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| RESEARCH ARTICLE

Why Face Masks Should not be Imposed on the Public Again: A Review Article

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| ABSTRACT

Viral epidemics of acute respiratory infections pose a global threat. Influenza outbreaks occur almost every year. Specifically, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), causing coronavirus disease 2019 (COVID-19), emerged in late 2019. This unprecedented event resulted in many countries requiring masks in public spaces to contain the spread of SARS-CoV-2. However, the early and previous systematic reviews of randomized controlled trials (RCTs) found that medical/surgical masks did not appear to reduce respiratory viral infections. Also, N95 respirators did not provide superior protection over surgical masks against viral infections or influenza-like infections among healthcare workers (HCWs), although N95 respirators theoretically provide better protection. This led to the recommendation not to wear facemasks as potential benefits are limited, and there is a risk of self-contamination if misused. However, with the ongoing spread of SARS-CoV-2, several health authorities suddenly shifted their recommendations and advised the general public to wear masks, with some governments even mandating it. By July 2023, the health-protective benefits of wearing facemasks are still conflicting, and debate over the idea of a mask mandate is ongoing. Therefore, this review aims to discuss ten reasons why face masks should not be imposed on the public again, which include the functional weaknesses of facemasks, lack of justification for the sudden change in the recommendations during the COVID-19 pandemic, the effectiveness of facemasks in the community and among HCWs based on the systematic reviews of the RCTs, their effectiveness based on the RCTs, the effectiveness of N95 respirators versus surgical masks in protecting from acute respiratory infection based on the systematic reviews, their potential harms, the poor quality of most masks used by the public, their misuse, the trajectory of the COVID-19 pandemic despite masking, and the importance of acknowledgment of the rights of people in wearing masks or not.

| KEYWORDS

COVID-19, influenza, harms, mandating, N95, respirators.

| ARTICLE INFORMATION

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1. Introduction

Prevention is better than treatment when it comes to managing infectious diseases. Preventive measures for viral respiratory infections include vaccines, physical distancing, isolating sick individuals, quarantining those exposed, maintaining good hand hygiene, wearing facemasks, and other interventions. However, the effectiveness of most of these measures in preventing respiratory infections is still a topic of debate, particularly outside healthcare settings (Jefferson et al., 2020). For healthcare workers (HCWs), facemasks are part of personal protective equipment (PPE). Still, the amount of protection varies based on the clinical environment, current risk level, and local directives (Jefferson et al., 2020; Cheng et al., 2022).

Before 2020, the public's use of facemasks to protect against respiratory infectious diseases was not common (Zhang et al., 2022). Even during previous epidemics and pandemics, widespread use of facemasks was not advised. However, certain societies in East and Southeast Asia have sometimes been using masks (Zhang et al., 2022). Additionally, in the early coronavirus disease 2019 (COVID-19) pandemic, the World Health Organization (WHO) and many authorities did not recommend mask use among the general population (Cheng et al., 2022). The United States Centers for Disease Control and Prevention (CDC) initially advised the

public against wearing masks until April 4, 2020, when the CDC recommended cloth face coverings (Greenhalgh et al., 2020). As severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) continued to spread, there was a growing push for public mask use, with a rationale based on the potential for benefit over harm (Cheng et al., 2022; Greenhalgh et al., 2020).

Facemasks have been used since the late 19th century to protect sterile spaces from respiratory droplets generated by the wearer, such as in surgical procedures. Therefore, surgeons and their assistants wear facemasks to reduce the possibility of wound contamination (Strasser & Schlich, 2020). The secondary function was to protect the mouth and nose of the wearer (surgeons) from the sprays, blood splatter, and body fluids that arise during surgery. Until then, no one wore them for fear of infection. In the early twentieth century, masks were used to capture infectious droplets expelled by their wearers, and thus, the possibility of reducing the transmission of the disease to others, according to their beliefs. Covering the nose and mouth to control infection began in the early twentieth century when it was discovered that exhaled droplets could transmit culturable bacteria (Schlich & Strasser, 2022). Wearing a facemask is considered an effective way of preventing the spread of germs, as it focuses on keeping them away rather than killing them with chemicals. Although some people have raised concerns about the effectiveness of this strategy, masks have become increasingly popular as a means of infection control. During the 1930s, reusable masks were gradually replaced by disposable paper masks. In the 1960s, there was a shift towards using synthetic materials for single-use masks (Strasser & Schlich, 2020). From the mid-20th century to the present day, facemasks have increasingly been used for the exact opposite function: namely, to prevent the wearer from inhaling respiratory pathogens (Strasser & Schlich, 2020).

Regarding evidence-based medicine, it is well recognized that some research designs are more powerful than others in their ability to answer research questions on the effectiveness of interventions. When discussing the evidence for evaluating the effectiveness of an intervention, we have to look at randomized controlled trials (RCTs) that look at outcomes of interest to the patient. The RCT is considered to provide the most reliable evidence on the effectiveness of interventions because the processes used during the conduct of an RCT minimize the risk of confounding factors influencing the results. Because of this, the findings generated by RCTs will likely be closer to the actual effect than those generated by other research methods (Akobeng, 2005). Systematic reviews are aimed to involve a detailed and comprehensive plan and search strategy derived a priori to reduce bias by identifying, appraising, and synthesizing all relevant studies on a particular topic. Often, systematic reviews include a meta-analysis component involving statistical techniques to synthesize the data from several studies into a single quantitative estimate or summary effect size (Uman, 2011).

Before the COVID-19 pandemic, many RCTs were conducted to evaluate facemasks' effectiveness in preventing or reducing respiratory tract infections. However, examination of the efficacy of masks in most settings has largely failed to demonstrate their value despite a large volume of mostly low- to moderate-quality evidence more than a century after the 1918 influenza pandemic (Liu et al., 2023). Furthermore, upon a critical review of the available literature, Matuschek et al. found only weak evidence for wearing a facemask as an efficient tool to prevent the spread of viral infection (Matuschek et al., 2020). Although RCTs have been considered the gold standard in medical research, RCTs have been ignored regarding mask-wearing. Instead, observational studies suggest that wearing masks lowers the risk of viral respiratory infections (Jefferson et al., 2011; Offeddu et al., 2017). However, the observational design is at high risk of confounding. Experimental laboratory-based studies of masks and mask types seem to provide good and vital information, but translation into meaningful clinical differences is often lacking (Smith et al., 2016).

Unfortunately, some recent reviews (Howard et al., 2021) promoting mask-wearing rely on observational studies. One review included both observational studies and RCTs on the effectiveness of masks, and the results were different between these two types of studies; RCTs showed no significant differences, while observational studies did (Chou et al., 2021). Additionally, it is essential to thoroughly review and critique the methods and results of RCTs or systematic reviews of RCTs before drawing any conclusions from the author's findings.

Therefore, this review aims to discuss ten reasons why face masks should not be imposed on the public again, which include the functional weaknesses of facemasks, lack of justification for the sudden change in the recommendations during the COVID-19 pandemic, the effectiveness of facemasks in the community and among HCWs based on the systematic reviews of the RCTs (published by July 2023), their effectiveness based on the RCTs, the effectiveness of N95 respirators versus surgical masks in protecting from acute respiratory infection based on the systematic reviews, their potential harms, the poor quality of most masks used by the public, their misuse, the trajectory of the COVID-19 pandemic despite masking, and the importance of acknowledgment of the rights of people in wearing masks or not.

2. First reason: The functional weaknesses of facemasks

The majority of masks commonly used to reduce the transmission of SARS-CoV-2 can be classified into three categories: high-efficiency face protection, also called respiratory protective devices (e.g., filtering facepiece 2, also known as FFP2, and N95) intended for respiratory protection; medical/surgical masks designed for professional use in healthcare settings with generally lower protection efficiencies and looser fit; cloth masks which are inexpensive and often made of everyday cotton fabric (Schmitt

& Wang, 2022). For cloth masks, it is usually recommended to have three layers, and they can also be made at home. So, the quality of these masks varies widely. Surgical masks and respirators are designed for only a single use because they work by trapping harmful particles inside the mesh of fibers from which they are made (Schmitt & Wang, 2022).

Much of the evidence favoring wearing masks in public is based on the surrogate endpoint of droplet dispersion. These reductions are hypothesized to correlate with reductions in disease transmission. This intuition is because masks (and indeed any sufficiently dense object or material) can act as a barrier that reduces the amount of larger respiratory secretions that are projected forward or the distance they travel (Jefferson et al., 2011; Liu et al., 2023; Offeddu et al., 2017; Smith et al., 2016). There is also plenty of research showing how well different fabrics used to make masks can filter out particles (Matuschek et al., 2020; Schmitt & Wang, 2022).

However, one issue with facemasks, including high-quality respiratory masks, is that viruses and certain bacteria are smaller than the mask's existing pores. N-95 respirators contain a 0.3 micron (300 nm) filter that can filter out 95% of particles 0.3 microns in diameter or larger (Schmitt & Wang, 2022). This pore size is still larger than coronaviruses, which are about 0.125 microns (125 nm) in diameter. A separate study revealed that surgical masks can still allow about 85% of influenza particles and 90% of staphylococcus aureus bacteria to pass through despite the particles of the bacteria being six times larger than those of influenza viruses (Shimasaki et al., 2018).

Surgical masks have a wide range of filtration efficiencies (i.e., they vary in quality), with most showing 30% to 50% (Brosseau & Sietsema, 2020; Droegemeier, 2020). An aerosol permeation study showed that two of the five surgical masks studied had a penetration rate of 51% to 89% of aerosols (Rengasamy et al., 2010). In the early COVID pandemic, one study found that neither surgical nor cotton masks effectively filtered SARS-CoV-2 during coughs by infected patients, but this study was retracted (Bae et al., 2020). Previous studies have shown that surgical masks effectively filter the influenza virus (Johnson et al., 2009), recommending that those with confirmed or suspected COVID-19 wear masks (Feng et al., 2020). However, the size and concentrations of SARS-CoV-2 in aerosols generated during coughing were unknown in the early pandemic. Research by Oberg and Brousseau (2008) found that surgical masks did not provide reliable filtration against aerosols measuring 0.9, 2.0, and 3.1 µm in diameter. Similarly, Lee et al. (2008) discovered that particles as small as 0.04 to 0.2 µm could penetrate surgical masks. As the estimated size of the SARS-CoV-2 particle is approximately 0.1 µm (Laue et al., 2021), it is unlikely that surgical masks will effectively filter this virus. One quantitative study showed leakage of airborne droplets through all surgical and cloth masks in both configurations of a susceptible person wearing a mask for protection and a virus carrier wearing a mask to prevent the spreading of the virus (Akhtar et al., 2020). Additionally, surgical masks do not protect against respirable particles, so they were not suggested by Douglas et al. (2020) for HCWs in locations where they may be exposed to symptomatic or diagnosed COVID-19 patients.

Furthermore, the engineering problems of the masks are not considered. The studies examine the ability of fabric to filter particles as they pass through—rather than around—mask material (Liu et al., 2023). Facemasks reduce forward flow when an infected person coughs or sneezes, but the force of a sneeze and cough is not stopped, simply redirected; this is the basics of physics. Surgical masks, homemade masks, and face coverings generate many leaks (Schmitt & Wang, 2022; Ogbuoji et al., 2021). Therefore, blocking the forward force of exhaled air means it is redirected to the sides, down the mask, and presumably up (Ogbuoji et al., 2021; Viola et al., 2021), which is why many people find that their glasses fog up easily while wearing a mask. These risks still need to be fully understood.

3. Second reason: Recommendation regarding facemasks before June 2020

RCTs are the most substantial scientific evidence to establish the effectiveness of treatments or preventive measures. There is simply a lack of clear evidence that people not infected or caring for a patient should wear a facemask to reduce transmission of influenza or other respiratory infections, including coronaviruses (ECDC, 2020). Moreover, there was conflicting evidence on the protective effect of the wearer of surgical masks for influenza-like illness and laboratory-confirmed influenza in household settings (Aiello et al., 2010; ECDC, 2020; Larson et al., 2010; MacIntyre et al., 2015; WHO, 2019).

Therefore, during the first three months of the declaration of the COVID-19 pandemic, it was not recommended that people who were not ill or not providing care to a patient should wear a mask to reduce COVID-19 transmission (ECDC, 2020). The WHO did not recommend using masks for the general population and expanded the risk and hazard list of masks within just two months. While the April 2020 guideline highlighted the dangers of self-contamination, possible breathing difficulties, and a false sense of security, the June 2020 guideline found additional potential adverse effects (ADRs) such as headache, development of facial skin lesions, irritant dermatitis, acne, or increased risk of contamination in public spaces due to improper mask disposal (Kisielinski et al., 2021). At the same time, according to the WHO website on the subject of masks, the widespread use of masks by healthy people in the community setting was not yet supported by high-quality or direct scientific evidence, and cloth (e.g., cotton or gauze) masks were not recommended under any circumstance (Marasinghe, 2020).

It is often argued that there is no evidence (Marasinghe, 2020), but the statement "there is no evidence" can be misleading; it is named because all relevant evidence comes from studies on influenza and other coronaviruses and may not be directly applicable to COVID-19. However, we can build informed decisions by applying what we know about similar infectious diseases and pairing it with what the data show with this novel coronavirus and what common sense tells us. Coronavirus strains have been studied since the mid-60s; size, method of entry, infection, and genetic structure are known. None of this has changed since the 60s. Moreover, this strain has 75% compatibility with all other coronavirus strains (Kaur et al., 2021). Additionally, all viruses associated with respiratory diseases have approximately the same transmission mode (Leung, 2021). SARS-CoV-2 can be transmitted by small and large droplets, considering that small droplets provide a higher risk than large droplets as they can remain airborne for extended durations (Leung, 2021). Literature is not entirely consistent in describing the size distribution of particles generated from breathing, coughing, and sneezing (Clase et al., 2020). However, despite over a century of research on upper respiratory tract infections, studies have not effectively contributed to curbing the spread of respiratory viruses, especially in developed countries (Gandhi et al., 2022).

One proposed solution was mask-wearing, but the results have been disappointing. No statistically significant differences have generally been found in preventing respiratory virus infections by wearing masks (Jefferson et al., 2011; Jefferson et al., 2020; Xiao et al., 2020). Hence, apart from the COVID-19 pandemic, there have been no recommendations for healthy individuals to wear masks to prevent virus infections or the spread, even in previous epidemics and pandemics (Chung et al., 2014). Infection control practitioners at the debate cited their experiences during the severe acute respiratory syndrome (SARS) epidemic and highlighted the use of a mixture of different masks with different outcomes. Some HCWs exposed to SARS with minimal precautions did not contract the disease, while there were anecdotal reports of those who used the N95 mask and contracted SARS (Chung et al., 2014).

Despite all this, there was a sudden shift in the recommendations of several health authorities regarding the use of masks. Many advised the general public to wear masks; some governments even made it mandatory (Greenhalgh et al., 2020; Matuschek et al., 2020). The CDC recommended that the public wear homemade cloth masks. This was essentially done to try and reduce community transmission, especially from people who may not perceive themselves as symptomatic, not to protect the wearer. However, this evidence was scant (Isaacs et al., 2020). The WHO's response (in late 2020) to why we wear a mask the answer was "Masks should be used as part of the holistic “do it all!” approach" (WHO, 2021). So, as part of a comprehensive strategy of transmission control measures, the WHO and others recommend that everything possible be done to suppress the ongoing transmission. The media and numerous institutions supported this approach. However, it is well known that wearing a mask outside healthcare facilities offers little, if any, protection from infection (Klompas et al., 2020). It is believed that masks could be visible reminders of an otherwise invisible yet widely prevalent pathogen. It may remind people of the importance of social distancing and other control measures (Klompas et al., 2020). So, people in many countries were required to cover their noses and mouths in any way.

4. Third reason: The effectiveness of masks versus no masks based on the systematic reviews

After all, the hierarchy of evidence implies that when looking for evidence on the effectiveness of interventions or treatments, properly conducted systematic reviews of RCTs, with or without meta-analysis, will provide the most potent form of evidence (Uman, 2011). By July 2023, we found 19 systematic reviews on the effectiveness of facemasks (including those comparing the different types of masks) in protecting or reducing respiratory tract infections. However, one review was not included in the table (see Table 1) because we could not reach the full text (Tran et al., 2021). Fourteen reviews included a comparison of masks to no masks, see Table 1. Generally, there was no statistically significant difference between mask and no-mask groups in laboratory-confirmed influenza, laboratory-confirmed viral infection, influenza-like illness, or clinically respiratory infections. Settings for studies included households, community, and healthcare. Based on a more recent and comprehensive systematic review (Jefferson et al., 2023), 18 RCTs focused on using facemasks, of which two (Abaluck et al., 2022; Bundgaard et al., 2021) were conducted during the COVID-19 pandemic. Wearing masks in the community probably makes little or no difference to the outcome of influenza/COVID-19-like illness and laboratory-confirmed influenza/SARS-CoV-2 compared to not wearing masks (Jefferson et al., 2023).

Table 1: Systematic reviews on the effectiveness of facemasks.

Authors & year*	No. of the RCTs#	Surgical masks vs. none	N-95 respirators vs. surgical masks	Comments
Jefferson et al., 2023	18 RCTs.	There were 12 RCTs (10 in the community & 2 among HCWs); the results showed no significant difference in	The RCTs showed no significant difference for LCI, ILI, or CRI€. Evidence for ILI & CRI was limited by imprecision and	Based on the authors' conclusions, the pooled results of RCTs did not show a clear reduction in respiratory viral infection with surgical masks

		the outcome of ILI€/COVID-19 like illness or LCI.	heterogeneity for these subjective outcomes.	nor benefit for N-95 over surgical masks.
Ollila et al., 2022	18 RCTs; however, 2 included studies were about health education.	There was no statistically significant association overall when the unadjusted or adjusted intervention effect estimates were used.	-	Based on the subgroup analysis, facemasks could reduce CRI (self-reported) in adults (only in unadjusted estimates) or the community but not in hospitals or households or based on source control.
Chen et al., 2022	6 RCTs.	The results suggested that wearing masks effectively prevented LCVI€ (RR= 0.66, 95% CI: 0.50-0.88, P= 0.01). Five out of the 6 RCTs showed no significant difference on the LCVI.	-	The author's conclusions were not taken into consideration as their review included many observational studies (25 in No.).
Li et al., 2022	8 RCTs; the authors included the RCTs only on surgical masks in the community.	Surgical masks could slightly protect against CRI (self-reported) (OR= 0.84; 95% CI= 0.71–0.99).¥	-	The subgroup analysis of intervention settings (households, resident halls, or tents) and population (by index, contacts, or both) showed no significant difference.
Collins et al., 2021	4 RCTs among HCWs.	-	The pooled result of the 4 RCTs reported no significant difference in the risk of LCI with N95 respirator use vs. surgical masks.	The meta-analyses of the other outcomes (CRI, ILI…) were not included because they included observational studies.#
Coclite et al., 2021	3 cluster RCTs.	The difference in the incidence of infection rates was not statistically significant (adjusted OR 0.90, 95% CI 0.78–1.05).	-	The SR also included observational studies (10 in number), which reported almost similar findings to the RCTs.
Wang et al., 2020	5 RCTs among non-HCWs.	The pooled results showed no significant difference for CRI (OR= 0.87, 95% CI 0.74-1.04).	-	Based on the observational studies, overall and subgroup analysis was also not significant.
Jefferson et al., 2020 (update of the SR done in 2011)	14 RCTs.	Nine trials indicated overall no significant difference for ILI (low certainty evidence) or LCI (medium certainty evidence) in healthcare or community settings.	Five RCTs showed no significant difference for LCI, ILI, or CRI. Evidence for ILI & CRI is limited by imprecision and heterogeneity for these outcomes.	Based on the authors' conclusions, the pooled results of RCTs did not show a clear reduction in respiratory viral infection with surgical masks nor benefit for N-95 over surgical masks.
Bartoszko et al., 2020	4 RCTs among HCWs.	-	No significant difference between N-95 respirators and masks for LCVI (low certainty) or CRI (very low certainty).	One trial evaluated coronaviruses separately and found no difference between the two groups.
Dugré et al., 2020	11 SRs, including 18 RCTs (6 among HCWs)	No significant diff for ILI/CRI, LCI, or other confirmed viruses in the community or among HCWs.	No significant difference for LCI or other confirmed viruses, but possible slight benefit from N-95 for ILI or CRI.	Wearing masks by everyone for 6 weeks could slightly reduce ILI (cough and at least another symptom), based on the pooled results of 2 RCTs.

				However, the results of each study were insignificant.
Brainard et al., 2020	12 RCTs	No statistically significant difference for ILI in the community or among households.	-	When both persons (ill & well) wear masks, the effect of preventing secondary ILI was modest but insignificant.
Xiao et al., 2020	10 RCTs in nonhealthcare settings.	The evidence suggested that using facemasks by infected or uninfected persons does not substantially reduce LCI.	-	11 RCTs on hand hygiene with or without masks suggested no substantial effect on influenza transmission.
Long et al., 2020	6 RCTs among HCWs.		No statistically significant differences in preventing LCI, LCVI, ILI, or laboratory-confirmed respiratory infections.	Meta-analysis indicated a protective effect of N95 respirators against laboratory-confirmed bacterial colonization.
Offeddu et al., 2017	6 RCTs among HCWs.	Wearing a mask or N95 throughout the work shift conferred significant protection against self-reported CRI & ILI.	Wearing N95 respirators (throughout the work shift; 3 trials) conferred significant protection against self-reported CRI but not ILI.	One study (Jacobs 2009, showing no significant difference in LCI or LCVI) was excluded from the meta-analysis.
Smith et al., 2016	3 RCTs among HCWs.	-	Meta-analysis of the RCTs showed no significant difference between N95 and masks in the associated risk of LCVI, ILI, or reported workplace absenteeism.	N95 respirators appeared to have a protective advantage over surgical masks in laboratory settings but not in clinical studies.
Bin-Reza et al., 2012	8 RCTs.	There was no significant difference for LCI or other infections in the community or among HCWs.¥	No significant diff for LCI but lower rates of CRI in non-fit-test N-95.	There is a limited evidence base to support using masks and/or N-95 in healthcare or community settings.
Jefferson et al., 2011	7 RCTs.	Six trials indicated overall no significant difference when comparing masks to the control.¥	N95 respirators were non-inferior to surgical masks.	The authors also included observational studies because there were few RCTs.
Cowling et al., 2010	6 RCTs.	No significant difference overall (five RCTs) in the community or among HCWs.¥	No significant difference in protection against LCI with the use of masks or N95 among HCWs (one trial) and households (one trial).	Based on the authors' conclusions, there was little evidence to support the effectiveness of facemasks in reducing the risk of infection.

* Abbreviations; RCTs: Randomized-controlled trials, ILI: Influenza-like illness, LCI: Laboratory-confirmed influenza, HCWs: healthcare workers, CRI: Clinical respiratory infection, LCVI: Laboratory-confirmed viral infection, RR: Relative risk, OR: Odd ratio, SR: Systematic review.

Some SR and meta-analyses included observational studies. However, only RCTs and meta-analyses that considered the RCTs were used in our review to evaluate the effectiveness of facemasks.

€ Clinical respiratory illness (CRI), defined as two or more respiratory or one respiratory symptom and a systemic symptom; Influenza-like illness (ILI), defined as fever ≥38°C plus one respiratory symptom (i.e., cough, runny nose, etc.). However, there is some heterogeneity in these subjective outcomes between the studies.

¥ Two trials showed that the mask + hand hygiene arm (but not the mask-only arm) had significantly fewer ILI than the control arm if the intervention duration was >2 weeks or started <36 hours after the onset of illness in a household.

Another systematic review found that the evidence from ten RCTs suggested that using facemasks either by infected or uninfected persons does not substantially affect influenza transmission (Xiao et al., 2020). Moreover, the effect of hand hygiene combined with facemasks on laboratory-confirmed influenza was not statistically significant (Xiao et al., 2020). Similarly, Brainard et al. (2020) discovered that wearing a facemask may only very slightly reduce the odds of developing influenza-like illness/respiratory symptoms by around 6% (Odd Ratio (OR) 0.94, 95% confidence interval (CI) 0.75 to 1.19; low-certainty evidence) in the community and among households. In the early COVID-19 pandemic, Jefferson et al. (2020) examined 14 RCTs investigating the effect of

masks on HCWs and the general population. Compared to no masks, there was no significant reduction of influenza-like illness (Risk Ratio (RR) 0.93, 95% CI 0.83 to 1.05) or influenza (RR 0.84, 95% CI 0.61 to 1.17) for masks in the general population, nor HCWs (RR 0.37, 95% CI 0.05 to 2.50). Lastly, an umbrella systematic review (Dugré et al., 2020) of mask-wearing is consistent with other reviews.

Before 2020, there were four systematic reviews (Bin-Reza et al., 2012; Cowling et al., 2010; Jefferson et al., 2011; Offeddu et al., 2017). Similar to the recent systematic reviews, wearing masks did not significantly reduce respiratory viral infection compared to not wearing masks. However, Offeddu et al. (2017) found that wearing a medical mask or N95 respirator among HCWs throughout the work shift conferred significant protection against self-reported clinical respiratory illness (RR 0.59, 95% CI 0.46 to 0.77) and influenza-like illness (RR 0.34, 95% CI 0.14 to 0.82). However, the clinical outcomes assessment was self-reported and prone to bias, as the intervention cannot be masked (Offeddu et al., 2017). The most objective and vital outcome is the laboratory-confirmed viral infection, but again, there was no significant difference. Moreover, this systematic review included one cluster RCT (MacIntyre et al., 2011) in which 15 hospitals were randomized into three groups (intervention arms), but the fourth group containing HCWs from nine other hospitals (mask-wearing was not routine) was selected as the no-mask group (not part of randomization) for secondary analysis, see Table 2. The risk of bias for the RCTs and cluster RCTs was mainly high or unclear (Jefferson et al., 2023). During the Influenza A pandemic, there was little evidence to support the effectiveness of facemasks in reducing the risk of infection. While there was one experimental evidence that masks should be able to minimize infectiousness under controlled conditions (Johnson et al., 2009), there was less evidence on whether this translates to effectiveness in natural settings (Cowling et al., 2010). A 2012 systematic review found that out of the 17 studies considered, none could definitively prove a link between the use of masks/respirators and protection against influenza infection (Bin-Reza et al., 2012).

Table 2: Characteristics of the randomized controlled trials on facemasks among health care workers.

Author & year*	Setting	Intervention (No. of participants). When	Outcomes	Comments
Loeb et al., 2022	Canada, Israel, Pakistan, and Egypt: 1009 HCWs in direct care to patients with suspected or confirmed COVID-19.	Surgical masks (497) vs. N95 fit-tested masks (507). HCWs should use the type of device they were allocated to for 10 weeks. Universal masking was the policy implemented at each site.	In the ITT analysis, RT-PCR–confirmed COVID-19 did not significantly differ between the two groups (10.46% vs. 9.27%) (hazard ratio, 1.14 [95% CI, 0.77 to 1.69]).	An unplanned subgroup analysis by country also found no significant difference.
Radonovich et al., 2019 (cluster)	United States of America, outpatient sites (clinics, primary care clinics, ED).	Surgical masks (2,668 person-seasons) and N95 masks (2,512 person-seasons). Whenever positioned within 6 ft of a patient with suspected respiratory illness.	No significant difference (both ITT & PP analysis were used) in the incidence of LCI among HCWs using N95 respirators (8.2%) vs. medical masks (7.2%), LCVI, ILI[#], or CRI[#].	The study was carried out each year for 4 years (2011-2015) during the 12 weeks of peak viral respiratory illness. The adherence was reported as always or sometimes about 90% of the time in both groups.
MacIntyre et al., 2015 (cluster)	Vietnam, hospitals (ED, ICU, ID, respiratory wards, or pediatric ward)	Surgical masks (580), cloth masks (2-layer cotton) (569), control (458)—"standard practice" of mask use. Worn masks all the time; the control as usual.	No significant diff. for CRI, ILI, or LCVI between the masks and control. ILI was significantly higher in the cloth mask arm than in the medical one as well as the control.	Compliance with mask-wearing was 24% in the control arm & about 57% in the others.
MacIntyre et al., 2013 (cluster)	China, hospitals (ED & respiratory wards) in the	Surgical mask (572), targeted use of N95 (516), N95 (581). Worn all the time except for targeted N95 as	Continuous use of N95 was significantly more protective against CRI than intermittent use of N95 or	The PP analysis of compliant participants showed essentially the same results. The diff. in

	winter of 2009-2010.	needed. They were followed for 5 weeks.	the mask arm, but no significance for ILI, LCI, or LCVI was found among the three groups.	compliance with the targeted N95 (82%), the surgical mask (66%), and the N95 arms (57%) were significant (P< 0.001).
MacIntyre et al., 2011 (cluster)	China, hospitals (ED & respiratory wards). Fifteen hospitals were randomized into 3 groups (intervention arms) from Dec. 2008 and followed for 5 weeks.	Surgical masks (492), N95 fit-tested masks (461), and N95 masks not fit-tested (488). All should wear while on the shift. HCWs from the other 9 hospitals (mask-wearing was not routine) were selected as the no-mask group (not part of randomization) for secondary analysis.	Compared to the mask arm, only the N95 non-fit-tested arm was significantly protective against CRI. Compared to the non-randomized no-mask group, N95 non-fit-tested arm was significantly protective against CRI and LCVI but not against ILI or LCI.	The surgical mask and N95 fit-tested mask arms had no significant difference compared to the non-randomized no-mask group. Adherence with mask or respirator wearing was high and not significantly different in all intervention arms.
Loeb et al., 2009	Canada, tertiary hospitals.	Surgical masks (212), N95 masks (210). When caring for patients with febrile respiratory illness.	No significant diff in LCI, other confirmed viral infection, ILI, or work-related absenteeism between the two groups.	Follow-up lasted from January 12 till April 23, 2009. Both ITT and PP analyses showed noninferiority.
Jacobs et al., 2009	Japan, tertiary hospital.	Masks (17), no masks (15). Wearing masks when they were in the hospital.	Masks worn by HCWs don't prevent cold symptoms or catching colds.	Participants recorded symptoms daily for 77 consecutive days, starting in Jan. 2008.

* Abbreviations; HCWs: healthcare workers, ITT: Intention-to-treat, RT-PCR: Reverse transcription polymerase chain reaction, CI: Confidence interval, ED: Emergency departments, PP: Per-protocol, LCI: Laboratory-confirmed influenza, LCVI: Laboratory-confirmed viral infection, ILI: Influenza-like illness, CRI: Clinical respiratory infection, ICU: Intensive-care unit, ID: Infectious disease.
# Clinical respiratory illness (CRI), defined as two or more respiratory or one respiratory symptom and a systemic symptom; ILI, defined as fever ≥38°C plus one respiratory symptom (i.e., cough, runny nose, etc.). However, there is some heterogeneity in these subjective outcomes between the studies.

In contrast, a few systematic reviews favored wearing masks to reduce respiratory infection in the community (Chen et al., 2022; Li et al., 2022; Tran et al., 2021). However, the clinical outcomes assessment was self-reported. Moreover, choosing a particular statistical analysis may cause results to differ. For instance, 16 RCTs involving 17,048 individuals were included in a network meta-analysis by Tran et al. (2021). Overall, the evidence was weak and lacking statistical power, but when they performed a pairwise meta-analysis of 11 RCTs, they revealed a substantially lower infection risk in those donning surgical masks than those without masks (RR 0.83, 95% CI 0.71 to 0.96).

Surprisingly, Coclite et al. (2021) concluded that the findings of their systematic review and meta-analysis support using facemasks in a community setting. However, the results of the RCTs and observational studies showed no significant differences. So, it is essential to thoroughly examine the results before drawing any conclusions from the author's findings.

5. Fourth reason: Surgical masks versus N-95 respirators based on the systematic reviews

Theoretically, N-95 respirators should be better than surgical masks. A systematic review published in 2016 included 23 surrogate studies comparing N95 respirators and surgical masks using manikins or adult volunteers under simulated conditions (Smith et al., 2016). N95 respirators were associated with less filter penetration, face-seal leakage, and total inward leakage under experimental laboratory conditions than surgical masks. However, the same review also included six clinical studies (three RCTs, one cohort study, and two case-control studies). In the meta-analysis of the clinical studies, there was no significant difference between N95 respirators and surgical masks in associated risk of laboratory-confirmed respiratory infection, influenza-like illness, or reported workplace absenteeism .

Based on 11 systematic reviews, N95 respirators were generally non-inferior to surgical masks, as shown in Table 1. However, few systematic reviews showed that wearing N95 respirators throughout the shift could be slightly superior to surgical masks in self-reported clinical outcomes (Dugré et al., 2020; Offeddu et al., 2017). For instance, N95 masks appeared to reduce influenza-like illness (RR 0.78, 95% CI 0.61 to 1.00) and any clinical respiratory infection risk (RR 0.95, 95% CI 0.90 to 1.00) (Dugré et al., 2020). A network meta-analysis of six RCTs suggested that continuously wearing N95 respirators on the whole shift can be the best preventive measure for HCWs from viral respiratory infectious diseases but not clinical respiratory illness (Yin et al., 2021). However, Yin et al. (2021) found that other measures (targeted N95, continuous or targeted wearing surgical masks, or continuous wearing cloth masks) were not significantly better than not wearing masks (Yin et al., 2021). An umbrella review slightly favored N95 or equivalent respirators over surgical masks (OR 0.79, 95% CI 0.64 to 0.98; P= 0.031); eight of the ten meta-analyses were appraised as having very low certainty, and the other two as having low certainty (Lu et al., 2023).

Surgical masks are primarily used by surgeons in operating rooms to safeguard sterile wounds from unintended contamination caused by respiratory droplets from the surgical team (Strasser & Schlich, 2020). Nevertheless, substantial evidence is lacking to support claims that facemasks protect either patients or surgeons from infectious contamination (Da Zhou et al., 2015). In a systematic review (Vincent & Edwards, 2016), including three RCTs with 2,106 participants, there was no statistically significant difference in infection rates between the group wearing surgical masks and the group wearing nothing. So, wearing surgical masks by surgical team members has almost no impact on surgical wound infection rates for patients undergoing clean surgery. With their original purpose highly questionable, it should come as no surprise that the ability of facemasks to function as respiratory protective devices should now be under intense scrutiny (Oberg & Brosseau, 2008).

Indeed, the scientific basis for HCWs using masks does not come from clinical trials of influenza outbreaks or pandemics. Instead, it comes from laboratory simulations showing that masks can prevent viral particles from getting through and from observational studies, particularly during the 2003 coronavirus epidemic that caused SARS (de Sá-Caputo et al., 2021; Smith et al., 2016).

6. Fifth reason: The effectiveness of facemasks based on the RCTs

We found 21 RCTs that evaluated the effectiveness of facemasks; see Tables 2-4. Seven trials were conducted among HCWs; see Table 2—five compared N-95 respirators versus surgical masks. The RCT recently published (Loeb et al., 2022), and therefore not included in the systematic reviews assessed, did indeed directly compare surgical masks to respirators for HCWs caring for known or suspected COVID-19 patients; it added strong support to the other trials (Loeb et al., 2009; MacIntyre et al., 2011; MacIntyre et al., 2013; Radonovich et al., 2019) in the lack of significant differences between the two types of masks in clinical outcomes. A per-protocol analysis was additionally done in some trials (Loeb et al., 2009; MacIntyre et al., 2013; Radonovich et al., 2019) and showed almost the same results.

However, two trials have shown that N95 masks can reduce clinical respiratory illness (MacIntyre et al., 2011; MacIntyre et al., 2013). In one trial, only wearing non-fit-tested N95 throughout the shift was significantly more protective against clinical respiratory illness (3.3%, OR 0.48, 95% CI 0.24 to 0.98; *P*= 0.045) compared to the surgical mask group (6.7% as ref.) (MacIntyre et al., 2011). Continuously using N95 respirators was significantly more protective against CRI and bacterial colonization than intermittent N95 or surgical mask arms (MacIntyre et al., 2013) Therefore, MacIntyre et al. (2013) concluded that continuous use of N95s resulted in significantly lower rates of bacterial colonization, a novel finding that points to more research on the clinical significance of bacterial infection in symptomatic HCWs (MacIntyre et al., 2013; MacIntyre et al., 2014). However, continuous wearing did not offer better protection than targeted wearing at a 95% confidence level, according to two meta-analyses (Lu et al., 2023; Yin et al., 2021). It is essential also to note that facemasks are primarily worn by HCWs to protect against serious viral diseases, not to reduce cold or flu symptoms or prevent bacterial colonization. Moreover, the human body is always colonized by bacteria; for example, different types of bacteria colonize the nose and skin. Staphylococcus aureus (associated with many diseases) is among the most common (Sakr et al., 2018). One study included 269 patients and 108 HCWs, of whom 15% and 12% were carriers of methicillin-resistant Staphylococcus aureus for each group, respectively. However, no direct evidence warrants investigation that colonized HCWs increase the risk of methicillin-resistant Staphylococcus aureus infection in patients (Espinosa et al., 2013).

Of the seven RCTs examining the use of masks by HCWs, only two had a control group randomized to no mask (Jacobs et al., 2009; MacIntyre et al., 2015). In these trials, surgical masks did not reduce influenza-like illness, any clinical respiratory infection, laboratory-confirmed influenza, or laboratory-confirmed viral respiratory infection compared with no masks; this was also confirmed by one of the systematic reviews (Dugré et al., 2020).

Other nine RCTs were conducted among households with an index case (a patient with influenza-like illness or confirmed influenza), as shown in Table 3. All were cluster RCTs (see Table 3). Except for one RCT (Barasheed et al., 2014), wearing masks among households when someone was ill did not reduce the risk of laboratory-confirmed influenza or influenza-like illness. However, some studies used per-protocol analysis in which those who did not adhere to wearing a mask were excluded from the intervention group; two studies found that masks could be protective (MacIntyre et al., 2016; Suess et al., 2012).

Table 3: Characteristics of the randomized controlled trials on facemasks in the households.

Author, year, country*	Description	Intervention (No. of participants)	Outcomes	Comments
MacIntyre et al., 2016, China	Index patients with ILI[#] were randomly allocated to two groups.	Surgical mask (123) and control (122) arms. A sick person in the mask arm should wear a masks whenever the same as someone else.	The ITT analysis showed no statistically significant effect between the two arms on CRI[#], ILI, or LCI.	A post hoc comparison (between those who used masks -regardless of the original groups- and those who did not) showed only a protective effect of the mask against CRI.
Barasheed et al., 2014, Saudi Arabia	At the 2011 Hajj, 22 tents were randomized into two arms.	Mask arm (75): everyone in mask tents (index and contact sleeping within 2 meters in the same tent) should wear a mask, control arm (89).	Fewer contacts became symptomatic in the mask tents than in the control tents (31% vs. 53%, p= 0.04), but no difference in LCVI.	Mask use compliance was 76% in the mask group and 12% in the control group.
Suess et al., 2012, Germany	During the influenza seasons 2009-2011, households with an influenza-positive index case were involved.	Surgical mask group (69): all household members wear masks whenever there is a sick patient, control group (82).	The ITT analysis showed no statistically significant difference between the groups on secondary infections (LCI or ILI), even if implemented <36 h after symptom onset of the index.	In a PP analysis, significant results (for LCI) were reached in the mask group when analyzing the complete data set and when considering only A (H1N1) households.
Simmerman et al., 2011, Thailand	Between April 2008 and August 2009, 442 index children (LCI) with 1147 household members were randomized into three groups.	Surgical masks & hand wash arm (291), hand wash arm (292), or control arm (302). For the mask arm, all household members should wear masks once a child gets sick.	The ITT analysis showed no statistically significant diff between the groups on secondary infections, LCI, but ILI was statistically significantly lower in the control arm.	The ORs for secondary influenza infection were also not significantly different in the hand wash arm or the hand wash plus mask arm.
Larson et al., 2010, United States of America	About 509 primarily Hispanic households were randomized into three groups and followed for up to 19 months.	Surgical masks + hand hygiene (938), hand hygiene (946), or control (904). For the mask arm, sick patients & household members (caretakers) should wear masks once someone gets sick.	No significant difference in the incidence of CRI, ILI, or LCI between the three groups.	There was a significant decrease in secondary attack rates in the mask + hand hygiene arm compared to the control arm regarding the total infections.[¥] Adherence to masks was poor (50%).
Canini et al., 2010, France	During the 2008-2009 influenza season, household members with a positive rapid influenza A test and symptoms lasting <48 hours were recruited.	Surgical masks (148), no masks (158). In the mask arm, a sick person should wear masks whenever the same as someone else for 5 days from the first medical visit.	In an ITT analysis, ILI was reported in 16.2% of the contacts in the mask arm and 15.8% in the control arm; the difference was statistically insignificant.	In various sensitivity analyses, the researchers did not identify any trend in the results suggesting the effectiveness of facemasks.
MacIntyre et al., 2009, Australia	During the 2006 and 2007 winter seasons, 286 exposed adults from 143 households exposed to a child with CRI were recruited.	Surgical masks (94), N-95 masks (92): healthy people should wear masks whenever in the same room as the index patient, control (100).	ITT analysis showed no significant difference in the group's relative risk of ILI or LCVI.	The authors concluded that household use of masks is associated with low adherence (<50%) and is ineffective for controlling seasonal ILI.

Cowling et al., 2009, Hong Kong	To investigate whether hand hygiene and mask use prevent household influenza transmission. The participants were randomized into 3 groups.	Control (279), hand hygiene (257), and surgical masks plus hand hygiene (258): all household members should wear masks once in the same room as the index patient for the mask arm.	The secondary LCI, in general, did not significantly differ across the intervention arms. Different sensitivity analyses were used.	No significant difference was found between the mask + hand hygiene and the hand hygiene arms in LCI if interventions started <36 hours after the onset of illness.
Cowling et al., 2008, Hong Kong	Cluster RCTs of households (composed of at least 3 members) where an index patient presented with ILI of <48 hours duration.	Surgical mask (61); all household members should wear masks when in the same room as the index patient, control (205).	The LCI or secondary clinical attack ratios did not significantly differ across the intervention arms.	The results did not change even if interventions started <36 hours after the onset of illness.

* Abbreviations; ILI: Influenza-like illness, ITT: Intention-to-treat, CRI: Clinical respiratory infection, LCI: Laboratory-confirmed influenza, LCVI: Laboratory-confirmed viral infection, PP: Per-protocol, ORs: Odd ratios.

Clinical respiratory illness (CRI), defined as two or more respiratory or one respiratory symptom and a systemic symptom; ILI, defined as fever ≥38°C plus one respiratory symptom (i.e., cough, runny nose, etc.). However, there is some heterogeneity in these subjective outcomes between the studies.

¥ The arm, composed of two interventions (hand hygiene and mask), was better than the control; however, the comparison to the hand hygiene-only arm, which is essential to conclude the mask's effectiveness, was not concluded in the study.

Five other RCTs were conducted in the community (see Table 4); two were about SARS-CoV-2 (Abaluck et al., 2022; Bundgaard et al., 2021). In April-May of 2020, a Danish RCT was conducted to evaluate the effectiveness of surgical masks in preventing COVID-19 infection among around 6,000 participants (Bundgaard et al., 2021). Of those, 42 mask-wearing participants (1.8%) and 53 control participants (2.1%) got infected with SARS-CoV-2. The difference between the two groups was insignificant (OR 0.82, 95% CI 0.54 to 1.23; *P*= 0.33). Additionally, the researchers examined 11 other respiratory viruses and found that only 0.5% of the mask group tested positive for one or more of these viruses, compared to 0.6% in the control group. However, this difference of 0.1% was also not statistically significant. In a per-protocol analysis that excluded participants in the mask group who reported nonadherence (about 7%), SARS-CoV-2 infection occurred in 40 participants (1.8%) in the mask group and 53 (2.1%) in the control group; no statistically significant interactions were identified. Abaluck et al.'s RCT (2022) was considered to have a high risk of bias in selective reporting; they did not report on prespecified seroconversion, and none of the outcomes reported were prespecified in the trial registry (Jefferson et al., 2023). In contrast to Bundgaard et al.'s RCT, Abaluck et al. depended on the seroprevalence conversion in diagnosing COVID-19. Not all symptomatic seroprevalence results from infections occurring during our intervention; individuals may have had preexisting SARS-CoV-2 infections and then became symptomatic (perhaps due to an infection other than SARS-CoV-2) (Abaluck et al., 2022). However, the intervention effects were weak; the proportion of individuals with COVID-like symptoms was 7.62% in the intervention arm and 8.62% in the control arm. This translates into a relative risk reduction of about 11% but an absolute difference of only 1%. More than one-third of symptomatic participants agreed to blood collection. Symptomatic seroprevalence was 0.76% in control villages and 0.68% in the intervention villages, i.e., the relative risk reduction is about 11%. Therefore, the presence of statistical significance (if any) does not necessarily mean that the intervention is valuable because the magnitude may be weak, as seen here (Abaluck et al., 2022).

Table 4: Characteristics of the randomized controlled trials on facemasks in the community.

Author, year, country*	Description	Intervention (No. of participants)	Outcomes	Comments
Abaluck et al., 2022, Bangladesh	A cluster RCT measured the effect of mask use in the community on symptomatic SARS-CoV-2 infection.	About 572 villages: surgical masks (200), cloth masks (100), and control (272).	Surgical masks (but not cloth masks) could reduce symptomatic seroprevalence of SARS-CoV-2 compared to no masks. However, the intervention magnitude was low.	7.6% had COVID–19–like illnesses in mask arm vs. 8.6% in control. Symptomatic seroprevalence was 0.76% in the control and 0.68% in the intervention arms, i.e., relative risk reduction is about 11%.
Bundgaard et al., 2021, Denmark	To assess whether recommending facemask use outside the home	In the surgical mask arm (2392), the participant wears a mask whenever	Infection with SARS-CoV-2 occurred in 1.8% of the mask group vs.	No statistically significant difference was identified in the PP analysis that

	reduces wearers' risk for SARS-CoV-2 infection.	outside the home among other persons together with a supply of 50 masks, control arm (2470).	2.1% in the control; the difference was small and insignificant (by ITT).	excluded participants in the mask group who reported nonadherence.
Alfelali et al., 2020, Saudi Arabia	Over three consecutive Hajj seasons (2013-2015), pilgrims' tents in Makkah were allocated to two groups.	Mask arm (3199): 50 facemasks were offered to participants in each intervention tent, to be worn over four days, control arm (3193).	The CRI and LCVI did not significantly differ across the two groups by ITT and PP analysis.	This trial could not provide conclusive evidence on mask efficacy against viral infections, likely due to poor adherence.
Aiello et al., 2012, United States of America	A cluster RCT followed 1,178 young adults living in 37 residence houses in 5 university halls during the 2007-2008 influenza season for 6 weeks.	Surgical mask arm (392): participants wear masks >6 hours a day, control arm (370). Our review did not consider the third arm (mask & hand hygiene).	The ILI and LCI did not significantly differ between the mask and control arms, even when including the third arm.	Even after covariate adjustment, ILI was not significantly different between the mask and the control arms in any week of the 6 weeks.
Aiello et al., 2010, United States of America	About 1,437 young adults living in university residence halls during the 2006-2007 influenza season were randomized into three groups followed for 6 weeks.	Surgical mask arm (378): participants wear masks as much as possible, control arm (552). Our review did not consider the third arm (mask and hand hygiene).	The ILI and LCI did not significantly differ between the mask and control arms, even when including the third arm (mask and hand hygiene).	In unadjusted analyses only, significant reductions in ILI incidence were observed in the mask-only group (weeks 3–5) compared to the control group.

* Abbreviations: RCT: Randomized-control trial, SARS-COV-2: Severe acute respiratory syndrome coronavirus 2, ITT: Intention-to-treat, PP: Per-protocol, CRI: Clinical respiratory infection, LCVI: Laboratory-confirmed viral infection, ILI: Influenza-like illness, LCI: Laboratory-confirmed influenza. [#] Clinical respiratory illness (CRI), defined as two or more respiratory or one respiratory symptom and a systemic symptom; ILI, defined as fever ≥38°C plus one respiratory symptom (i.e., cough, runny nose, etc.). However, there is some heterogeneity in these subjective outcomes between the studies.

In the three remaining trials, masks were used in a prespecified healthy population group, either American university students randomized by residence hall (Aiello et al., 2010; Aiello et al., 2012) or Australian Hajj pilgrims randomized by accommodation tent (Alfelali et al., 2020). None of these trials showed any statistically significant difference in the incidence of laboratory-confirmed influenza or influenza-like symptoms when comparing wearing masks to not wearing masks, even after using per-protocol by Alfelali and his colleagues. In a superiority RCT, the intention-to-treat (ITT) analysis is the main analysis method, while the per-protocol (PP) approach could be added as a secondary supportive analysis (Tripepi et al., 2020). In contrast, in a non-inferiority trial, as in the trial that aimed to demonstrate that surgical masks were not inferior to N95 respirators (Loeb et al., 2009), both the ITT and PP analyses have equal importance, and their results should lead to similar conclusions for a robust interpretation. However, the researchers of the RCTs, other than non-inferiority trials, often tried to find statistically significant differences to support wearing a facemask versus not wearing it by doing a PP analysis, although the ITT analysis did not show any significant differences.

Furthermore, some of the original investigators in these studies undertook logistic regression to adjust their findings for other confounders. They found evidence that early facemask wearing (<36 hours after symptom onset) could be protective but acknowledged that their models were underpowered (Brainard et al., 2020).

Surprisingly, none of the RCTs investigated the impact of mask-wearing on mortality or hospitalization, which are indicators of severe illness. Instead, they only focused on developing respiratory symptoms, with or without confirmation from laboratory tests.

7. Sixth reason: Harms

A careful risk-benefit analysis is becoming increasingly relevant for HCWs, patients, and general people regarding facemasks. Although many descriptive and experimental studies have shed some light on the potential ADRs of wearing masks, the potential harms of wearing a mask were rarely measured and poorly reported by trials. Less than half of the trials comparing masks with no masks addressed the harms of mask-wearing (Jefferson et al., 2023; Bakhit et al., 2021). In one RCT (MacIntyre et al., 2013), researchers concluded that wearing an N95 respirator during the entire shift might reduce clinical respiratory illness versus wearing a targeted N95 respirator. However, as usual, the researchers overlooked the potential ADRs of wearing a respirator for a prolonged period, which might reach over eight hours, against the potential to reduce the risk of self-reported respiratory symptoms, such as headache, cough, sore throat, etc. Prolonged N95 respirator wearing (over one hour) has been reported to cause significant

physiological effects, including headache, increased breathing burden, and nervous system and cardiovascular system changes (e.g., reduced cognition, decreased cardiac contractility) due to the elevated carbon dioxide (CO_2) concentration (USFDA, 2023).

Regardless of the type of facemask, wearing a mask has many ADRs (Kisielinski et al., 2021). Unlike clothing worn over closed skin, masks cover body areas close to the mouth and nose, i.e., body parts that are involved with respiration. Hence, warmth, respiratory difficulties, humidity, and discomfort were the most frequently reported ADRs (Jefferson et al., 2023), particularly for long periods in warm environments (Brooks et al., 2021). Of course, general discomfort and inconvenience, which increase with mask-wearing duration (Bakhit et al., 2021), will reduce wear adherence (Jefferson et al., 2023; Li et al., 2022). The discomfort, even the feeling of suffocation, comes simply because of the mask's function, which suppresses airflow (Alqahtani et al., 2016). The extent to which a mask could cause respiratory difficulties and discomfort (and maybe increased CO_2 levels) varies depending on several factors (Kisielinski et al., 2021). These include the materials used to make the mask, how snugly it fits, how long it is worn, the wearer's exertion, and the wearer's demographic data (Kisielinski et al., 2021). Moreover, a fraction of CO_2 previously exhaled is inhaled at each respiratory cycle. Those phenomena increase breathing frequency and deepness and may worsen the burden of influenza/COVID-19 if infected people wearing masks spread more contaminated air. This may also worsen the clinical condition of infected people if the enhanced breathing pushes the viral load down into their lungs (Kyung et al., 2020; Lazzarino et al., 2020).

From a medical standpoint, there is a theoretical possibility of airflow resistance when wearing a mask, more with N-95 respirators. An increase in work breathing can occur, especially during physical exertion (Matuschek et al., 2020). In a recent intervention study conducted on eight subjects, measurements of the gas content for oxygen and CO_2 in the air under a mask showed a lower oxygen availability even at rest than without a mask (Kisielinski et al., 2021; Pifarré et al., 2020). Another consequence of wearing a mask that has often been experimentally proven is a statistically significant drop in blood oxygen saturation (Kisielinski et al., 2021). A reduction in blood oxygen partial pressure with the effect of an accompanying increase in heart rate as well as an increase in respiratory rate has been proven (Kisielinski et al., 2021; Fikenzer et al., 2020). Ventilation, cardiopulmonary exercise capacity, and comfort are reduced by surgical masks and highly impaired by N95 respirators in healthy individuals (Fikenzer et al., 2020). The increase in heart rate and the corresponding feeling of exhaustion was accompanied by a sensation of heat and itching due to moisture penetration of the masks after only 90 min of physical activity (Li et al., 2005). In a mask experiment from 2020, significantly impaired thinking and impaired concentration were found for all mask types used (cloth, surgical, and N95 masks) after only 100 min of wearing the mask (Liu et al., 2020). The thought disorders correlated significantly with a drop in oxygen saturation during mask use (Kisielinski et al., 2021).

The harm becomes more with denser masks. Based on one RCT (MacIntyre et al., 2011), participants wearing N-95 experienced more discomfort, forgetting to wear their masks, their patients uncomfortably, trouble communicating with the patient, headaches, difficulty breathing, pressure on the nose, and other problems than those who wore a surgical mask. Both groups almost suffered equally from skin rash and allergy. Kunstler et al. (2022) reported that HCWs who wore respirators over a prolonged period experienced significantly more headaches (OR 2.62, 95% CI 1.18 to 5.81), respiratory distress (OR 4.21, 95% CI 1.46 to 12.13), facial irritation (OR 1.80, 95% CI 1.03 to 3.14) and pressure-related injuries (OR 4.39, 95% CI 2.37 to 8.15) when wearing respirators compared to surgical masks. Moreover, significantly increased headache ($P < 0.05$) could be observed not only for N95 but also for surgical masks in participants of another RCT of HCWs (Jacobs et al., 2009).

Furthermore, the ADRs of facemasks were evaluated from November 2021 to February 2022 with a structured Google Forms online questionnaire worldwide (Gyapong et al., 2022). Almost 60% of the 2,136 participants indicated discomfort while using facemasks. Breathing difficulties and pain around the ears were cited as major causes of discomfort, accounting for 32% and 22%, respectively. Headaches were reported by 26.8% of the respondents, with 44.6% experiencing one within one hour of wearing a mask. Nasal discomfort was also reported, while 412 individuals reported various skin-related discomfort, including excessive sweating around the mouth and acne (Gyapong et al., 2022). Notably, tolerance for wearing a facemask differs between HCWs and others; tolerance is lower among general people. For example, 34% of participants who wore a surgical mask when a family member had respiratory symptoms complained of difficulty breathing, compared to 12% of HCWs (Bakhit et al., 2021).

Those mentioned physiological and subjective physical effects of masks on healthy people at rest and under exertion indicate the impact of masks on sick and elderly people even without exertion (Kisielinski et al., 2021). Therefore, people with respiratory or heart conditions or other chronic medical conditions that make breathing difficult should see a healthcare provider before using an N-95 respirator, as these respirators can make breathing more difficult for the wearer, as the United States Food and Drug Administration warns (USFDA, 2023). N95 mask negatively impacts the physiological variables of HCWs. The ADRs may lead to excessive exhaustion after long shifts in the intensive care unit while treating patients with serious respiratory viral infections (Hussain et al.,2022).

On the other hand, innate immunity's efficacy highly depends on the viral load (Chen et al., 2018). Suppose masks determine a humid habitat where the SARS-CoV-2 can remain active due to the water vapor continuously provided by breathing and captured

by the mask fabric. In that case, they determine an increase in viral load; therefore, they can cause a defeat of innate immunity and an increase in infections (Lazzarino et al., 2020).

At first glance, the mask-induced adverse changes are relatively minor, but repeated exposure by the pathogenetic principle over extended periods is clinically relevant. With correspondingly repeated and prolonged exposure to physical, chemical, biological, physiological, and psychological conditions, some of which are subliminal but which are significantly shifted towards pathological areas, health-reducing changes and clinical pictures can develop, such as high blood pressure and arteriosclerosis as well as neurological diseases and mild but sustained increases in respiratory rates (Kisielinski et al., 2021). For slight increases in CO_2 in the inhaled air, this disease-promoting effect has been proven with the creation of headaches, irritation of the respiratory tract, and neuropathological and cardiovascular consequences (Azuma et al., 2018). Masks are responsible for the aforementioned physiological changes, and policymakers have often ignored these potential changes.

Children are particularly vulnerable and may be more likely to receive inappropriate treatment or additional harm. Special attention must be paid to the respiration of children, which represents a critical and vulnerable physiological variable due to higher oxygen demand, increased hypoxia susceptibility of the central nervous system, lower respiratory reserve, smaller airways with a more substantial increase in resistance when the lumen is narrowed (Kisielinski et al., 2021). The masks used for children are exclusively adult masks and have neither been specially tested nor approved for this purpose (Smart et al., 2020).

8. Seventh reason: Masks people wear are usually of poor quality

If we have decided that the evidence for wearing the mask is both valid and important, we need to consider whether we can apply it to the population. When conducting a trial of mask-wearing, the intervention group is usually trained to wear a mask correctly and provided with a good number of masks, so if there is an intended benefit from wearing a mask, could the results be similar when applied to the general population? In other words, how good are the masks that people wear? Can people correctly apply the instructions for wearing, removing, and disposing of masks?

Although none of the RCTs tested the cloth masks among the general population, the CDC has recommended them (Greenhalgh et al., 2020). Various shapes, forms, and materials were used and advertised to the point that in 2020, the business of producing and selling facemasks was born (Matuschek et al., 2020). Most community members used reusable fabric face masks (cloth masks) or homemade masks during the COVID-19 pandemic. Some might use disposable medical/surgical masks. However, many surgical masks are not usually certified to medical standards, commonly called non-medical masks (commercial masks). Moreover, surgical masks used in healthcare settings typically fail to exhibit adequate filter performance and facial fit characteristics to be considered respiratory protection devices (Douglas et al., 2020; Mottay et al., 2020; Oberg & Brosseau, 2008). Medical and general masks provided little protection against respiratory aerosols (Jung et al., 2014).

Health officials should have cared about the details or taught the public to wear masks. Instead, what was important during the COVID-19 pandemic was for people to cover their noses and mouths when outside in any way. With the increase in global demand for masks, it was natural that types of masks of different quality, usually of poor quality, were seen. Therefore, people were typically willing to wear a less effective facemask for long periods without washing it. Additionally, they lack knowledge of how to disinfect masks properly (Lee et al., 2021). Despite wearing a mask, a man touching his nose or mouth repeatedly (23–26 times per hour) with an unsensitized hand has been a severe worry (Rahman, 2020).

An RCT was carried out in 2014 to compare the efficacy of cloth masks to surgical masks among HCWs (MacIntyre et al., 2015). Particle penetration for cloth masks was about 97%, and for surgical masks, 44%. Interestingly, cloth masks had significantly higher influenza and laboratory-confirmed virus rates. The results caution against the use of cloth masks. Moisture retention, reuse of cloth masks, and poor filtration can increase the risk of infection. So, cloth masks should not be recommended for HCWs, as the researchers alert (MacIntyre et al., 2015). Although this trial (the only RCT on cloth masks) was published in 2015, such studies were ignored, and instead, many governments force people to wear any mask, whether cloth or any commercial surgical mask. These masks are ineffective in reducing the spread of COVID-19 and can probably hurt you (Daoud et al., 2021). According to the cluster RCT conducted in rural Bangladesh, cloth masks did not offer a statistically significant rate reduction of symptomatic seroprevalence of COVID-19 (cloth mask: 0.74%, control: 0.76%, P= 0.540) (Abaluck et al., 2022). Tran et al. (2022) also concluded that people should not use cloth masks in the outbreak hot spots and places even where social distancing is impossible.

It is worth noting that even with those intended for single use, some people reuse them, possibly for days (Lee et al., 2021), while others reuse cloth masks without washing them (as advised). This practice is probably related to a health belief of having inadequate facemasks (Lee et al., 2021). People generally keep cloth masks for a long time and reuse them frequently, with various cleaning and storage methods (Lee et al., 2021). Therefore, wearing masks may increase the appearance of symptoms similar to those of influenza/COVID-19, such as headache, feeling uncomfortable in breathing, runny nose, etc. (Kisielinski et al., 2021; Rosner, 2020). Some respondents experienced resolved the ADRs once masks were removed, while others required physical or medical intervention (Rosner, 2020). One paper referred to the psychological and physical deterioration and multiple symptoms described

because of their consistent, recurrent, and uniform presentation from different disciplines as a Mask-Induced Exhaustion Syndrome (Kisielinski et al., 2021). Hence, physicians should consider mask-wearing in the differential diagnostic pathophysiological cause when such symptoms occur, especially when wearing a mask is common. Besides, several types of masks of questionable effectiveness are being sold at markets and tried on by people before making a purchase (Rahman, 2020). Previously, wearing masks was almost exclusively restricted to HCWs and in certain circumstances. So, at least, we were guaranteeing the quality of the masks, in contrast to the time since 2020 when the trade in masks has spread.

9. Eighth reason: Misuse of masks

There is a big difference between advising people to wear facemasks and forcing them to do so. Although some might argue that this was to protect others, trials before the COVID-19 pandemic failed to prove any significant benefit for the wearers or others; even if there were any benefit, it would be negligible. The WHO recommended wearing masks in crowded, enclosed, or poorly ventilated areas when people cannot maintain distance during the COVID-19 pandemic (WHO, 2021). However, people were forced to cover their faces in many countries; otherwise, they would be fined, imprisoned, or banned from entering workplaces, shops, etc. For example, it was required in the Philippines to wear face shields in addition to facemasks outside their homes, although they can suffocate and cause accidents (Magsambol, 2021). In other countries, large fines were imposed on those who did not cover their faces when they left home. Others made wearing masks in public mandatory, with violators facing up to three years in jail and fines of as much as $55,000 (Aljazeera, 2021).

However, most people do not follow the instructions when wearing a mask, in addition to the fact that many people wear masks not voluntarily but out of fear of punishment or to enter shops, workplaces, and so on. It is not only the functional weaknesses of the masks mentioned so far that lead to problems, but also their misuse.

According to the literature, mistakes are made by both HCWs and lay people when using masks, as hygienically correct mask use is by no means intuitive. Overall, 65% of HCWs misuse masks (Gralton & McLaws, 2010). A study of ten nurses observed for 10 min/hour over two shifts found that they touched their faces two to three times per hour, their mask five times per hour, and their eyes once per two hours (Rebmann et al., 2013). In a study of HCWs, 13 of the 53 reported wearing masks only covering their mouths, not their noses (Vanjak et al., 2006). A cross-sectional study evaluating the proficiency of the Singaporean public in wearing N95 masks found that only 90 out of 714 subjects passed the visual mask fit test; the most common criteria performed incorrectly were strap placement, leaving a visible gap between the mask and skin, and tightening the nose-clip (Yeung et al., 2020). In Pakistan, for example, PPE was unavailable in many health facilities during the COVID-19 pandemic, compliance with PPE (including facemasks) use was low, and its reuse was reported (Chughtai & Khan,2020).

Of course, compliance would be lower among other people. When used by the general public, scientists consider masks to pose a risk of infection because the general public cannot follow the standardized hygiene rules of hospitals (Chughtai et al., 2020). In one study, 78% of the general population misused masks (Gralton & McLaws, 2010). The media showed pictures of people wearing facemasks on their chins or necks without covering their mouths and noses or merely covering their mouths with their noses exposed. People who use masks are usually observed to pull their masks down to their chins to speak and then drag them back over their mouths and noses after speaking (Rahman, 2020). People are often found to touch the top part of the mask to adjust, remove, or scratch their face as an automatic reflex. Many people use the same mask over an extended period, even when damp or spoiled (Rahman, 2020). Moreover, despite the mandatory use of masks in many countries, people reportedly circulate without wearing a mask in some places (Rahman, 2020).

There is a great deal of wearer variability. Some wearers are much more anxious about wearing masks than others. Some wearers can tolerate hot, humid conditions inside masks, whereas others cannot. In addition to the potential ADRs of facemasks, wearing a mask interferes with normal respiration, vision (especially when wearing glasses), feelings of well-being, and communication, and also presents an inhibition to habitual actions such as eating, drinking, touching, scratching, and cleaning the otherwise uncovered part of the face, which is consciously and subconsciously perceived as a permanent disturbance, obstruction, and restriction (Johnson, 2016). Facemasks can limit the amount and intensity of work that can be done compared to when not wearing one (Johnson, 2016). Because of this variability, each wearer must be treated as an individual.

However, in the COVID-19 pandemic, masks were universally worn in public, on the streets, in automobiles, etc., where they were not needed but where arrest or punishment would follow if not worn. They were very generally laid aside when the wearer was no longer subject to observation by the police, such as in private offices and gatherings of all kinds. This type of gathering with the attendant social intercourse between friends and office associates seems to afford a particular facility for transferring the virus. This contact form, where people are conversing with one another, would be much more dangerous than a crowd association of strangers, even when gathering in churches and theatres, a scenario similar to the 1918-1919 influenza pandemic when wearing a mask was mandatory in some parts of the world (Kellogg & Macmillan, 1920).

On the other hand, wearing a mask may give a false sense of security and make people adopt a reduction in compliance with other necessary infection control measures (Lazzarino et al., 2020). Moreover, the quality and the volume of speech between people wearing masks are considerably compromised, and they may unconsciously come closer. The risk of infection could increase as the mask makes the exhaled air go into the eyes. This generates an impulse to touch your eyes (Lazzarino et al., 2020).

The appropriate use, storage, and cleaning or disposal of masks are essential to make them as effective as possible. However, the improper use of facemasks may increase the risk of ADRs and possibly increase bacterial/viral contamination (Lazzarino et al., 2020). Masks cause the retention of moisture (Roberge et al., 2010). Poor filtration performance, incorrect use of surgical and cloth masks, and frequent reuse imply an increased risk of infection (MacIntyre et al., 2015; Loeb et al., 2009). The warm and humid mask favors the accumulation of germs on and underneath the masks (Luksamijarulkul et al., 2014), and the germ density is measurably proportional to the length of time the mask is worn (Chughtai et al., 2019; Zhiqing et al., 2018). From a microbiological and epidemiological point of view, masks in everyday use pose a risk of contamination. This can occur as foreign contamination but also as self-contamination. On and in the masks, there are quite serious, potentially disease-causing bacteria and fungi such as E. coli, Staphylococcus, Candida, Klebsiella, Enterococci, Pseudomonads, Enterobacter and Micrococcus even detectable in large quantities (Monalisa et al., 2017). In another microbiological study, the bacterium Staphylococcus aureus (57% of all bacteria detected) and the fungus Aspergillus (31% of all fungi detected) were found to be the dominant germs on 230 surgical masks examined (Luksamijarulkul et al., 2014). After more than six hours of use, the following viruses were found in descending order on 148 masks worn by medical personnel: adenovirus, bocavirus, respiratory syncytial virus, and influenza (Chughtai et al., 2019).

The WHO lists the basics of how to wear a mask on its website, which include cleaning hands before and after taking the mask off and touching it at any time, covering the mouth and nose well, making sure there are no gaps between your face and the mask, and avoiding touching the mask while using it (WHO, 2020). However, most people do not wash their hands before and after wearing a mask or when touching it; how can they wash their hands or use an alcohol-based hand sanitizer while they are outside? It is common for individuals to touch or place their masks on their chin because they may not believe it is effective (when it is mandatory), find it uncomfortable, or have other reasons. Often, the mask is lowered or removed for drinking, eating, or even speaking. The results of one meta-analysis showed that only about one-third of the European respondents had worn facemasks during an epidemic/pandemic (Li et al., 2022). The reason for negative attitudes towards facemask use in these countries may partly be due to the stigma associated with wearing facemasks. In some contexts, masks implicitly or explicitly oppose the concepts of transparency and authenticity (Sin, 2016). Face mask-wearing may thus be regarded as a symbol of compliance, regulation, manipulation, and the government's opposition to freedom of speech (Sin, 2016).

On the other hand, the COVID-19 pandemic has affected the environment due to the large volume of waste in the form of discarded PPE. The remarkable increase in the global use of facemasks, which mainly contain polypropylene, and improper waste management led to a serious environmental challenge called microplastic pollution (Asim et al., 2021). These plastics undergo physical and biochemical degradation and turn into microplastics that are more difficult to control (Ó Briain et al., 2020). Moreover, plastic waste adsorption of organic and inorganic nutrients will provide a stable environment for the further propagation of pathogenic bacteria, contaminants, and viruses (Asim et al., 2021). It is estimated that the total daily facemasks during the pandemic were about 6.6 billion (Asim et al., 2021; Prata et al., 2020). Therefore, facemasks must be disposed of safely. However, some people discard masks randomly on roads, footpaths, hospital areas, police stations, rivers, or others (Rahman, 2020). Within the framework of these findings, everyday masks are even considered a general risk for microplastic pollution as well as infection in the general population, which does not come close to imitating the strict hygiene rules of hospitals and doctors' offices: the supposed safety, thus, becomes a safety risk itself (Kisielinski et al., 2021).

10. Ninth reason: The trajectory of the COVID-19 pandemic despite masking

The mask, which originally served a purely hygienic purpose, has been transformed into a symbol of conformity and pseudo-solidarity (Kisielinski et al., 2021). The WHO, for example, lists the advantages of using masks by healthy people in public, including a potentially reduced stigmatization of mask wearers, a sense of contribution to preventing the virus spread, and a reminder to comply with other measures (Kisielinski et al., 2021; Escandón et al., 2021). However, adherence to the rules of mask use is impaired and not adequately followed due to reduced wearability with heat discomfort, skin irritation, and other problems (Liu et al., 2020).

Globally, COVID-19 cases increased despite mandatory masking in many parts of the world. In the span of three years, from 2020 to 2022, 2021 was the worst year regarding the number of global deaths attributed to COVID-19, while in 2022, the highest number of cases was recorded (Alrasheedi, 2023). It is important to note that studies comparing outcomes before and after the intervention (e.g., facemasks) without a control group can be biased as changes may simply reflect natural regression to the mean (any changes in outcomes that might occur naturally in the absence of the intervention) (Clarke et al., 2019). Additionally, population data may not accurately measure the mask effects due to ignored confounders like natural immunity and seasonal effects. Therefore, the study on this topic is usually conflicting. Some show a relationship between wearing masks and decreasing cases (Brooks & Butler, 2021), while others do not (Spira, 2022).

With the number of cases increasing in 2021, despite strict mass masking, some suggested that wearing two masks could be more efficacious (Brooks et al., 2021). It was just an assumption based on common sense that wearing two masks would reduce the respiratory droplets spread to others. However, the spread of respiratory droplets can be safely reduced by simple instructions like covering the nose and mouth when sneezing or coughing. Still, it was clear that wearing a mask did not contribute to combat SARS-CoV-2. Moreover, using three or four facemasks should provide better protection if the recommendations follow common sense. However, wearing a double mask should theoretically lead to more ADRs and costs (Isikalan et al., 2022). According to one descriptive study, excessive sweating (68.4%), high cost of masks (66.4%), and difficulty in breathing (66.1%) were frequently reported as significant barriers to double masking (Nalunkuma et al., 2022).

Despite strict mass masking, the number of COVID-19 cases continued to rise in 2021. Some experts suggested that wearing two masks could offer greater protection (Brooks et al., 2021). However, this was just an assumption based on common sense, as there was no evidence to support it. Simple instructions like covering the nose and mouth when sneezing or coughing can safely reduce the spread of respiratory droplets. While wearing one mask was not enough to combat SARS-CoV-2, using three or four masks could provide better protection than two masks if it makes sense to do so. However, wearing two masks could theoretically lead to more adverse reactions and higher costs (Isikalan et al., 2022). According to the descriptive study, many people reported excessive sweating (68.4%), high mask costs (66.4%), and difficulty breathing (66.1%) as significant barriers to double masking (Nalunkuma et al., 2022).

Nevertheless, what was remarkable during the COVID-19 pandemic is that the number of COVID-19 cases and deaths have been directly proportional to the number of COVID-19 tests conducted (Alrasheedi, 2023; Nguimkeu & Tadadjeu, 2021). Without the tests, cases of COVID-19 cannot be detected, and thus, deaths cannot be attributed to SARS-CoV-2. In Africa, for example, many citizens do not have access to the healthcare they need, as the continent's quality of health services is generally poor (Oleribe et al., 2019). Therefore, in the context of COVID-19, most African countries could not conduct a reasonable number of tests; Africa's testing rate per population was 0.08, while Europe's was 3.74 (Alrasheedi, 2023). Moreover, the COVID-19 vaccine coverage rates across the continents have been inconsistent, with the lowest rate being seen in Africa. However, Africa has been the least affected continent by COVID-19 (Alrasheedi, 2023). Similarly, Africa does not seem to have been better regarding the availability of PPE, including surgical masks.

The history of modern times shows that the influenza pandemics/epidemics of 1957–1958, 1968, 2002, in SARS 2004–2005, and with influenza in 2009, ended without mandatory face coverings or a vaccine. Moreover, healthy people were not advised to wear masks. Although some trials and studies were conducted during the SARS epidemic to evaluate the effectiveness of masks, scientists concluded that the masks used daily could not achieve the hoped-for success in combating viral infections (Cowling et al., 2009; MacIntyre et al., 2009). Even later, scientists and institutions rated the masks as unsuitable to protect the user safely from viral respiratory infections (Cowling et al., 2010; Kisielinski et al., 2021; Neilson, 2016).

Finally, the health-protective benefits of the non-professional use of facemasks are doubtful. Moreover, neither higher-level institutions such as the WHO or the European Centre for Disease Prevention and Control nor national ones, such as the CDC, substantiate with sound scientific data a positive effect of masks on the public (in terms of a reduced rate of spread of COVID-19 in the population) (Kisielinski et al., 2021).

11. Tenth reason: Acknowledgement of the rights of people

The mask was originally designed to protect wounds from surgeons' breath and predominantly bacterial droplet contamination (Strasser & Schlich, 2020). However, it has been visibly misused in recent years, especially in Asia (Burgess & Horii, 2012). Unfortunately, the mask only protects symbolically and simultaneously represents the fear of infection. This phenomenon is reinforced by collective fear-mongering, constantly nurtured by mainstream media (Neilson, 2016). Contrary to the scientifically established standard of evidence-based medicine, national and international health authorities have issued theoretical assessments on masks in public places, even though the compulsory wearing of masks gives a deceptive feeling of safety (Liu et al.,2023; Sharma et al., 2020).

In 2020, several countries mandated wearing masks in public areas to limit the spread of SARS-CoV-2. Most of these countries canceled the requirement to wear a mask in 2021 and 2022 before the WHO declared the end of the state of emergency related to the COVID-19 pandemic in May 2023. Although the requirement of wearing a mask was exceptional due to the COVID-19 pandemic, it may still be imposed or re-imposed for any reason (e.g., for the influenza season that occurs every year). Facemasks were only temporarily acceptable in liberal Western societies. Previous studies report that many American adults may not desire to be forced to wear a mask because doing this could infringe on their constitutional rights and civil liberties (Vuolo et al., 2020). However, some argue that facemask mandates should be enforced when there is an epidemiological need (Zimmermann et al., 2021), but determining this need relies on subjective criteria and assumptions. Furthermore, as is common in East Asia (even before the 2020 pandemic), some people may continue wearing masks, which is achieved by fear. Individuals can habituate to fear-based

propaganda, thinking that they are safe from getting an infection and that these masks do not carry any risks or harm to health. Two authors used P-value plotting to evaluate the statistical reproducibility of meta-analysis studies for surgical mask use in community settings to prevent airborne respiratory virus infection; however, they failed to demonstrate the benefit of mask use (Young & Kindzierski, 2023). Furthermore, recommendations could originate from some models supporting community face masking that suggest large beneficial effects based on assumptions that facemasks could reduce SARS-CoV-2 transmission by 40-50%— assumptions not adequately supported by existing data (Liu et al., 2023). Although weak evidence should not preclude precautionary actions in the face of unprecedented events such as the COVID-19 pandemic, ethical principles require that the strength of the evidence and best estimates of the amount of benefit be truthfully communicated to the public. The best scientific studies have shown that any benefit from wearing a mask must be residually small (Liu et al., 2023). Therefore, we are not against voluntarily wearing masks for the general public but against imposing them by force. We acknowledge the right of every person to wear a mask or not. However, those who want to wear a mask must follow the correct and safe way to wear, take off and dispose of the mask.

On the other hand, HCWs have long relied heavily on masks to protect against influenza and other infections. However, as we discussed, overall, we found limited evidence regarding the effect of masks on viral respiratory infections in the community and healthcare settings, and most analyses showed neither statistically significant differences between mask groups versus no mask groups nor benefits for N-95 respirators over surgical masks. Moreover, the efficacy of any respiratory device depends on user compliance. Workers' tolerance for wearing most types of masks is poor and often declines over a work shift (Radonovich et al., 2009). Some RCTs involved a per-protocol analysis (excluding those who did not wear a mask); however, the results were roughly the same. It is essential to point out that, apart from the COVID-19 pandemic, wearing facemasks among HCWs to protect against respiratory tract infections is uncommon in many countries other than East Asia (Sergi Leung, 2020). Healthy workplaces are a priority. We believe education and access are crucial to improving uptake, but we do not think mandatory masking is the way forward. It is also essential to consider the preferences and acceptability of recommendations by HCWs to prevent rejection of recommendations or less desirable workarounds to avoid unpleasant side effects of masks and respirators.

In any case, the Mask-Induced Exhaustion Syndrome potentially triggered by masks contrasts with the WHO definition of health: "Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity" (IHC, 2002). So, discomfort alone when wearing a mask should be enough to undermine mandatory mask-wearing; however, there are other significant ADRs of mask-wearing, as well as its misuse. For certain diseases, it is also necessary for the attending physician to weigh up the benefits and risks of a mask obligation.

In addition to protecting the health of their patients, physicians should base their actions on the guiding principle of the 1948 Geneva Declaration, as revised in 2017. According to this, every physician vows to put the health and dignity of his patient first and not to use his medical knowledge to violate human rights and civil liberties, even under threat (WMA, 2018). Within the framework of these findings, we advocate for a medically sound and legally compliant approach that considers scientific facts against a predominantly assumption-led claim to the general effectiveness of masks. It is also important to consider possible unwanted individual effects for the patient and mask wearer concerned while adhering to evidence-based medicine principles and ethical guidelines for physicians.

After all, the scientific basis for using masks does not come from clinical trials of influenza outbreaks or pandemics (Vainshelboim, 2021). It usually arises from hypotheses, laboratory experiments, or observational studies. For example, the CDC's policy change to support masks occurred. The agency's statement attributes the change to accumulating evidence that people can be contagious and asymptomatic and that the virus may be spread by talking, coughing, or sneezing. Likewise, no clinical trials prove that a 6-foot social distance prevents infection, as we know. Nor do clinical trials demonstrate that washing our hands for 40 seconds is superior to doing so for 20 or 10 seconds when it comes to limiting the spread of disease in a respiratory disease pandemic (Xun et al., 2021). The scientific basis for that 40-second handwashing advice from the CDC derives from laboratory studies measuring viruses on the hands after different washing times (Chu et al., 2020).

Finally, public health requires that scientists openly discuss their differences in the quality of available studies and data. Such discussions should be encouraged by providing a forum for scientists to engage respectfully with one another without having to worry about silencing campaigns. Silencing debate will lead to ever more distrust in public health.

12. Limitations

The current review has some limitations. This review did not comprehensively look for all systematic reviews and meta-analyses on the effectiveness of masks, but we expect that most of them were included. Different literature selection and appraisal criteria between the systematic reviews and meta-analyses (e.g., study design, population, intervention vs. comparison, types of effect, etc.) could contribute to the variability of the findings. For instance, the RCTs (Loeb et al., 2009; MacIntyre et al., 2011; MacIntyre et al., 2013; Radonovich et al., 2019) selected by Collins et al. (2021) were identical to the RCTs included in Bartoszko et al.'s review

(2020). They were chosen by Jefferson et al. (2020) as well. However, Collins et al. (2021) concluded differently, as there were also observational studies in the pool.

Additionally, some studies used self-reported clinical symptoms as the outcomes, which could be biased. Moreover, our review might not be able to include (1) recent ongoing research on facemasks, (2) high-quality research that might not be published in the studied databases but as technical reports or in gray literature, and (3) other critical scientific findings which might not be published in English.

Besides wearing masks, some participants might take other measures to prevent respiratory tract infections, such as hand hygiene and wearing gloves/goggles/full face shields. Nevertheless, this information needed to be more available. Lastly, only a few studies investigated the balance of the pros and cons of wearing a mask; most only focused on the pros.

13. Conclusions

In the COVID-19 pandemic, contrary to early and previous recommendations, general people were advised to wear masks while others were forced to. Likewise, HCWs have long relied heavily on masks to protect against influenza and other infections. However, based on the systematic reviews and meta-analyses of RCTs, we generally found limited evidence regarding the effectiveness of masks on viral respiratory infections in the community and healthcare settings; most meta-analyses and RCTs showed neither statistically significant differences between mask groups vs. no mask groups nor benefits for N-95 respirators over surgical masks. Any statistically significant benefit would be negligible and often of low-certainty evidence (because it relies on self-reported symptoms).

Furthermore, wearing a mask has many ADRs, including warmth, respiratory difficulties, humidity, and discomfort, particularly when worn for long periods in warm environments. However, these ADRs are often ignored by researchers and policymakers. Moreover, any benefit of mask-wearing shown by any RCTs is usually not applicable to the general public in real life due to the low adherence and misuse, especially if imposed by force.

Therefore, we are against making wearing masks compulsory in settings outside of healthcare. We acknowledge the right of every person to wear a mask or not, even among HCWs. However, using facemasks for short periods by particularly vulnerable individuals in transient higher-risk situations is still recommended. For HCWs, it is essential to consider the preferences and acceptability of recommendations to prevent rejection of recommendations or less desirable workarounds to avoid unpleasant side effects of masks and respirators and to ensure the HCWs' well-being.

Finally, public health requires that scientists openly discuss their differences in the quality of available studies and data. Such discussions should be encouraged by providing a forum for scientists to engage respectfully with one another without having to worry about silencing campaigns. Silencing debate will lead to ever more distrust in public health.

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