and respirators are available in different sizes, shapes, and designs. Making these highly accessible and minimizing cost by direct provision or subsidies are likely to support their uptake, particularly for disproportionately affected communities (354). • Measures to minimize inequities: ensuring equity across demographic, socioeconomic and ethnic groups will require developing active partnerships with diverse populations and communities, particularly those who are underserved and disproportionally affected by respiratory infections, and providing resources and support as needed (354); • Resources and mechanisms to monitor the policy: including sustaining the response, adjusting it as knowledge and circumstances change (including building in regular policy review mechanisms which incorporate ongoing evidence updates from research, surveillance, and evaluation), and deciding when to discontinue it.

[a]A mask policy which will usually be part of an overall infection prevention and control policy and strategy, along with other public health and social measures.

Some have predicted that biomedical waste (of which PPE is a major component) may soon overwhelm existing waste management systems and produce backlogs (377).

Disposal of these potentially toxic products via incineration (one approach to large amounts of waste in health-care facilities) releases particulate matter, heavy metals, carbon monoxide, carbon dioxide, and other greenhouse gases (378). However, carcinogenic dioxins, released with burning of plastics, are not released in the burning of polypropylene and other non-halogen containing polymers.

With increasing concerns about the worsening climate crisis, estimates have been made of how much single-use masks contribute to greenhouse gas emissions. One study gave the global warming potential of the mask at 21.5 g/CO_2eq, comprising 40.5% for raw materials, 30% for packaging, 15.5% for production, and 7.4% for transportation (379); other studies produced lower estimates (379–381). However, these studies did not factor in the consequences of mask use (e.g., protection against infection) nor comparisons with more common consumer items. To determine the true climate impact of masks, one would have to compare the estimated increase in greenhouse gas emissions and other harms from mask use with the estimated decrease in emissions from, for example, averted hospitalizations and medication prescriptions.

Mitigating environmental harm from single-use masks and respirators: what can be done?

While environmental concerns were, perhaps understandably, put aside in the early months of the COVID-19 pandemic, action to address the environmental impact of the ongoing response to this and other respiratory diseases is now urgent (358). Several reviews have proposed measures for addressing the growing threat of mask pollution (360, 363, 364, 366, 369, 370). The recommendations below are based on those reviews.

Increase public awareness

The environmental hazards posed by discarded masks need to be made clear, and information and resources need to be provided for more environmentally friendly disposal. Without public understanding and support, little change is likely to occur.

Improve mask waste management

Many environmental reviews reproduce a widespread but probably flawed assumption that because masks may be contaminated with infectious organisms, all mask waste should be treated as a significant biohazard with substantial waste worker protection and special waste incineration (360, 368, 371, 382). While it is hypothetically possible that discarded single-use masks and respirators may act as fomites and contribute to virus spread (see What Are Masks and How Do They Work?), we believe that the biohazard of masks has been substantially overestimated in the past because of an assumed droplet mode of transmission. Scaling back the special biohazard measures in mask waste disposal would reduce their environmental impact. In addition, as Wang et al. recommend, dedicated mask disposal bins and systematic decontamination will maximize opportunities for recycling (360).

Recycle mask waste

A reliable and scalable approach to recycling (or "upcycling") such products has proved challenging for scientists. Difficulties include risk of contamination (e.g., with blood or non-mask waste), the multiple materials they contain (polymeric filters, aluminium nosepiece, and elastic loops), and adverse cost-benefit balance. However, studies have begun to demonstrate that shredded mask waste can be incorporated into roads and pavements, building materials (e.g., concrete), membranes and filtration materials, various kinds of fuel (through a high-temperature thermochemical process called pyrolysis), battery electrodes, adsorbents, and various specialist chemical products, in each case improving performance of the end material (360, 363, 364, 366, 369, 370). While few of these solutions are ready to be implemented at scale, they offer some hope for the future.

Promote reuse and extended use

Reuse and extended use are partial solutions that could potentially be implemented promptly and in a highly cost-effective way. Surgical masks are not designed for reuse or even prolonged use, with a recommended maximum duration of 6 hours (383), but respirators are designed for prolonged use; a single respirator can be worn repeatedly and for long periods and still be effective (384, 385). A UK analysis showed that reusing respirators once reduced waste by 65%–80% when compared to single-use respirators but still generated more waste than single-use surgical masks, though this narrowed and then reversed with the number of reuses (386). Another study found similar results (387). Further research is needed, however, on when and how to decontaminate respirators prior to reuse. Although several decontamination methods like ultraviolet irradiation and hydrogen peroxide vapor have been explored (383), these can compromise fit and filtration performance, leading some manufacturers to advise against reuse (87, 388).

Normalize elastomeric respirators

Elastomeric respirators provide a high level of protection as well as comfort and fit, are reusable, and have a lightweight solid frame and replaceable filters. They are a promising solution for both community and health-care facility use (389, 390). While their initial cost ($30–$150) is high compared to a single-use device, their long-term financial and environmental costs are lower. Depending on the model, they can be reused for 5 years or more, resulting in up to 96% less waste over single-use or decontaminated and reused options (386, 387).

Develop biodegradable and reusable masks

Biodegradable polymers range from natural types like cellulose, chitin, and silk fibroin to semi-synthetic and synthetic varieties such as polylactic acid (PLA) and polyvinyl alcohol (PVA) (391). PLA and PVA, in particular, have shown significant potential as filter materials, with studies demonstrating their effectiveness in creating high-performance, environmentally friendly masks (391, 392). Wang et al. summarize additional studies on these and a range of additional materials including gluten, banana stems, and biodegradable nanofibers (see Toward Better Masks) (360). While cloth masks provide a lower level of protection than surgical masks (179), they can be reused. There is ongoing research into developing novel anti-microbial fabrics impregnated with graphene, copper, silver, or zinc nanoparticles, as well as design of fabric masks with improved fit that can perform as well as a surgical mask (92, 393, 394).

Formulate relevant policies and regulations

While 175 countries around the world have committed to ending plastic pollution, there are currently no international laws, regulations, or restrictions regarding mask disposal (360). Measures by national governments are needed, along with incentives (e.g., tax breaks) for those developing more environmentally friendly alternatives.

The above approaches should be pursued alongside other protections against airborne pathogens, notably attention to indoor air quality. If all indoor spaces were optimally ventilated, for example, protection would be less reliant on individuals' ability and willingness to mask (395, 396).

Toward better masks

The design of masks and respirators continues to evolve, especially in relation to novel materials designed to address both the limitations (filtration, breathability, and susceptibility to contamination) of traditional materials (see What Are Masks and How Do They Work?) and their environmental risks (see Mitigating Environmental Harm from Single-Use Masks and Respirators: What Can Be Done?). Nanofibers, produced using electrospinning techniques from various polymers, are an important advance. They offer superior performance due to their light weight, adjustable surface chemistry, small pore sizes, and large surface areas. In particular, nanofibers permit creation of a highly efficient and breathable filter that is thinner and lighter than traditional polypropylene filters, with filtering performance comparable to highly effective electret type filters (397–400). These properties mean that masks and respirators made of nanofibers can reduce moisture, heat, and pressure build-up, enhancing their fit and comfort, while also minimizing communication issues and possessing the potential to physically block viruses (401, 402). They also allow the use of polar liquids such as ethyl alcohol to decontaminate the device (401, 402).

In response to the COVID-19 pandemic, there has been a significant push to develop masks and respirators which are capable of not just trapping but destroying pathogens, though the contribution of such technologies to reducing transmission relative to more traditional designs is debated. As a reviewer of an earlier draft of this article pointed out, "Pathogen-trapping efficiency is orthogonal to pathogen-killing ability. A mask could be made of highly effective antimicrobial materials, but if the material is only marginally effective at physically capturing pathogens in the first place, then the antimicrobial capability is moot."

Traditional non-woven fabrics with electrostatic filtration tend to lose their pathogen-trapping efficiency as the electrostatic charge diminishes over time (403). To address this, a novel stream of research focuses on embedded anti-microbial materials, including carbon-based (e.g., activated carbon, carbon nanotube, graphene, and carbon aerogel) and biopolymers, which can kill or inactivate pathogens upon contact (86, 249, 404–406). Non-reusable versions of these nanocomposite materials incorporate elements like metal (such as copper, silver, and zinc) nanoparticles and quaternary ammonium compounds, which have shown high efficacy in inactivating viruses and bacteria (249, 404, 405). More environmentally friendly anti-microbial materials involve coatings or treatments that can be reactivated or remain effective after multiple uses, such as salt-based functionalization, photoactive materials, metal ions and metal-organic frameworks embedded within the filter matrix (86, 404).

While these developments have theoretical potential, research continues on the safety, costs, and environmental impact (especially with metal derivatives) of these novel products.

Other developments which may improve the performance and acceptability of masks in the future include masks with advanced detection and decision-making capacities (407); 3D printing technology to allow customizing of masks for individual facial structures, ensuring better seals and reduced leakage (408); and hydrogel patches applied to the edges to ensuring a snug fit without compromising comfort (409).

Lastly, and somewhat speculatively at the present time, the integration of smart technologies into masks creates the potential for enhanced detection and monitoring (e.g., by identifying pathogens, monitoring air quality, and even tracking the wearer's physiological biomarkers) (86, 410, 411). More prosaically, existing designs need to be produced in a broader range of sizes and shapes to accommodate different facial dimensions, anthropomorphic types, and presence of facial hair (91), and greater attention should be paid to color and style to improve acceptability, especially to younger generations (266).

SUMMARY AND CONCLUSION

This review was commissioned partly because of controversy around a Cochrane review which was interpreted by some people as providing definitive evidence that masks don't work (9). Our extensive review of multiple streams of evidence from different disciplines and study designs builds on previous cross-disciplinary narrative reviews (233, 412) and aligns with the recent call from philosophers of science to shift from a "measurement framework" (which draws solely or mainly on RCTs) to an "argument framework" (which systematically synthesizes evidence from multiple designs including mechanistic and real-world evidence) (19). Using this approach, we have demonstrated a more nuanced set of conclusions, summarized below, and have revealed why certain inaccurate assumptions and defective reasoning about the science of masks and masking seem to have become widely accepted among certain groups.

We began by reviewing basic science evidence on the transmission of SARS-CoV-2 and other respiratory pathogens and showed that there is strong and consistent evidence that they spread predominantly by the airborne route. We also showed that masks are effective, and well-fitting respirators are highly effective, in reducing transmission of respiratory pathogens, and that these devices demonstrate a dose-response effect (the level of protection increases as adherence to masking increases).

We then provided a methodological critique of clinical trials of masks in the control of respiratory disease epidemics and outbreaks, including listing common design flaws. We summarized evidence from RCTs, including repeating methodologically flawed meta-analyses, and showed that respirators are significantly more effective than medical or cloth masks, especially (and to the extent that) they are actually worn in all potentially hazardous circumstances.

We also reviewed an extensive body of observational and modeling evidence which showed that, overall, masking and mask mandates are effective in reducing community transmission of respiratory diseases during periods of high community transmission. The observational findings are particularly striking since various inherent limitations of such designs are likely to bias findings toward the null.

Our review of adverse effects and harms of masks found strong evidence to refute claims by anti-mask groups that masks are dangerous to the general population. We also found that masking may be relatively contraindicated in individuals with certain medical conditions and that certain groups (notably D/deaf people) are disadvantaged when others are masked.

We summarized evidence from multiple countries and cultures which shows that masks are important sociocultural symbols about which people care deeply (positively or negatively). We also showed that adherence (and non-adherence) to masking is sometimes linked to political and ideological beliefs and to widely circulated mis- or disinformation, and hence hard to change.

In a section on mask policy, we described how governments and organizations need explicit policies on using masks for prevention and control of respiratory infections, covering personal protection of at-risk groups; protection in specific settings, including workplaces and healthcare facilities; seasonal respiratory infections; and pandemics. These policies need to be based on sound risk assessment, risk management, and implementation principles.

Finally, we reviewed environmental impacts from single-use masks and respirators and highlighted novel materials and designs with improved performance and less environmental risk.

We believe this evidence supports several important conclusions and implications for further research.

First, the claim that masks don't work is demonstrably incorrect, and appears to be based on a combination of flawed assumptions, flawed meta-analysis methods, errors of reasoning, failure to understand (or refusal to acknowledge) mechanistic evidence, and limitations in critical appraisal and evidence synthesis. Masks and respirators work if and to the extent that they are well-designed (e.g., made of high-filtration materials), well-fitting and actually worn. The heterogeneity of available mask RCTs does not appear to have been fully understood by some researchers who have conducted high-profile meta-analyses of the same. It is time for the research community to move on from addressing the binary question "do masks work?" through unidisciplinary and epistemologically exclusionary study designs and pursue more nuanced and multi-faceted questions via *interdisciplinary* designs.

A fruitful avenue for future research, for example, would be the combination of experimental, observational and modeling data to refine our understanding of *when* universal masking should be introduced during respiratory epidemics and *how best* to promote and support masking policies in different situations and settings, and especially for groups at increased risk, during such outbreaks. Research on ventilation, filtration and other measures to improve indoor air quality was beyond the scope of this review [it has been covered elsewhere (330, 395)], but there is scope for cross-disciplinary modeling to bring the science of indoor air into more direct dialogue with that of infectious disease transmission and masking to address the question of when and in what circumstances indoor masking can be deemed unnecessary (or, alternatively, advised or mandated) based on air quality. As noted in Modeling Masking, some research groups have begun to contribute to this interdisciplinary knowledge base.

Second, given that masking is an effective (though not perfect) intervention for controlling the spread of respiratory infections, and that it may be particularly important in the early stages of pandemics (when the pathogen may be unknown and drugs and vaccines are not yet available), improving understanding among scientists, clinicians, policymakers and the public about the effectiveness of masks and respirators is an urgent priority. The continuing recalcitrance of many (though not all) in the infection prevention and control community on this issue could prove a major threat to public health in future pandemics, particularly since such individuals often hold influential positions on global and national public health decision-making bodies.

Third, mask policies should better reflect the actual risks and harms of masks rather than being overly influenced by speculative risks (such as retention of carbon dioxide) that have no empirical foundation, or by adverse effects affecting certain defined groups (e.g., some people with autism) which could be covered by exemptions. Rather, the focus should be on supporting effective mask use by addressing well-described and widely experienced adverse effects of masking such as communication difficulties, physical discomfort, and skin reactions. Communication is a vital human need, so communication resources and best practice guidelines should be integral to mask policy and operational in every setting where masking is required or advised. Physical adverse effects of masks should be addressed by better mask design, which should be a priority for research.

Fourth, there is scope for research centered on helping people find masks that they find comfortable, aesthetically appealing, and which fit them well. If masking is to be normalized in certain risk situations, there needs to be a range of masks and respirators available in different sizes, shapes, colors, and designs to take account of the many physical and sociocultural factors affecting uptake, fit, and use. This stream of research is especially important for people who are clinically vulnerable (e.g., immunosuppressed), who may need to mask much or all of the time and, in some cases, lifelong.

Fifth, research should continue into novel materials which could lead to masks with improved comfort, lower breathing resistance, and good quality reusable products which will greatly reduce waste and environmental pollution. Plastic-backed medical masks that are ill-fitting, uncomfortable, and made of non-biodegradable materials should be phased out and replaced with masks and respirators that meet a higher standard for filtration efficacy, breathability, fit, and environmental sustainability. Research should also be directed at maximizing options for recycling mask waste.

Finally, as the COVID-19 pandemic continues into a fifth (and, quite possibly, subsequent) year, the grave danger posed by ideologically driven anti-mask narratives to public and global health should be acknowledged and systematically addressed. Anti-mask sentiment is increasing, along with anti-vaccine sentiment (413), and this bodes ill for both the current and any future pandemics. While there are no simple solutions to the problem of widespread disinformation, clear and consistent messaging from public health bodies on masks and other mission-critical topics would help considerably.

These suggestions for further research are summarized in Box 2.

BOX 2: SOME SUGGESTIONS FOR A NEW GENERATION OF RESEARCH ON MASKS AND RESPIRATORS

1. Interdisciplinary and multi-method designs which go beyond "do masks work?" and ask nuanced, multi-faceted questions such as "what kind of masks should be introduced in respiratory epidemics and pandemics, at what stage, for whom, how and with what support?"
2. Studies of how to address the mismatch between the strong and consistent evidence base on the effectiveness of masks and respirators and the lack of acceptance of this evidence by influential scientists, clinicians and policymakers.
3. Studies to improve the quality of communication when [some people are] wearing face coverings.
4. Studies to optimize acceptability, fit and comfort of masks and respirators and minimize side effects such as skin reactions and headache. We recommend a wider range of mask materials, designs and styles, including consideration of specific need groups.
5. Studies of new materials and combinations of materials for masks and respirators, with a view to optimizing filtration efficacy, breathability, fit and environmental sustainability.
6. Studies of how to address the widespread, sinister and growing phenomenon of anti-mask misinformation and disinformation on social and mainstream media.

The time is well overdue for international policy bodies to acknowledge the totality of evidence on the science of masks and masking and to show leadership in providing such messaging to policymakers, clinicians, and the public.

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AUTHOR AFFILIATIONS

[1]Nuffield Department of Primary Care Health Sciences, University of Oxford, Oxford, United Kingdom
[2]Biosecurity Program, The Kirby Institute, University of New South Wales, Sydney, Australia
[3]Department of Public Health, University of Otago, Wellington, New Zealand
[4]School of Mechanical and Manufacturing Engineering, University of New South Wales, Sydney, Australia
[5]School of Population Health, University of New South Wales, Sydney, Australia
[6]Dalla Lana School of Public Health, University of Toronto, Toronto, Ontario, Canada
[7]Centre for Social Research in Health and Social Policy Research Centre, Faculty of Arts, Design and Architecture, University of New South Wales, Sydney, Australia
[8]Professional Standards Advocate, Edmonton, Canada
[9]Faculty of Veterinary Medicine; Department of Biomedical Engineering, Schulich School of Engineering; Alberta Children's Hospital Research Institute, University of Calgary, Calgary, Alberta, Canada

[10]Department of Emergency Medicine, Cumming School of Medicine, University of Calgary, Calgary, Alberta, Canada

AUTHOR ORCIDs

Trisha Greenhalgh http://orcid.org/0000-0003-2369-8088
C. Raina MacIntyre http://orcid.org/0000-0002-3060-0555
Michael G. Baker http://orcid.org/0000-0002-1865-1536
Shovon Bhattacharjee http://orcid.org/0000-0003-1241-641X
Abrar A. Chughtai http://orcid.org/0000-0003-4203-7891
David Fisman http://orcid.org/0000-0001-5009-6926
Mohana Kunasekaran http://orcid.org/0000-0001-5779-7979
Amanda Kvalsvig http://orcid.org/0000-0002-4184-001X
Deborah Lupton http://orcid.org/0000-0003-2658-4430
Matt Oliver http://orcid.org/0000-0002-7197-3032
Essa Tawfiq http://orcid.org/0000-0001-8147-079X
Mark Ungrin http://orcid.org/0000-0002-7410-1491
Joe Vipond http://orcid.org/0000-0002-1475-9814

AUTHOR CONTRIBUTIONS

Trisha Greenhalgh, Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Project administration, Writing – original draft, Writing – review and editing | C. Raina MacIntyre, Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Supervision, Validation, Writing – original draft, Writing – review and editing | Michael G. Baker, Data curation, Writing – original draft, Writing – review and editing | Shovon Bhattacharjee, Data curation, Writing – original draft, Writing – review and editing | Abrar A. Chughtai, Data curation, Formal analysis, Investigation, Methodology, Writing – original draft, Writing – review and editing | David Fisman, Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Writing – original draft, Writing – review and editing | Mohana Kunasekaran, Data curation, Formal analysis, Writing – review and editing | Amanda Kvalsvig, Conceptualization, Data curation, Formal analysis, Investigation, Writing – original draft, Writing – review and editing | Deborah Lupton, Data curation, Formal analysis, Investigation, Writing – original draft, Writing – review and editing | Matt Oliver, Data curation, Formal analysis, Investigation, Writing – original draft, Writing – review and editing | Essa Tawfiq, Data curation, Formal analysis, Writing – review and editing | Mark Ungrin, Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Writing – original draft, Writing – review and editing | Joe Vipond, Data curation, Formal analysis, Writing – original draft, Writing – review and editing

DATA AVAILABILITY

The meta-analysis datasets will be made available to bona fide researchers from academic institutions on reasonable request.

ETHICS APPROVAL

The review was based on publicly available published sources, so no specific ethical approval was needed.

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AUTHOR BIOS

Professor Trisha Greenhalgh is a researcher at the University of Oxford, Oxford, UK. A medical doctor and social scientist, she leads a programme of interdisciplinary research at the interface between medicine and the social sciences. She has brought this interdisciplinary perspective to bear on the research response to the COVID-19 pandemic, looking at diverse themes including remote clinical assessment of the patient with acute COVID-19 in the community, the science and social science of face coverings, and policy decision-making in conditions of uncertainty. She is a member of Independent SAGE, an interdisciplinary academic team established to provide independent advice on the pandemic direct to the lay public. Her many awards include Order of the British Empire from Her Majesty the Queen for Services to Evidence-Based Medicine.

Professor C. Raina MacIntyre is Head of the Biosecurity Program at the Kirby Institute, UNSW Sydney, Australia. She leads research on prevention and detection of epidemic infections, with a focus on vaccines and facemasks. She has conducted several RCTs of masks and N95 respirators. She has received many awards including the Sir Henry Wellcome Medal and Prize from the Association of Military Surgeons of the US. She is on the editorial boards of Vaccine, BMJ Open and Epidemiology & Infection. She has served on committees for the US National Academies of Science, Engineering and Medicine and WHO.

Professor Michael G. Baker is a public health physician, epidemiologist, and Professor in the Department of Public Health, University of Otago, Wellington. He leads a group focussed on infectious disease and environmental health research. Michael took a leading role in shaping New Zealand's COVID-19 pandemic response, particularly the elimination strategy. He has a strong interest in science communication and evidence translation and is the inaugural director of the Public Health Communications Centre Aotearoa. He has been a member of the New Zealand Government's COVID-19 Technical Advisory Group throughout the pandemic and serves on World Health Organisation expert groups.

Dr. Shovon Bhattacharjee is a Research Fellow at UNSW Sydney, Australia, and is affiliated with both the School of Mechanical and Manufacturing Engineering and the Kirby Institute. His research operates at the intersection of materials science and healthcare, aiming to develop and leverage functional materials for environmental health safety and personalized healthcare applications. This interdisciplinary pursuit is particularly focused on the discovery and integration of potential materials, cutting-edge technologies, and innovative strategies. These efforts are dedicated to advancing the design and functionality of next-generation Personal Protective Equipment (PPE) and medical devices, targeting improvements in environmental and occupational health and safety.

Dr. Abrar Chughtai is a medical epidemiologist and is working as a Senior Lecturer in the School of Population Health, UNSW Sydney, Australia. He is also Director of the Master of Infectious Diseases Intelligence (MIDI) Program at School. His research interests include epidemiology and control of infectious diseases, focusing on emerging and re-emerging infections. He has published more than 160 journal papers and one book chapter during the last 10 years. Abrar provided leadership during COVID-19, through publications, media interactions and a committee membership. During 2021, he was on secondment to NSW Health COVID-19 Emergency Operation Center.

Professor David Fisman is a physician-epidemiologist with research interests that fall at the intersection of applied epidemiology, mathematical modeling, and applied health economics. He completed a residency in Internal Medicine at McGill and Brown Universities, before completing a fellowship at the Beth Israel Deaconess Medical Centre in Boston, and an MPH at Harvard School of Public Health. He was also an AHRQ fellow in Health Policy (1998-2001) at Harvard Centre for Risk Analysis, and has held faculty appointments at McMaster, Princeton and Drexel Universities. He is an author of over 260 scientific articles, and a Fellow of the Canadian Academy of Health Sciences and the College of Physicians of Philadelphia. He co-leads the Pandemic Readiness Stream at the University of Toronto's new Institute for Pandemics.

Dr. Mohana Kunasekaran is a research associate in the Biosecurity Program at the Kirby Institute, UNSW Sydney, Australia. Her research interests include multivariable methods, systematic review and meta-analysis and the epidemiology of infectious diseases, particularly in aged care settings. Her work is focused on enhancing the aged care sector's capacity for outbreak control by utilising data on facility design and past outbreaks to guide decision-making.

Dr. Amanda Kvalsvig is an epidemiologist and Research Associate Professor at the University of Otago Wellington, Aotearoa New Zealand. She has a clinical paediatrics background. Since early 2020 her work has been strongly focused on generating evidence to inform NZ's pandemic response, including border measures, the Alert Level system, children and schools, equitable policy, pandemic strategy and preparedness, and face masks. Other research areas include meningococcal disease, respiratory infection surveillance and control, and the syndemic relationships between infectious diseases, chronic conditions, and structural inequities. She is deaf with cochlear implants and disability advocacy is an important aspect of her work.

Professor Deborah Lupton is SHARP Professor in the Centre for Social Research in Health and the Social Policy Research Centre at UNSW Sydney, Australia. Her background is in sociology, communication and cultural studies, with a particular focus on the sociocultural aspects of health, risk and medicine. She is one of the world's leading sociologists of the COVID-19 pandemic. She edited a special section on the pandemic for *Health Sociology Review* (2020), co-edited a book collection, *The COVID-19 Crisis: Social Perspectives* (2021), and authored/co-authored *The Face Mask in COVID Times: A Sociomaterial Analysis* (2022) and *COVID Societies: Theorising the Coronavirus Crisis* monographs. She has also published numerous articles and book chapters on the social impacts and everyday experiences of the pandemic.

Matt Oliver is a commissioner involved in the regulation of utilities, an aerospace/electrical engineer with long history in regulation, legal analysis, forensic engineering, theology and restorative justice. Experience assessing legal and technical causation and investigating failure modes in complex underdetermined systems led to pandemic efforts involving ventilation, filtration, respiratory protection, risk assessment, professional & research ethics and public policy. A graduate of the Royal Military College of Canada, he retired from the Canadian Armed Forces as a senior officer. Matt is one of Canada's three Indigenous groups – Red River Métis – and teaches about the collision between Western and Indigenous cosmologies.

Dr. Essa Tawfiq is a medical doctor by background. He has an MPH degree from Tulane University, USA and a PhD degree from Victoria University of Wellington, New Zealand. Essa worked for more than 20 years in clinical and public health settings in Afghanistan and New Zealand. In April 2023, Essa joined the Kirby Institute, UNSW Sydney, Australia, and has been involved in research on COVID-19, personal protective equipment (PPE), health impacts of bushfires, and effects of flu vaccination on cardiovascular disease.

Dr. Mark Ungrin is an Associate Professor in the Faculty of Veterinary Medicine, Department of Biomedical Engineering, and Alberta Children's Hospital Research Institute at the University of Calgary. An interdisciplinary biomedical researcher, his interests centre on the practical, safe and effective translation of biomedical research and associated supporting technologies into benefits to health, with emphasis on ensuring rigour, reproducibility and efficiency. His work impacts global practice in multiple areas with contributions to international standards, community outreach, and technologies in use around the world and on the International Space Station.

Dr. Joe Vipond has worked as an emergency physician for over twenty years, currently at the Rockyview General Hospital. Outside of clinical work, he has focused his efforts on advocacy, both on climate and COVID policy. He is Past President of the national charity Canadian Association of Physicians for the Environment. He is also the co-founder and board member of the local charity the Calgary Climate Hub, and over the last four years, the co-founder of #masks4Canada, the Canadian COVID Society, and ProtectOurProvinceAB.