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Mask mandates for the prevention of respiratory infections: a mechanism-informed systematic review

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ADMINISTRATIVE INFORMATION

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Review Stage at time of this submission - Preliminary searches.

Conflicts of interest - JW developed the Evidential Pluralism methodology that is the basis for the proposed Systematic Review+ approach. TG led a previous narrative review on masks and is a member of Independent SAGE. All other authors declare no conflicts of interest.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 15 April 2025 and was last updated on 15 April 2025.

INTRODUCTION

Review question / Objective Empirical objectives (this protocol): 1. To determine the efficacy of face mask mandates in reducing the spread of respiratory infections in different contexts and circumstances.
2. To identify the mechanisms through which this effect is achieved.

Methodological objective (described in detail in a separate protocol paper). Using this mask mandate review as a worked example:
1. To produce a potentially generalisable methodology (both qualitative and quantitative) for combining associative and mechanistic evidence in systematic review (known as 'mechanism-informed systematic review', Systematic Review + or SR+).
2. To examine the extent to which SR+ mitigates key criticisms of orthodox systematic reviews, both epistemological and ethical.

Rationale The question of whether face masks and face mask mandates are effective in reducing transmission of respiratory diseases generated much controversy during the COVID-19 pandemic. An orthodox systematic review, analysing only randomised controlled trials (RCTs) and published in the Cochrane Library, concluded that the existing evidence on face mask efficacy was not definitive (i.e. the authors decided that they could not firmly conclude either that masks were effective or that they were ineffective).[1] One review which included non-RCT evidence, especially evidence of mechanism ('mechanistic evidence'), concluded that there was evidence of efficacy; it proposed explanations for why some RCTs demonstrated efficacy while others did not. [2] A key area of contestation is whether trials were testing masking itself or 'advice to mask'. If masks work, and people are reluctant to follow mere advice, the question then arises: what happens if we require people to wear masks.

To demonstrate causality, we typically need two kinds of evidence: associative (to show that a change in one phenomenon is associated with a change in another) and mechanistic (to be confident that any observed association is genuinely causal). In biomedicine, the former is, ideally, obtained from RCTs but the latter may come from a wide range of study designs. Orthodox methods of evidence synthesis, such as those used for Cochrane reviews and informed by the GRADE criteria, classify mechanistic evidence as inherently lower quality than RCT evidence. But this position can be challenged on both epistemological grounds (since mechanistic evidence can raise or lower confidence in a causal claim) and on ethical grounds (since dismissing certain forms of evidence is a form of epistemic injustice). In this study, which seeks to extend the emerging scholarly tradition of 'EBM+' with 'SR+'. SR+ will formally and systematically evaluate mechanistic evidence and use that evidence to complement and challenge findings from RCTs and other associative evidence.

The evidence pertaining to whether and how mask mandates work is heterogeneous and comes from multiple disciplines. The associative evidence consists mostly of observational (before and after) studies from the COVID-19 pandemic, where such mandates were introduced either country-wide or regionally (e.g. in particular US states or German regions), sometimes but not always with strict enforcement sanctions. These studies are of variable methodological quality (for example, some used only self-report data to capture frequency of mask usage). Mechanistic evidence (e.g. on the legal, institutional, economic, communicative, psychological, cultural and other ways in which mask mandates might affect compliance with mandates) comes from a wide range of (mostly) qualitative studies including interview, ethnographic and documentary data.

1. Jefferson T, Dooley L, Ferroni E, et al. Physical interventions to interrupt or reduce the spread of respiratory viruses. Cochrane Database Syst Rev 2023;1(1):Cd006207. doi: 10.1002/14651858.CD006207.pub6 [published Online First: 20230130]
2. Greenhalgh T, MacIntyre CR, Baker MG, et al. Masks and respirators for prevention of respiratory infections: a state of the science review. Clinical Microbiology Reviews 2024:e00124-23.

Condition being studied Face mask mandates in reducing transmission of respiratory infections in the context of respiratory infection outbreaks. (Note: the question of how effectively face masks filter out pathogens from the air, while relevant to related question of "[how effectively] do masks work?", is outwith the scope of this protocol; it will be considered in a separate protocol.)

Examining the relationship between mask mandates and rates of mask usage (and, where measured, incidence of respiratory infections) requires both associative evidence (i.e. whether and to what extent mask mandates affect usage of masks) and mechanistic evidence (i.e. how do mask mandates increase mask usage). There are many candidate mechanisms, at different levels, including

- Policy and legal mechanisms, including direct enforcement (e.g. fines or other penalties for non-compliance) and visibility of enforcement (e.g. signage, police presence). The wording and scope of the mandate, as well as the level of enforcement, are likely to influence uptake.
- Mechanisms for institutional compliance, including health and safety requirements for businesses, schools, hospitals and other organisations. These can create a consistent environment where mask-wearing is expected and normalised among both employees and customers/clients. These organisations can refuse entry or service to those not complying, further reinforcing the mandate.
- Communicative mechanisms. Mandates minimise ambiguity about whether and when mask-wearing is required, simplifying public health messaging and reducing confusion. Positive messaging and public health campaigns associated with mandates can reinforce the benefits of mask-wearing. Communicative messages can reinforce social responsibility and behaviours intended to protect the vulnerable (e.g. wear a mask to protect your grandparents).
- Social norms, conformity and civic responsibility. Mandates signal that mask-wearing is the expected behaviour, increasing social pressure to conform, and people are more likely to comply when they perceive that others are doing so. The perception of a collective effort can increase compliance, as individuals feel they are contributing to a shared goal and the public good. Wearing a mask can also be a symbol of social solidarity, showing that we're all in this together.
- Group identification and peer pressure. In communities with strong social cohesion, peer pressure can be a powerful motivator for compliance with mask mandates. Conversely, some group identification (e.g. with libertarians) may help explain non-compliance with mask mandates.
- Altruism. Mandates can reinforce the altruistic motives (a selfless concern for the well-being of others) held by some people. In such

circumstances, people choose to wear a mask not primarily for their own protection but to reduce the risk of transmitting to others (especially those who are vulnerable).
- Risk perception and fear. Mandates can heighten awareness of the severity of the pandemic, increasing perceived risk and motivating individuals to take protective measures. The official nature of a mandate can reinforce the seriousness of the situation.
- Authority and trust. People are more likely to comply with mandates issued by trusted authorities (e.g., public health officials, government leaders). The perception that the mandate is based on scientific evidence increases compliance.
- Habit formation. Consistent enforcement of mandates can help establish mask-wearing as a routine behaviour, making it more likely to persist even after the mandate is lifted.
- Media and public discourse. Mandates often generate media attention, which can increase public awareness of the importance of mask-wearing.
- Community level action. Mandates can spur community level action, such as volunteer groups distributing masks, or local businesses providing mask wearing encouragement.
- Economic and practical mechanisms. For example, mandates may be accompanied by the distribution of free or low-cost masks, reducing the financial burden of compliance. Making masks readily available increases the ease of compliance.

METHODS

Search strategy Searching will be iterative and use multiple methods. These will include
- key word search of at least 7 databases (Medline, Cinahl, Cochrane, Psychinfo, SSCI, SCOPUS, JSTOR);
- author search (authors of seminal papers will be name-searched in relevant databases to identify additional papers by them);
- citation-tracking (via Google Scholar);
- mining previous systematic reviews.

KEY WORDS:

Related to masks: masks, respirators, face coverings, non-pharmaceutical interventions (NPIs), respiratory protective devices.

Related to mask mandates: mask mandate, face covering mandate, mask regulation, mask policy.

Related to respiratory outbreaks: respiratory outbreak, respiratory pandemic, epidemic control, public health intervention,

Specific respiratory illness keywords: COVID-19, SARS-CoV-2, influenza, SARS (Severe Acute Respiratory Syndrome), MERS (Middle East Respiratory Syndrome).

Policy and implementation keywords: mandate effectiveness, compliance, enforcement, policy analysis, implementation study, legal aspects, public policy.

Outcome and Effect Keywords: transmission rate, infection rate, disease spread, hospitalization rate, mortality rate, community transmission, effectiveness, impact, efficacy.

Mechanism keywords: social norms, behavioural science, public perception, risk perception, compliance behaviour, altruism, social psychology.

DATABASE SEARCH STRATEGIES:

Combine keywords using Boolean operators (AND, OR, NOT).
Example: (mask mandate OR face mask policy) AND (COVID-19 OR influenza) AND transmission rate

Use truncation (*) to capture variations of words.
Example: mandate* will find mandates, mandated, etc.

Use phrase searching (quotation marks) to find exact phrases.
Example: "public health intervention".

Use MeSH terms (Medical Subject Headings) in PubMed/MEDLINE.
Example: masks, respiratory protective devices.

EXAMPLE SEARCH STRINGS:

PubMed: (mask mandate[Title/Abstract] OR face covering mandate[Title/Abstract]) AND (COVID-19[MeSH Terms] OR influenza[MeSH Terms]) AND (transmission[Title/Abstract] OR infection[Title/Abstract]).

Google Scholar: mask mandate AND (respiratory outbreak OR pandemic) AND (transmission OR effectiveness).

These keywords and search strategies will be piloted in the specific databases and modified in response to emerging findings.

Participant or population Any setting with a mask mandate (either legally enforced or strong public health advice recommending masks). These will

include: national, regional or locality-wide mandates, and mandates in specific settings (e.g. public transport, workplaces, care settings). Participants will include members of the public and occupational groups (e.g. health workers).

Intervention Mask mandates (defined as a legal requirement or strong public health advice to wear masks that is expected to be followed).

Comparator Settings without a mask mandate in force at the time of the study.

Study designs to be included No restriction in study design. We anticipate that a wide range of designs including observational, qualitative and modelling studies.

Eligibility criteria Empirical research or evidence syntheses which contribute to establishing both the association between mandates and mask use and examining specific mechanism hypotheses underlying this association. Peer reviewed literature will be prioritised but if there is insufficient evidence on important aspects of the review question, publicly available preprints will be considered.

Information sources Electronic databases, sources known to the authors, topic experts in the field.

Main outcome(s) For the association studies, whether and to what extent the introduction of mask mandates affects the incidence of respiratory infections.

Additional outcome(s) For the association studies, whether and to what extent the introduction of mask mandates affects mask use. In addition, evidence supporting or refuting mechanism hypotheses explaining the relationship between mandates and mask use.

Data management Data will be stored on University of Manchester, University of Oxford and University of Exeter computers. Eligible papers will be stored, organised and coded on an Endnote database. Data extraction will occur using summaries on Microsoft Office packages (e.g. Word, Excel). Specialist data management packages compliant with university data policies will be used if needed.

Quality assessment / Risk of bias analysis The study seeks to draw upon, challenge and extend the GRADE criteria and methodology for ranking and evaluating empirical evidence. With that in mind, we will use the GRADE checklists reflexively and critically rather than as a source of settled truth. Using appropriate GRADE checklists, primary studies will be critically appraised for trustworthiness (internal validity) e.g. risk of bias.

Strategy of data synthesis Tables will be prepared of key studies, including author/year, study design, methods, sample, findings, strengths/limitations and comments.

Where appropriate, formal meta-analysis techniques will be applied to quantitative data to gain an estimate of effect size and confidence interval. Where studies are too heterogeneous to justify meta-analysis, disaggregated data will be presented.

Qualitative evidence will be analysed thematically and with attention to key theories (e.g. of motivation, social influence and so on), and combined using the hermeneutic cycle in which each new data source is used to refine and enrich the understanding of the whole. In this way, rich explanations will be generated of how an effect may be obtained, should one exist, or why such an effect is not obtained.

Mechanistic evidence will be combined with associative evidence to produce an emerging synthesis of causality in mask mandates, thereby contributing further insights into the overall strength of evidence and to estimates of the generalisability (external validity) of particular empirical findings.

The findings from the mask mandate review will be used to inform the methodological objective of developing SR+ as a generalisable method for combining associative and mechanistic evidence; this aspect of the study will be described in a separate protocol.

Subgroup analysis Hypotheses about subgroup effects will be tested as appropriate if and when they emerge as the review unfolds.

Sensitivity analysis Sensitivity analyses will be undertaken as appropriate if and when they become necessary as the review unfolds.

Language restriction No restriction. Studies published in languages not spoken by the review authors will be translated.

Country(ies) involved United Kingdom (University of Oxford).

Keywords See search strategy above.

Dissemination plans Dissemination plans include preparation of academic papers, including methods and publication guidance for SR+ to be submitted to the EQUATOR network. In addition, we will produce training materials, build links with policymakers and advocacy groups, and hold a series of workshops for academic reviewers, evaluators and lay (e.g. advocacy) groups.

Contributions of each author

Author 1 - Trisha Greenhalgh - Co-investigator on grant. Conceptualised the study with JW and RH. Provides topic expertise in masks. Designed search strategy. With SR, will undertake searches and data extraction and synthesis (including meta-analysis), with input from other authors. Will support postdocs as needed in producing publications.
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Author 2 - Jon Williamson - Chief investigator on grant. Co-developed the philosophical approach to be used and refined in SR+. Conceptualised the study with TG and RH. Leads philosophical aspects and line manages two philosophy postdocs.
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Author 3 - Rebecca Helm - Co-investigator on grant. Conceptualised the study with JW and TG. Leads on legal and policy aspects of mask mandates.
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Author 4 - Sahanika Ratnayake - Postdoctoral philosopher. Lead researcher on the mask mandate example. With TG, will undertake searches and data extraction and synthesis (including meta-analysis), with input from other authors. Will lead on some publications.
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Author 5 - Luana Poliseli - Postdoctoral philosopher. Will support other authors in all aspects of searching, data extraction, data synthesis and writing up.
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