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Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

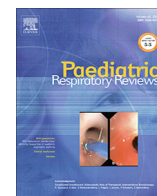
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Clinical Usefulness

The United States' decision to mask children as young as two for COVID-19 has been extended into 2023 and beyond: The implications of this policy

Introduction

During the COVID-19 pandemic, guidelines issued by the US Centers for Disease Control and Prevention (CDC) for masking children were out of step with peer nations. The European Centre for Disease Prevention and Control never recommended masking children under the age of 12 [1]. The World Health Organization did not recommend masking under the age of 6 and, for children ages 6–11, only in specific circumstances [2].

In accordance with these guidelines, no European countries recommended masking children under the age of 6, and the United Kingdom and multiple Nordic countries did not recommend masking children under 12. Over the course of the last year, with the exception of the United States, all European and American countries, including Canada, lifted any remaining primary and secondary public school masking requirements.

The CDC's unshifting position on masking

On February 8th, 2023, at the Joint Oversight and Investigations Subcommittee and Health Subcommittee Hearing "The Federal Response to COVID-19," the United States further solidified its position as an international outlier in continuing to recommend masking for children. Representative Cathy McMorris Rodgers asked CDC Director Rochelle Walensky why the CDC is currently the only national or international public health agency that recommended masking two-year-old children. Dr. Walensky responded, "Our guidance doesn't really change with time" and further clarified that the CDC continues to recommend masking children as young as two when community disease levels are considered high [3].

Multiple international pediatric experts have expressed concerns about masking of children [4,5] and, as we show in Fig. 1, weighing the highest quality evidence we have on masking effectiveness with the potential harms, masking children appears increasingly unfavorable. The CDC's unchanging policy in spite of this calls into question the agency's ability to make appropriate, evidence-based guidance, particularly for the youngest in our society.

Masking children: no high quality evidence of benefit

The initial recommendation to mask children was presumably based on the assumption that unproven benefits would outweigh

any harm(s). As shown in Fig. 1, prior to the COVID-19 pandemic, nine randomized trials of medical/surgical masking versus no mask were reviewed in a previous Cochrane report. Together these studies failed to find evidence of effectiveness of surgical or N95 masking in the community or healthcare setting for common respiratory illnesses, such as influenza and respiratory syncytial virus. In an updated Cochrane Review published in 2023, three additional randomized studies were added, making a total of 12, two of which were specific to COVID-19.

Although the evidence still demonstrates a wide confidence interval, point estimates are null, and both Cochrane reviews conclude that community masking "may have" and, more recently, "probably" made "little to no difference" in the prevention of COVID-19 or influenza-like illness.

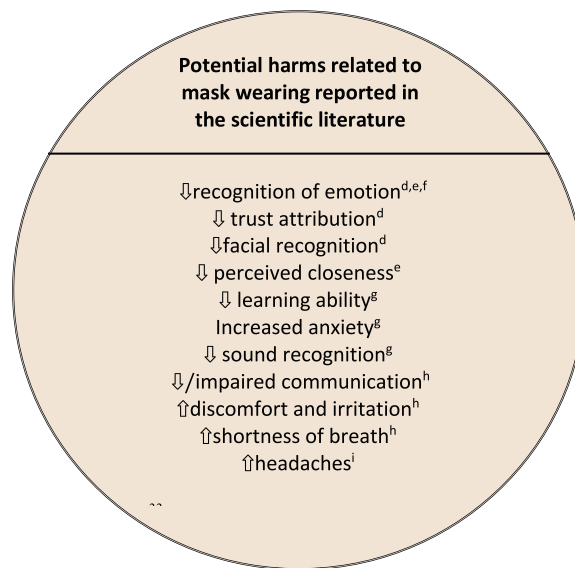
Two natural experiments also provided relevant information on masking children in the school setting. The first is a regression discontinuity design from Spain of masked 6-year-olds and unmasked 5-year-olds (Fig. 1), and the second compares two cities in Finland with different masking policies for 10–12-year-olds. The second is not shown in Fig. 1, as it had yet to be peer reviewed at the time of this writing. Both failed to identify an impact of masking on transmission or case numbers.

Importantly, the results of these studies are only a product of real-life effectiveness in that they are limited by the extent to which people can properly mask for longer durations. However, they could not rule out a high degree of effectiveness of the fit-tested high-quality mask in short encounters. In addition, smaller effects of even low-compliance community masking cannot be entirely ruled out, given the wide confidence intervals.

A handful of studies conducted in the United States, either without control groups or which failed to adequately control for critical confounding variables have demonstrated the pitfalls of attributing causation to mask mandates when the association of lower case rates with mask usage or mandates may have had a number of other causes besides the masks. It is not appropriate to use such studies over more robust or randomized evidence to guide policy.

Moreover, the risks to children from COVID-19 are diminishing. Immunity from prior infection has been found to be protective against severe disease, and it is estimated as of November 2022 to be almost 95% [6], of the US population has already been infected. MIS-C has become exceedingly rare, with less than 20 cases reported to the CDC since November 2022, and seroprevalence-based research on the prevalence of Long Covid in children indicates that it is rare [7].

High quality evidence of Mask Effectiveness/Efficacy: RCTs, Natural Experiments	Finding	Benefit
Cochrane Review of RCTs 2020 ^a	There is moderate certainty wearing a medical/surgical mask makes little to no difference for influenza Risk ratio 0.91, 95% CI 0.66-1.26	Not identified
Cochrane Review of RCTs 2023, including 2 COVID-19 RCTs ^b	Community medical surgical masking “probably makes little to no difference” for influenza-like illness/COVID-19 Risk ratio 0.95, 95% CI, 0.84-1.09	Not identified
Spanish Regression Discontinuity natural experiment of unmasked 5-year-olds compared with masked 6-year-olds ^c	School mask mandates were not associated with lower SARS-CoV-2 incidence or transmission. Comparing masked 6-year-olds to unmasked 5-year-olds the IRR was 0.96, 95% CI, 0.82-1.11	Not identified



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Fig. 1. An ethical benefit-harm analysis of masking children weighing only high quality evidence of effectiveness (left) with evidence of harms or side effects reported in the scientific literature (right).

Masking children: potential for harm

To date, there are no robust studies showing the impact of long-term masking of children, in part because no society has engaged in such an experiment. However, a growing number of papers document negative impacts on children (Fig. 1): shortness of breath and other discomfort, impaired recognition of emotions and facial expressions (most pronounced in 3–5-year-olds), reported negative effects on learning ability, and increased reported anxiety and decreased word identification which will likely disproportionately affect children with decreased hearing and non-native speakers.

Conclusion

As more high-quality studies accumulate that fail to show evidence of benefit, the required masking of children by the CDC has become even more difficult to justify. The US was already an international outlier by recommending masks for children down to 2 years of age, but continuing this policy despite diminishing disease severity in children, despite widespread infection with COVID-19, and without confirmatory, high-quality evidence of benefits raises deep concerns about the US policy and scientific reasoning.

The continued pursuit of irrational policy by the US CDC sets a concerning precedent and risks undermining trust in medicine and public health. The best available evidence never supported a net

benefit of masking very young children, and recent data only further highlight this case. The CDC, like all federal agencies, must be nimble. Policy must change when the evidence does not support it.

Conflict of interest disclosures

The other authors have no conflicts of interest to disclose.

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