Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

A rapid evidence update on face mask use by healthy people in the community to reduce SARS-COV-2 transmission

Submitted to NPHET: 24 November

Published: 17 December 2020

Version	1.1

Revision Record	
Revision Date	**Description of change**
24 Nov 2020	First draft circulated to Expert Advisory Group and National Public Health Emergency Team.
8 Dec 2020	Second draft (version 1.1) circulated to Expert Advisory Group and National Public Health Emergency Team. Changes: ▪ references and further explanation added to Background section ▪ addition of text to summarise findings, for each study type, of previous HIQA review on face masks in the community ▪ addition of details of further observational study evidence ▪ addition of further information on potential undesirable effects of face mask use, particularly with respect to facial dermatoses and difficulty in communication for some groups of people ▪ updating of international review to include changes to guidance published as of 4 December 2020 ▪ addition to Discussion section of further paragraphs summarising findings of report.

About the Health Information and Quality Authority

The Health Information and Quality Authority (HIQA) is an independent statutory authority established to promote safety and quality in the provision of health and social care services for the benefit of the health and welfare of the public.

HIQA's mandate to date extends across a wide range of public, private and voluntary sector services. Reporting to the Minister for Health and engaging with the Minister for Children and Youth Affairs, HIQA has responsibility for the following:

- **Setting standards for health and social care services** — Developing person-centred standards and guidance, based on evidence and international best practice, for health and social care services in Ireland.
- **Regulating social care services** — The Chief Inspector within HIQA is responsible for registering and inspecting residential services for older people and people with a disability, and children's special care units.
- **Regulating health services** — Regulating medical exposure to ionising radiation.
- **Monitoring services** — Monitoring the safety and quality of health services and children's social services, and investigating as necessary serious concerns about the health and welfare of people who use these services.
- **Health technology assessment** — Evaluating the clinical and cost-effectiveness of health programmes, policies, medicines, medical equipment, diagnostic and surgical techniques, health promotion and protection activities, and providing advice to enable the best use of resources and the best outcomes for people who use our health service.
- **Health information** — Advising on the efficient and secure collection and sharing of health information, setting standards, evaluating information resources and publishing information on the delivery and performance of Ireland's health and social care services.
- **National Care Experience Programme** — Carrying out national service-user experience surveys across a range of health services, in conjunction with the Department of Health and the HSE.

List of abbreviations used in this report

CDC	Centers for Disease Control and Prevention
CI	confidence interval
COVID-19	Coronavirus disease 2019
ECDC	European Centre for Disease Prevention and Control
HIQA	Health Information and Quality Authority
HPSC	Health Protection Surveillance Centre
HTA	health technology assessment
NPHET	National Public Health Emergency Team
OR	odds ratio
PPE	personal protective equipment
SARS-CoV-2	Severe Acute Respiratory Syndrome Coronavirus 2
WHO	World Health Organization

Rapid evidence update on face mask use by healthy people in the community to reduce SARS-CoV-2 transmission

Key points

- SARS-CoV-2 is a highly infectious virus responsible thus far for over 60 million cases and 1.4 million deaths from COVID-19. A range of infection prevention and control measures, including face masks, are required to reduce the spread of infection.
- Face masks aim to reduce the spread of infection by:
    - acting as a source control to stop the outward spread of infection from the wearer (including those who do not know they are infected), and
    - protecting the wearer from the inhalation of droplets or aerosols containing infectious material.
- During the COVID-19 pandemic, the use of face masks by the general public has been recommended by an increasing number of countries and for an increasing number of activities. In Ireland, at the time of writing of this report, non-medical face masks are mandatory on public transport, in shops and other retail outlets, and are recommended in situations where physical distancing may not be possible.
- HIQA published an evidence summary on the use of face masks in the community in August 2020. The present report is a rapid evidence update to this evidence summary, using a scoping approach to consider three elements: a review of available research evidence on effectiveness of mask wearing, additional considerations which may impact decision-making on mask usage, and a review of international guidance on the use of face masks in the community setting. Due to the extremely short timelines, a systematic search of the evidence was not possible.
- This overview of the evidence emerging from July 2020 onwards considers a variety of study designs, including: recent rapid reviews to inform policy, systematic reviews, randomised controlled trial evidence, observational studies, and laboratory studies.
    - Recommendations from a rapid review completed and updated by the Norwegian Institute of Public Health, which included a comprehensive and systematically sourced evidence base up-to-date until 2 November 2020, continues to support the use of face masks where COVID-19 incidence is high, increasing, or spread is

uncontrolled; such face mask use should be targeted towards settings where distance cannot be maintained.

- Results from a randomised controlled trial (DANMASK-19) presented inconclusive results with regards to the use of face masks aimed at reducing the risk of infection for the wearer. As this trial was conducted at a time when few members of the population wore masks and mask use was not recommended, it did not consider the effectiveness of face masks as an intervention to reduce community-level transmission, or to assess the effectiveness of masks for source control. Furthermore, the trial was subject to methodological limitations impeding the internal validity of the trial results overall.
- There is relatively consistent evidence from observational studies (individual level analysis) and ecological studies (analysis at community or population level) that favours the use of face masks to reduce transmission of SARS-CoV-2.
- There is evidence from laboratory-based studies that face mask usage reduces the transmission and spread of infected particles between the wearer and others. However, these are laboratory-based results and therefore are not fully transferable to real-world environments.

- Additional considerations with respect to face mask use were also presented within this evidence update, following a scoping of the available evidence:
  - Information is scarce on socio-behavioural factors affecting adherence to recommendations on use of face masks. Consistent and effective public messaging has been noted as vital in encouraging public adherence.
  - Collectively, the evidence favours the use of cloth face masks over face shields or visors. However, visors provide some level of protection to the wearer and may be considered as an alternative in certain scenarios where it is not possible for a person to wear a face mask.
  - Considering potential undesirable effects, there is little evidence to suggest that mask use adversely affects other public health interventions to reduce SARS-CoV-2 transmission, and there is some evidence that mask use may increase compliance with public health measures.
  - Considering undesirable effects to the wearer, personal problems arising from wearing masks appear to be minor and the proportion of people who experience these is uncertain. Nonetheless, prolonged

mask use, particularly medical mask use, may result in facial dermatoses such as acne, and mask use may give rise to difficulties in communication, particularly in medical communication situations or among people with hearing loss.

- The international review of public health guidance on face mask use included 20 countries, 17 of which are European. The guidance varied but all countries (with the exception of Sweden) recommend the widespread use of face masks in one or more settings. Briefly:
    - The majority of countries specifically referred to the use of face masks on public transport and in educational settings.
    - All countries providing recommendations on mask use referred to 'indoor closed' (i.e. enclosed) spaces or rooms. The detail provided ranged from a general statement on wearing face masks indoors to more detailed lists of indoor settings in which face masks must be worn.
    - Retail shops, cafes and restaurants specifically were cited by some countries with recommendations that face masks must be worn in establishments and places where catering activities are permitted, both for customers and staff, unless while eating, drinking or sitting at a table.
    - Several countries referred specifically to the use of face masks in outdoor settings, with some particularly recommending their use where physical distance cannot be maintained. Scenarios included busy public areas, such as streets, parks, and squares, or outdoor gatherings such as parades, school gates and alongside camps or training sessions. Italy currently recommends the use of face masks in all outdoor settings.
- The available research on this topic includes low certainty results. Studies that specifically consider SARS-CoV-2 transmission largely comprise observational studies, including ecological studies, and laboratory studies. There is a lack of high quality trial data on the effectiveness of face mask policies in reducing SARS-CoV-2 transmission in the community. Given significant ethical and methodological challenges for the conduct of such trials, and the multiple confounding factors which limit applicability across settings, it is unlikely that suitable trial data will become available on the effectiveness of face masks in reducing SARS-CoV-2 transmission in the community.
- Due to the challenges associated with obtaining a high quality evidence base, decision-making on the use of face masks in the community setting will need to draw from a broad and multidimensional evidence base; this will involve considering the biological plausibility of effectiveness of the intervention,

including evidence for the infectiousness of SARS-CoV-2, and a range of experimental designs, international standards, and expert opinion.

- Collectively, the evidence within this rapid evidence update points towards face mask use in the community providing a potentially beneficial effect in reducing SARS-CoV-2 infection, alongside a lack of evidence of significant harm associated with their use.

Face mask use by healthy people in the community to reduce SARS-COV-2 transmission - rapid evidence update

The Health Information and Quality Authority (HIQA) has developed a series of evidence syntheses to inform advice from HIQA to the National Public Health Emergency Team (NPHET). The advice takes into account expert interpretation of the evidence by HIQA's COVID-19 Expert Advisory Group.

The present evidence synthesis was conducted following a request from NPHET for an overview of the most recent evidence with respect to the following question:

> 'What evidence is available to indicate that routine wearing of face masks in the community reduces the transmission of SARS-CoV-2?'

This report follows a previous evidence summary performed by HIQA on the topic of face mask use in the community setting, which was published on 21 August 2020.

Background

Transmission of SARS-CoV-2

A suite of infection prevention and control measures are available that aim to limit the transmission of respiratory viral diseases. These include hand hygiene, respiratory etiquette, face masks, physical distancing and adequate ventilation. These measures target the different modes through which transmission of the respiratory virus typically occurs: contact, droplet and or aerosol.

Contact transmission can be direct, such as on an infected individual's hands, or indirect through the presence of virus particles on intermediate objects known as fomites. The distinction between droplet and aerosol transmission is more nuanced and relates to the size of the droplet. Droplet transmission occurs with exposure to large infectious respiratory particles containing viral material from a symptomatic individual, such as through coughing or sneezing, and typically requires close contact as the particle size denotes a relatively limited travel distance before settling to the ground or surrounding surfaces (less than one meter). Aerosols (droplet nuclei) are smaller particles (ranging from <5 μm to <10 μm in diameter) which, due to their smaller size, can travel a greater distance and have the potential to remain suspended in air for prolonged periods, contributing to air contamination and airborne transmission of infectious agents.[1] The frequency, degree and size of the aerosol emitted is dependent on the activity in question (such as breathing, talking,

singing, and, residually, following coughing or sneezing), the infection site (that is, upper or lower respiratory tract), and viral load, among other factors.[1, 2]

HIQA previously reviewed the evidence on airborne transmission of SARS-CoV-2 via aerosols and the relative importance of direct versus indirect droplet transmission for the spread of SARS-CoV-2 in two separate evidence summaries.[3, 4] While noting the lack of conclusive evidence regarding the viability and infectivity of SARS-CoV-2 in aerosols, the reviews suggested plausible evidence of clinical infectivity on the basis of:

- epidemiological studies which suggest possible transmission
- air sampling studies that have detected viral particles, including evidence of successful cultivation in a limited number of samples
- microbiological studies indicate such particles may represent live virus.

While the transmission routes of SARS-CoV-2 are not yet fully understood, specific activities or settings have been associated with an increased risk of transmission.[5] The secondary attack rate (SAR), defined as the probability that an infection occurs among susceptible people within a specific group (for example, household or close contacts), can provide an indication of how social interactions relate to the risk of transmission. SARS-CoV-2 appears to spread in clusters (that is, overdispersion).[5] It has been estimated that 80% of secondary transmissions may be linked to approximately 10-20% of infectious COVID-19 cases.[5] While the published literature is likely to be biased towards reporting of larger transmission events, there is evidence to suggest that the virus is more transmissible than other pandemic respiratory viruses and that clusters tend to occur in indoor environments and household settings, although clusters in outdoor environments have been observed.[5] Measures to reduce the risk of transmission, such as face masks, may prevent the occurrence of disease clusters or superspreading events, and may thereby help to control the spread of SARS-CoV-2, particularly:[5]

- at large gatherings
- when physical distance cannot be consistently maintained
- when there is mixing among groups.

Use of face masks to control the spread of SARS-CoV-2

The mode of transmission (and the degree to which it contributes to the overall spread of the virus), pattern of transmission, and the relative virulence of SARS-CoV-2 have important implications for infection prevention and control measures:

- the requirement for, and type of, personal protective equipment (PPE) that should be worn by healthcare workers
- the use of face masks by the general population.

HIQA has published evidence summaries of face mask use for use by healthcare workers and for use by individuals in the community.[6, 7] Face masks aim to reduce the spread of infection by two means:

- acting as a source control to stop the spread of infection by the person wearing the mask (including by those who are unaware that they are infected)
- protecting the wearer from droplet splashes or inhalation of infectious material.

There is a greater potential benefit considered to be associated with increasing numbers of people using masks consistently and correctly.[7, 8] However, it is noted that face masks have the potential to act as fomites; poor practice in terms of mask removal, disposal or hygiene could contribute to contact transmission via the mask in a similar manner to when individuals touch their face generally without washing hands.[9, 10]

Mask grades include respirators (classified as PPE and designed to also protect against aerosols), medical face masks and non-medical face masks. Masks do not include plastic visors/shields or other forms of face coverings (for example, protective glasses) which provide a level of eye protection only and should not be considered as an equivalent to face masks with regard to respiratory droplet protection and/or source control.[11] Medical masks (note: the terms 'medical masks' and 'surgical masks' are used interchangeably within this report) and respirators (for example, 'N95' masks) are single-use, disposable respiratory protective medical devices intended primarily for use in healthcare settings or certain clinical scenarios.[10, 12] Non-medical grade face masks, typically cloth masks, are suitable for use by the general public and can be washed after use.[10, 12]

Since the start of the current COVID-19 pandemic, the use of face masks in public spaces has been recommended as a complementary measure, to be implemented alongside physical distancing and hand-hygiene by an increasing number of countries. While acknowledging the lack of direct evidence from studies on the effectiveness of universal masking of healthy people in the community to prevent SARS-CoV-2 infection, the World Health Organization has advised that in areas of known or suspected community or cluster transmission, the general public should be encouraged to wear face masks in specific situations and settings as part of a comprehensive approach to suppress SARS-CoV-2 transmission including indoor and outdoor settings.[11] In Ireland, on the basis of the available evidence, the Department of Health made a recommendation for cloth face masks to be used in

the community in situations where physical distancing guidance cannot be adhered to at all times.[10] The wearing of cloth face masks became mandatory on public transport on 13 July 2020 and in shops and other retail outlets on 10 August 2020.[13] Also, when schools re-opened for the 2020-2021 academic school year, the use of masks was mandated for older school students, specifically those in second level schools, and teaching staff in situations where physical distancing may not be possible. Published public health guidance also recommends that face masks should be worn by individuals who are self-isolating due to suspected or confirmed infection with SARS-CoV-2 (and their household contacts in circumstances where they must be in the same room), and during international travel.[14, 15] Following the submission of the first draft of this review to NPHET, and HIQA's drafting of Advice to NPHET, mask use was further recommended in crowded workplaces, places of worship and in busy or crowded outdoor spaces where there is significant congregation; these recommendations were made on 27 November 2020.

This report is a rapid evidence update following HIQA's previous evidence summary on the effectiveness of face mask use in the community. As per the description of methods in the following section, important updates will be highlighted. However, a systematic review of all evidence and guidance published since the previous evidence summary was conducted was not feasible within the time available to conduct this review.

Methods

The processes outlined in HIQA's protocol for this review were followed. This report is a rapid evidence update to a previous HIQA evidence summary on the use of face masks in the community, published 21 August 2020.[6] A scoping methodology was used and considered three elements; research evidence on the effectiveness of face masks to reduce transmission of SARS-CoV-2, additional considerations which may impact decision-making, and an international review of public health guidance. The research evidence cited includes literature published from 24 June 2020 onwards (that is the last search date from the original review). A systematic search was not conducted in the present update due to the extremely limited time available in which to complete the update. Similarly, it was not possible to provide a description or review of all studies identified. As such, the present review provides an overview of key studies in the recent literature; particular emphasis was placed on studies included in other recent systematic reviews which were identified by the review authors to be of higher quality[6] or which were included in reviews performed by international health technology assessment (HTA) agencies or guidance bodies (for example, WHO, CDC).

The term 'face mask' is wide reaching and includes, but is not limited to, respirator masks, medical masks, and cloth masks. The studies included within this review largely considered either medical masks or cloth masks; data specific to particular masks are detailed as such. Masks do not include plastic face shields and visors and as such effectiveness data for these were not searched for specifically.

Review of evidence for the effectiveness of the use of face coverings in the community

Overall scoping search results

Due to the limited time available for the completion of this rapid evidence update, a scoping approach was adopted to identify relevant studies published between 24 June 2020 (the final search date of the previous HIQA review on face masks in the community[6]) and 20 November 2020.

Table 1 presents a summary of the range of study types identified within this rapid evidence update, including examples of some of the most recent and relevant studies included. These are discussed under the relevant sections below.

Table 1: Examples of key research studies identified in rapid evidence update

	Examples of updates found in scoping search	**Publication date (search date)**
Rapid reviews conducted to inform policy	Norwegian Institute of Public Health rapid review[16] Centers for Disease Control and Prevention (CDC): 'Scientific Brief: Community Use of Cloth Masks to Control the Spread of SARS-CoV-2'[17]	19 November 2020 (3 November 2020) Updated 20 November 2020
Systematic reviews	Chou et al. living rapid review:[18] 'Masks for Prevention of Respiratory Virus Infections, Including SARS-CoV-2, in Health Care and Community Settings: A Living Rapid Review'	28 October 2020, (2 October 2020)
Randomised controlled trials	Bundgaard et al. ('DANMASK-19')[19] 'Effectiveness of Adding a Mask Recommendation to Other Public Health Measures to Prevent SARS-CoV-2 Infection in Danish Mask Wearers'	18 November 2020

Observational studies: Analysis at individual level	Case control, retrospective cohort and cross-sectional studies Example: Doung-ngern et al.[20] 'Case-Control Study of Use of Personal Protective Measures and Risk for SARS-CoV 2 Infection, Thailand'	November 2020 (*included in previous HIQA review in preprint form)*
Observational studies: Analysis at community or population level	Ecological studies: Van Dyke et al. Morbidity and Mortality Weekly Report 'Trends in County-Level COVID-19 Incidence in Counties With and Without a Mask Mandate — Kansas, June 1–August 23, 2020'	20 November 2020 (early release)
Laboratory studies	Ueki et al.[21] 'Effectiveness of Face Masks in Preventing Airborne Transmission of SARS-CoV-2' Lindsley et al.[22] 'Efficacy of face masks, neck gaiters and face shields for reducing the expulsion of simulated cough-generated aerosols'	21 October 2020 (preprint) 16 November 2020 (preprint)

Rapid reviews to inform national-level policy

The most up-to-date review of the evidence identified is a rapid review performed by the Norwegian Institute of Public Health, which was updated on 3 November 2020 following an earlier report in June 2020.[16] The results of this rapid review are described below.

Norwegian Institute of Public Health Rapid Review[16]

This review was performed to inform a policy recommendation based on the following question:[16] 'Should individuals in the community without respiratory symptoms wear face masks to reduce the spread of COVID-19?'

This review, based on the setting of Norway and adopting a societal perspective, considered the following outcomes of interest:

- incidence of all COVID-19 infections
- COVID-19 infections in people wearing face masks
- COVID-19 infections in people exposed to asymptomatic, but infected, individuals
- incorrect use of face masks

- potential undesirable effects, including neglect of other preventive measures, such as hand washing and social distancing, and reduced access to face masks for people who need them most.

Overall, the categories of research incorporated in the review included: direct evidence, systematic reviews of studies, systematic reviews comparing different types of face masks, laboratory studies, and research on people's values regarding face mask usage or advice, resources required, cost-effectiveness, equity, acceptability and feasibility.

With respect to direct evidence on the effects of face masks on preventing SARS-CoV-2 infections in community settings, the review included 14 observational studies, including case-control, interrupted time-series, and ecological studies, and studies that modelled the impact of face mask use or policies. The review authors noted that there was a high risk of bias in all of the studies, and that was is difficult to control for confounding factors, including other measures in place or combinations of measures. Further sources of bias include the limited nature of the data available in particular jurisdictions, and the high risk of recall bias where survey methods are used.

Taking into consideration all forms of evidence, the recommendations of this review were as follows:

- recommendation against the use of face masks where the incidence of COVID-19 is low and controlled and where individuals in the community are not in close contact with people who are known or assumed to be infected
- consideration towards the use of face masks where the incidence is high, increasing or the spread is uncontrolled, either locally, regionally or nationally. This is despite the fact that study results were noted to be variable in protective effect and given low certainty of the evidence. Face mask use should be targeted to settings where distance cannot be kept in indoor settings, including on public transport, and especially where contact tracing is difficult.

Systematic reviews

The HIQA review of face mask use in the community published on the 21 August 2020 identified eighteen systematic reviews. These 18 systematic reviews included primary studies of face mask use in the community, but they also included studies of healthcare settings, with conclusions based on evidence from across all settings. Details of these systematic reviews, and associated quality appraisal, are included in the original evidence summary report.[6]

Update to review by Chou et al.[18]

Since the publication of the previous HIQA review of face mask use in the community, the living systematic review published by Chou et al. was updated to include studies published to 2 October 2020.[18] The update included one additional study on use of masks and SARS-CoV-2 infection in the community setting. This case-control study, by Doung-ngern et al.,[20] featured in the previous HIQA review, and included 200 cases and 839 uninfected controls in Thailand. The study found that wearing a mask all the time was associated with decreased risk of SARS-CoV-2 infection, versus no use, after adjusting for age, sex, exposure to contact, sharing of dishes, cups or cigarettes, and hand washing (adjusted odds ratio (OR) 0.23, 95% CI 0.09 to 0.60). Inconsistent use was not associated with decreased risk (adjusted OR 0.87, 95% CI 0.41 to 1.84) and mask type was not independently associated with risk of SARS-CoV-2 infection (p=0.54).

Chou et al. noted that their original systematic review conclusion had been that the evidence on mask use in community settings and risk of SARS-CoV-2 infection was insufficient, and had been based on one study with methodological limitations. The most recent update concluded that the strength of the evidence remains insufficient, that is, that the addition of the study by Doung-ngern et al. did not change the review conclusions.

Randomised controlled trials

The HIQA review of face mask use in the community published on the 21 August 2020[6] identified nine RCTs or cluster RCTs, all of which considered the transmission of influenza or influenza-like illness. These trials were predominantly set in households, with a smaller number conducted in schools and university halls of residence. The review concluded that the RCTs provide some weak evidence that medical masks worn by both index cases and healthy household contacts can reduce the risk of secondary household infections, when implemented early, combined with intensified hand hygiene and subject to good levels of compliance.[6]

One relevant RCT addressing face mask use and SARS-CoV-2 transmission in the community setting, the DANMASK-19 trial,[19] has been published since the last HIQA review.

DANMASK-19 Trial [19]

This nationwide trial was performed in Denmark from April to June 2020, a period when physical distancing recommendations were in place, but face masks were not recommended and were rarely worn outside of the hospital setting. During this time, infection rates in the community were modest, facilitating the ethical conduct of a clinical trial of a public health intervention.

The study aimed to identify the effect of a face mask recommendation on infection in the mask wearer, and recruited (via media, and by contacting private companies and public organisations) 6,024 adults who reported spending at least three hours outside their homes per day, whose line of work did not require face masks, and who did not have a previous known SARS-CoV-2 infection. Participants were randomly assigned to follow physical distancing measures with or without a recommendation to wear a mask when outside the home and among other people, and were supplied with surgical masks. Outcomes were determined by weekly surveys and self-administered antibody tests (finger-prick samples), in addition to RT-PCR-based testing at one month and or if the individual developed COVID-19 symptoms. Participants were instructed to perform the RT-PCR swab themselves at home and to return the kit for laboratory analysis.

The mean age of participants was 47.4 (SD=14) in the face mask group and 47.0 (SD=13) in the control group. Outcome assessment after one month of follow-up led to the observation that 1.8% (42/2,392) of those in the mask intervention group, and 2.1% (53/2,470) of those in the control group developed SARS-CoV-2 infection. This amounted to a risk difference of -0.3% (95% CI -1.2 to 0.4, p=0.38) and an OR of 0.82 (95% CI 0.54-1.23, p=0.33). As such, based on the results of this trial, an effect of face masks on infection in the wearer may be expected to range from -46% to +23%; the results are therefore inconclusive.

Compliance with masking

In DANMASK-19,[19] among those within the face mask group, 46% reported full adherence to face mask use, 47% reported partial adherence, and 7% reported no adherence. Participants were asked to choose among three reasons for lack of adherence to mask use. These were 'my work does not allow regular use of mask'; 'the mask becomes wet quickly making it no longer usable' and 'I do not want to wear a mask'. These were chosen by 50%, 32% and 18%, respectively, of participants reporting lack of adherence. [23]

Risk of bias

This trial had a number of important limitations. In addition to external validity concerns (for example, transferability of Danish population results to the Irish setting), the trial is subject to several internal validity issues. These include loss to follow-up (19%), lack of blinding of participants (due to the nature of the study), and the fact that results relied on patient-reported findings, including the results of self-administered home antibody tests which are subject to measurement bias. Concerns have also been raised regarding potential underpowering of the trial.[24] Nonetheless, reporting of the trial was satisfactory; results of the CONSORT checklist

of reporting quality, as performed within the present review, are presented in Appendix 2.

Implications of DANMASK-19 trial results for face mask effectiveness conclusions

The trial presented inconclusive results with regards to the use of face masks to reduce the risk of infection for the wearer. However, it did not consider source control, and furthermore study participants' exposure to potential infection with SARS-CoV-2 was overwhelmingly to persons not wearing masks. As such, these results do not provide evidence for the effectiveness (or lack thereof) of widespread use of masks in the community to reduce SARS-CoV-2 transmission. Details of the DANMASK-19 trial are summarised in Appendix 1.

Observational studies (individual level analysis)

The HIQA review of face mask use in the community published on the 21 August 2020[6] identified a total of ten observational studies which performed analysis at the individual level (for example, case-control, retrospective cohort, or cross-sectional studies) and which provided evidence on the effectiveness of face mask use in the community to reduce transmission of respiratory viruses. Six of these studies considered the transmission of influenza or influenza-like illness, or SARS. A further four observational studies were identified which specifically aimed to examine transmission of SARS-CoV-2: Cheng et al.,[25] Xu et al.,[26] Doung-ngern et al.[20] (described within Systematic Review section, above) and Wang et al.[27]

Subsequently, three additional studies were identified in an academic publication by the review authors which included a systematic search for articles published as of 27 August 2020.[28] These updates did not change the conclusions of the original HIQA review but were communicated to NPHET in September 2020.[29-31] Six of the seven studies suggested that the wearing of masks may reduce the risk of SARS-CoV-2 transmission. As noted in the academic publication of this review, while the findings across the six studies are mainly consistent and suggest that face masks may reduce the risk of infection in community and household settings, the quality of the evidence is low.

The seven studies of SARS-CoV-2 transmission are described in full within the previous HIQA review and academic publication; details of these studies are included in Table 2.[28] As noted within the Rapid Review and Systematic Review sections presented earlier within this report, the Doung-ngern et al. study has been highlighted as an important evidence update in recent reviews that conducted a systematic search for observational studies.

Several additional observational studies considering face mask use outside the healthcare setting have been considered within guidance issued by the CDC[17] and

the WHO.[11] One widely reported study published in July 2020 noted a lack of onward transmission of infection to 139 clients who were exposed to two hair stylists symptomatic with COVID-19, these stylists later being confirmed as SARS-CoV-2 positive on testing.[32] Both stylists and clients wore face masks, specifically double-layered cotton face coverings or surgical masks, while the clients were receiving the service, in accordance with local guidance. Following public health contact tracings and two weeks of follow-up, no COVID-19 symptoms were identified among the 139 exposed clients or their secondary contacts. Testing was offered to all clients following exposure; 67 underwent testing and no tests detected SARS-CoV-2 in the clients. In contrast, the stylist who was second to become infected with SARS-CoV-2 was noted to have been interacting with the first stylist without masks in intervals between clients. Furthermore, all four of the first stylist's close contacts outside of the occupational setting (co-habiting relatives and housemate) were found to develop COVID-19 symptoms and tested positive for SARS-CoV-2. The authors concluded that these results support the use of face coverings in places open to the public.[32]

A retrospective cohort study of SARS-CoV-2 transmission risk factors among high-risk close contacts was published in November 2020.[33] This study identified all close contacts of confirmed COVID-19 cases in Singapore between January 23 and April 3 2020 and performed a detailed risk assessment. Among non-household contacts, exposure to more than one case, being spoken to by an index case for 30 minutes or longer, or sharing a vehicle with an index case, were significantly associated with SARS-CoV-2 transmission; on univariable analysis, mask use was not identified to be associated with risk transmission.[33] However, the authors noted that the study was unable to assess the effectiveness of community face mask use; the prevalence of mask use was low as mask wearing was not mandatory at the time of the study. The authors further noted that on the basis of knowledge of other droplet-transmitted respiratory viruses, surgical mask wearing would be expected to be effective in preventing SARS-CoV-2 transmission.[33]

Table 2: Characteristics and results of seven observational studies of face mask use in the community and SARS-CoV-2 infection risk, as identified within previous HIQA evidence summary[6] and academic publication [28]

First author, Country, Study design	Population, Setting, Type of mask	Results: Face mask effect	Results: Reported adherence to face mask usage
Cheng et al.[25] Hong Kong Cross-sectional	961 patients diagnosed with COVID-19. Various community settings (incl. karaoke, dining, workplace). Mask type not reported.	11 clusters of 113 persons engaged in 'mask-off' activities, compared to 3 clusters of 11 people in workplace 'mask-on' settings (p = 0.036).	*Not reported for the clusters of cases.*
Xu [26] China Cross-sectional	8,158 adults (mask data reported by 5,120) Unspecified community settings. Mask type not reported	Not wearing a mask, compared with wearing a mask, was associated with significantly increased risk of infection (adjusted OR 7.20, 95% CI 2.24, 23.11). Wearing a mask, compared with not wearing a mask, was associated with significantly reduced risk of infection among those who practiced hand washing (RR 0.11, 95% CI 0.04, 0.29), proper coughing etiquette (RR 0.18, 95% CI 0.05, 0.57) and social distancing (RR 0.03, 95% CI 0.01, 0.11).	*Self-reported adherence:* 97.9% (5,012/5,120) wore a mask when going out.
Doung-ngern et al.[20] Thailand Case Control	1,050 contacts of confirmed COVID-19 cases (211 cases, 839 controls) Unspecified community settings. Medical and non-medical masks.	Compared with not wearing a mask, wearing either a medical or non-medical mask all the time was associated with a lower risk of infection (adjusted OR 0.23, 95% CI 0.09, 0.60). Wearing a mask sometimes was not associated with a lower risk of infection (adjusted OR 0.87, 95% CI 0.41, 1.84).	*Self-reported adherence:* *Cases:* Never 102/210 (49%); sometimes 79/210 (38%); all the time 29/210 (14%). *Controls:* Never 500/823 (61%); sometimes 125/823 (15%); all the time 198/823 (24%).
Wang et al. [27] China	335 individuals in 124 families with at least one laboratory confirmed COVID-19 case.	Compared with no family members wearing masks, household transmission was reduced when all family members wore masks all the time at home after the primary case's illness onset date	*Self-reported adherence*

Retrospective cohort	Household setting. All types of masks.	(unadjusted OR 0.20, 95% CI 0.07, 0.60), but not if only some family members wore masks (unadjusted OR 0.72, 95% CI 0.30 to 1.73). Transmission within families was also less likely when the primary case wore a mask at all times (unadjusted OR 0.30, 95% CI 0.11 to 0.82) after illness onset, but not when the primary case and/or family members wore a mask some of the time (unadjusted OR 1.15, 95% CI 0.46 to 2.87), compared to never wearing a mask. Face mask use before the primary case's illness onset date by one or more persons in the household (primary case or household contact) reduced transmission compared with no face mask use (adjusted OR0.21, 95% CI 0.06 to 0.79). It is not clear if masks were worn all the time or sometimes in this analysis	Never 41/124 (33.1%); sometimes 37 (29.8%); all the time: 46/124 (37.1%).
Hong et al. [29] China Retrospective cohort	Analysis based on 41 pre-symptomatic index cases with SARS-CoV-2 and 197 close contacts. Various community settings (incl. a chess and card room, households). Mask type not reported.	Close contacts of a pre-symptomatic index case who wore a mask were less likely to get infected with SARS-CoV-2 than close contacts who were in contact with a pre-symptomatic index case who did not wear a mask (8.1% (10/123) vs. 19.0% (14/74); OR 0.38, 95% CI 0.16, 0.91).	*Self-reported adherence* 28 (68.3%) index cases wore a mask during the pre-symptomatic phase, while 13 (31.7%) did not.
Speaker et al. [30] USA Case-control	Analysis based on 293 participants without known contact with a COVID-19 patient (68 cases developed COVID-19, 225 controls did not). Various community settings. All types of masks.	There was no statistically significant difference in mask wearing between cases (64% (43/68) reported always wearing a mask) and controls (55% (124/225) reported always wearing a mask); (unadjusted OR 1.40, 95% CI 0.80, 2.45). For cases and controls who wore masks, there were no statistically significant differences in the types of mask worn (respirator, surgical or cloth), although the numbers in some groups are very small.	Not reported.
Clipman et al.[31] USA Cross-sectional	1,030 adults. 55 (5.3%) self-reported ever testing positive for SARS-CoV-2, of whom 18 tested	In analyses restricted to participants who tested positive for SARS-CoV-2 within the previous 2 weeks (n=18), consistent indoor mask use within the previous 2 weeks (unadjusted OR 0.21, 95% CI 0.06 to 0.76) was associated with a lower likelihood of infection,	*Self-reported adherence* 53% (n not reported) always wore masks when

	positive in the previous two weeks. Unspecified indoor and outdoor settings. Mask type not reported.	compared to no or occasional mask use. Consistent outdoor mask use was not associated with a statistically significant reduction in infection (unadjusted OR 0.41, 95% CI 0.13 to 1.27) compared to no or occasional mask use.	visiting public indoor and outdoor locations.

Ecological studies (observational studies with analysis at community or population level)

Ecological studies are traditionally viewed within epidemiology as a weak source of evidence for causal inference; this is due to the inability to disaggregate effects of various interventions at play at the individual level and the community/population level. Nonetheless, ecological studies may help to indicate a potential effect and may be valuable in combination with sources of evidence from studies performed at the individual level.

Several ecological studies,[34-36] were identified in the HIQA review of face mask use in the community published on the 21 August 2020[6] and were included in the discussion. Study results suggested that policies mandating face masks are associated with a subsequent decrease in COVID-19 cases. The HIQA review[6] also identified mathematical modelling studies that considered the effects of face mask use on SARS-CoV-2 transmission; these modelling studies suggested a reduction in community transmission of SARS-CoV-2 with the adoption of face masks.[37, 38] The academic publication which updated the HIQA review, published by the same authors,[28] subsequently identified an additional mathematical modelling study also suggesting a reduction in community transmission with face mask use.[39]

Additional ecological studies have since been published, which concur with these earlier findings. In total, such studies now include analyses of transmission in regions within the US,[35, 36, 40, 41] Canada,[42] and Germany.[34]

Most recently, a US study published, on 20 November 2020 by authors including members of the CDC's Epidemic Intelligence Service and the CDC's COVID-19 response team suggests a protective effect of face mask use following implementation of a mask mandate.[43] This study by Van Dyke et al.[43], was an analysis of trends in county-level COVID-19 incidence in counties with and without a mask mandate in the state of Kansas. Trend analyses indicated that from 1 June 2020 to 2 July 2020, the COVID-19 seven-day rolling average incidence increased each day in both counties that had mask mandates in place and counties that did not. Following the governor's executive order, COVID-19 incidence was found to decrease each day in counties which had a mask mandate in place (mean decrease = 0.08 cases per 100,000 per day; 95% CI = -0.14 to -0.03), while in non-mandated counties, incidence continued to increase each day (mean increase = 0.11 cases per 100,000 per day; 95% CI = 0.01 to 0.21). Notably, in at least 13 (54%) of the 24 mandated counties, the mask mandates occurred alongside other county-level recommended or mandated mitigation strategies (e.g., limits on size of gatherings and occupancy for restaurants). However, in sensitivity analyses, similar decreases in COVID-19 incidence after 3 July were observed among mandated

counties with and without other mitigation strategies. This indicates the potential importance of mask mandates separate to the utility of other mitigation strategies, though implementing multiple strategies remains the recommended approach. The authors of this study noted that these findings were consistent with previous observations of declines in COVID-19 cases in states within the USA which implemented mask mandates.[35, 40]

Laboratory or mechanistic studies

Several laboratory-based simulation studies, or, mechanistic studies, have been published in recent months. These examine either the ability of face masks to block the passage of respiratory droplets, for example, as part of cough simulation studies, or the ability of face masks to filter particles containing SARS-CoV-2. The former type of study aims to examine the performance of face masks in 'source control' while the latter considers the ability of face masks to protect the wearer of the mask from inhaling infectious particles. While these studies provide indirect evidence to inform the potential of face masks to reduce SARS-CoV-2 transmission, they do not provide real-world evidence of the effectiveness of masks, and the transferability of their results to real-world settings is therefore unknown. Recent study developments are described below.

Ueki et al. published in October 2020, developed an *in vitro* airborne transmission simulator of infectious SARS-CoV-2-containing droplets/aerosols produced by human respiration and coughs.[21] Simulations involved a mannequin head through which nebuliser equipment released viral suspension, mimicking a person infected with SARS-CoV-2 and producing a mild cough. When a second mannequin exposed to the virus was equipped with various masks (cotton mask, surgical mask, or N95 mask), the uptake of the virus droplets/aerosols was reduced. A cotton mask led to an approximately 20% to 40% reduction in virus uptake compared to no mask. The N95 mask had the highest protective efficacy (approximately 80% to 90% reduction) of the various masks examined. However, infectious virus penetration was measurable even when the N95 mask was completely fitted to the face with adhesive tape. In contrast, when a mask was attached to the mannequin that released virus, cotton and surgical masks blocked more than 50% of the virus transmission. There was a synergistic effect when both the virus receiver and virus spreader wore masks (cotton masks or surgical masks) to prevent the transmission of infective droplets/aerosols.

Lindsley et al., who published their research as a preprint on 16 November 2020, used a cough aerosol simulator with a pliable skin head form to propel small aerosol particles (0 to 7 μm) into different types of face coverings.[22] An N95 mask was found to block 99% of the cough aerosol, a medical grade mask blocked 59%, a 3-ply cotton cloth face mask blocked 51%, and a polyester neck gaiter (or 'snood')

blocked 47% as a single layer and 60% when folded into a double layer. In contrast, a face shield blocked 2% of the cough aerosol.

Other laboratory-based studies do not test the ability of face masks to filter or block the transmission of particles containing SARS-CoV-2 but instead consider the ability of face masks to filter similarly sized non-infectious particles. A study published in December 2020, used a custom-built exposure chamber to simulate typical indoor air conditions and used a particle generator to introduce sodium chloride particles with a median diameter of 0.05µm (that is, slightly smaller than SARS-CoV-2 virions) to the chamber.(44) Seven consumer-grade reusable face masks of various cloth types (nylon, cotton, polyester, polypropylene) and five standard medical masks (including modifications such as clips and looping of ties to improve fit) were fitted on an adult male volunteer. The fitted filtration efficiency (FFE) of the masks was measured while the volunteer repeatedly moved their torso, head and facial muscles; particle concentration was measured in the chamber and in the breathing space behind the mask to allow for the calculation of filtration efficiency. The mean FFE for the reusable face masks ranged from 79.0% to 26.5% (higher results indicating improved filtration), the highest FFE being achieved by a two-layer woven nylon mask. In contrast, unmodified medical masks had a mean FFE of 38.5%, though this was improved with modifications to improve fit. The authors concluded that reusable consumer-grade masks may demonstrate equivalent, or improved, filtration efficiency as compared to standard medical masks.(44)

Conclusions on the current evidence of effectiveness

Guidance on use of face masks is aimed at whole population groups, and should be based on appropriate evidence. However, obtaining such evidence is highly challenging in the context of a pandemic. A cluster randomised trial is the most appropriate design for assessing the effectiveness of community-wide face mask usage in reducing transmission of SARS-CoV-2. However, at this stage of the pandemic, wherein masks are widely used in many jurisdictions, it is likely that such a design would be limited by ethical challenges associated with randomising one group of individuals to a 'no mask' intervention. No such study has published to date, although one is ongoing in Guinea-Bissau, West Africa.(45) Irrespective of concerns regarding internal validity, the transferability of the trial results to the local decision-making setting would require consideration. The DANMASK RCT trial results have contributed to the overall evidence base surrounding face mask usage. However, the trial did not consider source control and, as such, did not address the question of whether face mask recommendations reduce community transmission overall. Therefore, the current evidence base focusing specifically on SARS-CoV-2 transmission primarily comprises observational studies (including studies analysed at the individual level and at the community or population level) and laboratory studies.

Indirect evidence is also available for the effects of face masks on preventing other respiratory infections in community settings.

Review of evidence: additional considerations

A number of additional considerations were identified during the scoping for this rapid evidence update. As previously mentioned, a systematic approach was not adopted to identify these additional considerations, nor was a systematic search performed to identify findings relating to these considerations. The following section is intended to provide an overview of these considerations, and of relevant recent developments or guidance relating to these matters, to help inform decision-making.

Adherence to wearing of face masks

In Ireland, ongoing public opinion surveys conducted by Amárach Research, on behalf of the Department of Health, contain a section explicitly relating to the use of face coverings. Summary data from this research for the week of the 16 November 2020, indicates that self-reported wearing of face coverings in public places has been relatively consistent at approximately 90% since August, with similar rates reported across gender and age groupings; notably this coincides with the mandating of face masks in retail outlets. Specific questions regarding face covering use while shopping or using public transport indicate higher rates of adherence; these have consistently been above 95% since early October 2020.[46] Self-reported adherence results from the DANMASK-19 trial conducted by Bungaard et al. suggested that 46% of participants wore the mask as recommended, 47% predominantly as recommended, and 7% not as recommended.[19] Guidance for the use of face masks within this trial stemmed from those provided by the WHO in their interim guidance.[47]

Evidence appears scarce regarding the extent to which face masks are used correctly. One study involving direct observation of the public was identified; this examined public compliance on selected days in August 2020 following municipal rules requiring face masks to be worn in public spaces in Brittany, France.[48] This study noted that, on a weekend day, almost 82% of adults were complying with masking requirements and just over 18% were not, with the latter split between 12.5% unmasked and 5.8% semi-masked. On a week-day, compliance was lower; with 74.3% of all adults wearing masks and around 25.7% either unmasked (16%) or semi-masked (9.7%). As noted by the authors, most of those who were semi-masked wore their mask over their mouths, but under their nose. Some wore their masks under their chin, so over neither nose nor mouth. Where some members of family groups were unmasked in this way, others within the group appeared more likely to be semi-masked (under the nose), implying a sense of social permission to

modify mask wearing requirements and to fit in with group norms.[48] Further information regarding the appropriate donning, removal, handling, disposal, or cleaning of face coverings by the general public within the context of the COVID-19 pandemic appears lacking.

In a rapid review of face masks and coverings within the general public, Mills et al. note that socio-behavioural factors are vital to understanding public adherence to wearing face masks and coverings, including public understanding of virus transmission, risk perception, trust, altruism, individual traits, and perceived barriers.[49] The authors further note that consistent and effective public messaging is vital to public adherence of wearing face masks and coverings, with conflicting policy advice noted to generate confusion and lack of compliance with such recommendations overall.[49]

Types of face masks

The Health Protection and Surveillance Centre (HPSC) categorises four types of face coverings; respirator masks, surgical masks (or medical masks), cloth masks and visors. Recommendations regarding the type of face mask used are prescriptive in terms of healthcare settings, with respirators and medical masks used depending on environmental and patient related factors. Respirators and medical masks are generally not recommended for use by the general population with consideration towards preservation of PPE for healthcare workers.[50]

For the general public, recommendations regarding the use of face masks consider non-medical face masks (or cloth masks) and visors (or face shields). An evidence summary conducted by the HSPC, published 27 October 2020, examined the efficacy of visors compared with face masks for the prevention of transmission of SARS-CoV-2.[51] The evidence summary considered recommendations from international bodies such as the World Health Organisation (WHO), the European Centre for Disease Prevention and Control (ECDC) and CDC, alongside a literature review of research evidence, and expert opinion. The document concludes that collectively the evidence suggests that cloth face coverings are favoured over visors. However, there is evidence that visors do reduce exposure to droplets to a certain extent and may be considered as an alternative to cloth face masks in certain scenarios such as for people with breathing difficulties, people who are unable to remove masks/face coverings without help, individuals with particular needs who may feel upset or very uncomfortable wearing a face mask, or in settings where people who have learning difficulties or who are hard of hearing are present.[51]

Of note, a mechanistic study (a study which examines the mechanism of action of an intervention) conducted by Lindsley et al., published as a preprint on 16 November 2020, examined the prevention potential of different face masks using a cough

aerosol simulator.[22] Overall, the authors noted that an N95 respirator blocked 99% of the cough aerosol, a medical grade mask blocked 59%, and a three-ply cotton cloth face mask blocked 51%, while a face shield (or visor) blocked 2% of the cough aerosol. The authors highlight that such results highlight a preference of masks over visors.[22] Similar results were noted in a mechanistic study conducted by Pan et al., examining material filtration efficiency, that is, inward and outward protection efficiency, of a number of mask types, including cloth coverings and visors.[52] The authors recommend that a three-layer mask consisting of outer layers of a flexible, tightly woven fabric and an inner layer consisting of a material designed to filter out particles provide the best protection in terms of the outcomes investigated; mask fit was further noted as an important consideration.[52] Also, a study published in December 2020, which included a human volunteer and tested the effiency of masks in filtering sodium chloride particles (in place of SARS-CoV-2 virions), concluded that reusable consumer-grade masks may demonstrate equivalent, or improved, filtration efficiency as compared to standard medical masks.[44] Furthermore, among cloth masks, the highest filtration efficiency was observed to occur with a two-layer woven nylon mask.[44] These mechanistic studies are discussed in further detail in 'Laboratory or mechanistic studies' within the overall review of evidence within this report.

In June 2020, the National Standards Authority of Ireland (NSAI) developed a Specification Written in Fast Track (SWiFT) to address the need for a consensus-based specification for non-medical masks (barrier masks) for the general public. The document outlines the minimum requirements for barrier masks intended for consumers, single use or reusable including; design, manufacture, performance, packaging, marking, and information for use. In order to meet general requirements, the barrier mask must cover the mouth, nose and chin, sufficiently cover the user's face against the ambient atmosphere, when the user's skin is dry or damp, or when the user moves their head. Furthermore, the mask must have a means by which it can be fitted closely over the nose, mouth and chin of the wearer and which ensures that the mask fits closely at the sides, and does not contain valves.[53] Notably, the absence of valves is further emphasised by the CDC whereby valves may allow virus particles to escape should be wearer be infected with COVID-19.[54]

Potential undesirable effects of face mask use

Potential undesirable effects of face mask may be considered with respect to each of the following types of effects:

- potential interference with other public health guidance aimed at preventing SARS-Cov-2 transmission (for example, reduced physical distancing among wearers of masks) or increased risk of SARS-CoV-2 transmission due to contact with contaminated masks

- undesirable effects for the person wearing the mask or those interacting with that person (for example, discomfort).

With respect to the former type of undesirable effect, the previous HIQA evidence summary on face mask use in the community[6] considered the potential issue of 'risk compensation', that is the suggestion that face masks may introduce a false sense of security and lead wearers to neglect hand hygiene and physical distancing.[47] As discussed by Howard et al. and noted in the previous summary, any such risk compensation that may occur in some individuals is likely to be dwarfed by the potential protective impact at the population level. Concerns around risk compensation continue to be noted by the WHO in their 2 December 2020 update to Interim Guidance on mask use, though no more recent evidence was cited to support this.[11] Conversely, the WHO also suggests face mask use might encourage transmission prevention behaviours, such as avoiding face touching; evidence cited to support this premise included a cross-sectional study which found that mandatory mask-wearing policies introduced earlier this year were associated with reductions in face-touching behaviour in China and South Korea, though results from Europe and the US were inconclusive.[55] Similarly, the updated rapid review by the Norwegian Institute of Public Health,[16] noted that there is limited evidence of the extent to which face mask use may have unintended consequences with respect to SARS-CoV-2 transmission, and that there is some evidence that face masks can increase compliance with other measures in some circumstances.

With respect to undesirable effects for the person wearing the mask, the HIQA evidence summary on face mask use in the community published on the 21 August 2020[6] noted that while a limited number of potential harms of wearing masks were reported by some studies, mainly relating to discomfort, heat, humidity and pain, none of the studies included in the review specifically commented on safety. One systematic review, which specifically considered undesirable effects of face masks was also identified in the HIQA review. This systematic review, by Bakhit et al., has since been included in the updated rapid review conducted by the Norwegian Institute of Public Health,[16] and the 2 December 2020 WHO Interim Guidance [11], in their consideration of potential undesirable effects associated with face mask use. The Bakhit et al. review[56] has not yet been peer-reviewed as of the time of writing and the quality of the review is unclear. The review sought to identify evidence, based on trials and observational studies of mask use largely conducted prior to the current pandemic, of adverse events of face mask usage. Results relating to reported harms were largely derived from studies of healthcare workers wearing surgical masks throughout shifts; the review reported that such studies identified variable levels of discomfort and irritation (for example, acne or itch) among such workers wearing surgical masks for lengthy periods of time. Some increased difficulty in communication, for example, between healthcare staff and hospital

patients, was also reported, though this was not a consistent observation. Both the Norwegian Institute of Public Health rapid review and the WHO Interim Guidance notes that some people may experience minor adverse effects that include problems with breathing, discomfort, communication difficulty, or development of skin irritation or acne, and that masks may prove difficult for certain individuals (for example, those with mental illness).[11, 16] Also, there may be difficulty in accessing or paying for masks.[16] From a decision-making point of view, it was noted that these effects are mostly minor and the proportion of people who experience them is uncertain, however, if the population prevalence of COVID-19 is low, these undesirable effects could be large relative to potential benefits in terms of infections prevented.[16]

Considering the most recent primary research regarding undesirable effects, the present review identified the following studies examining particular outcomes. However, for all but the DANMASK-19 trial, quality assessment of study methodology and reporting has not been performed due to the rapidity of this review:

- Two recent studies were noted to have examined the physiological impact of face masks. Shaw et al. noted no discernable detrimental effect on blood or muscle oxygenation from mask wearing during vigorous exercise in young, healthy participants.[57] Within a cross-over study of 25 adults aged over 65 years, Chan et al. reported no associated decline in self-recorded oxygen saturation while wearing a three-layer nonmedical face mask while at rest or performing usual activities of daily living at home.[58]
- Dermatologists in Italy reported a case series of three patients from the general population who experienced mask-induced facial dermatoses, including rosacea, acne and seborrhoeic dermatitis.[59] Two of these patients wore masks throughout their occupational shifts. The report authors suggested recommendation of a surgical mask in preference to an N95 respirator in such patients, alongside skincare recommendations. The development of facial dermatoses following prolonged mask use has been well document in the healthcare setting.[60]
- Regarding psychological effects, within the DANMASK-19 trial conducted by Bundgaard et al., results indicated that, compared with the control group, the mask-wearing group reported feeling less worried and 50% (n=1,141) felt that masks provided assurance.[19] Adverse reactions from other citizens to the wearing of a face mask (unusual looks received from others) were reported by 14% of participants (n=320), while the remaining participants reported normal reactions from others or ignored the reactions of others. For both of these outcomes, it is important to note that this RCT was conducted in an earlier phase of this pandemic, during a time period and setting (April-June, Norway), wherein mask wearing was

highly uncommon in the general population.[19] In contrast, an online survey conducted in the UK (published on 27 November 2020), with oversampling of people with hearing loss, found that participants reported that face masks negatively impacted communication, particularly when communicating in medical situations or for people with hearing loss, and that this increased anxiety and stress during communication.[61]

Face masks as a protective measure for vulnerable groups

As of the time of submission of this report to NPHET, mandated use of face masks has been outlined in certain scenarios in Ireland, such as on public transport and in retail outlets. The use of face masks has also been advised by the Department of Health for people visiting the homes of those who are over 70 years of age or who are medically vulnerable, and by people who are being visited in their homes by those who are over 70 years of age or who are medically vulnerable.[62]

Within its advice for the public, the WHO recommends the use of non-medical masks for the general public.[11] However, for those with higher risk of severe complications from COVID-19, the WHO recommends such individuals should wear medical masks when physical distancing of at least 1 metre cannot be maintained. Such people include:[11]

- those who are over 60
- those who have underlying medical conditions such as:
    - cardiovascular disease
    - diabetes mellitus
    - chronic lung disease
    - cancer
    - cerebrovascular disease
    - immunosuppression

Review of international guidance

This review examined face mask guidance, published as of 11 December 2020, for 17 European countries (Austria,[63] Belgium,[64] Czechia,[65] Denmark,[19] France,[66] Germany,[67] Ireland,[68] Italy,[69] Netherlands,[67] Portugal,[70] Spain,[71] Sweden,[72] England,[73] Northern Ireland,[73] Scotland,[74] Wales,[75] and Switzerland[76]), that have been experiencing a resurgence in SARS-CoV-2 cases. Guidance from the USA,[54] Canada,[77] and Australia[78] was also considered. The rationale for choosing these countries is detailed in the Protocol for the present rapid evidence update.

As guidance for the USA, [54] Canada, [77] and Australia, [78] is devolved to state or municipal level authorities, these countries will not be discussed in the subsequent sections, but guidance for these countries is presented in Appendix 3, Table 2. Such devolution also occurs in some European countries, for example, Germany. [67]

Although a search of international resources was undertaken, it is possible that the sources identified in this review are not current or do not accurately capture all public health measures and strategies that are being undertaken. Guidance specific to certain settings (for example, education) may be issued separately by designated agencies, and may not have been captured within the scope of this rapid review. In addition, the public health measures that countries are adopting to limit the spread of COVID-19 are constantly changing. As such, the review may have missed relevant information that was published or due for publication at the time the review was completed.

Overview of international guidance (European countries)

The number and type of recommendations regarding face mask use varied across the included countries (Appendix 3, Table 1). This variation is summarised below with respect to particular areas of recommendations.

Public Transport: All European countries included in this review except Italy referred specifically in their guidance to the use of face masks on public transport (including buses, trains and airports) and for all but Sweden, such use is mandatory. The guidance includes information on wearing face masks while actually using the public transport, but also while waiting at platforms, at different stops, and in connecting buildings including waiting rooms. Italy does not specifically mention public transport; however, the wearing of face masks is mandatory in all indoor spaces other than homes, and in all outdoor spaces.[69] While Swedish guidance does not currently recommend face masks in public settings, the guidance lists situations where face masks can be useful, including when it is not possible to avoid using public transport under circumstances of crowding.[72]

Schools and children: Face masks are recommended for use in schools or educational settings in the majority of the included countries. However, the age at which children are exempted from wearing face masks varies. In Denmark, there is no requirement to wear a face mask in classrooms and auditoriums but a face mask is required in communal areas indoors including canteens and corridors as well as in a range of different educational settings (universities, secondary and further education, music schools, driving schools, folk high schools, day colleges and evening schools).[79] In Portugal, no specific reference is made to face mask use in schools in the guidance retrieved, though this guidance states that 'enclosed public spaces' are subject to face mask use.[70]

Indoor settings in general: With the exception of Sweden,[72] guidance from all countries included in the review specify the wearing of masks in indoor enclosed spaces or rooms. The guidance varies in terms of the level of detail provided. For example, Austrian guidance specifies only that mask and nose protection must be worn in 'public, closed rooms'.[63] However, other countries, such as Denmark, provide specific examples of when to wear a mask indoors, including at museums, galleries, entertainment venues, sports facilities and fitness centres, and in churches or other places of worship.[79]

Retail shops, cafes and restaurants: Recommendations specifically referring to retail shops, cafes, and restaurants are provided by a number of countries. Belgium provides detailed guidance for face mask use in these settings.[64] For example, face masks must be worn in establishments and places where catering activities are permitted, both for customers and staff, unless while eating, drinking or sitting at a table, and face mask use is also mandated in shops and shopping centres. This type of guidance is also the case in Denmark[80] and Ireland.[68]

Outdoors: A number of countries refer specifically to the use of face masks in outdoor settings. Italy currently recommends the use of face masks in all outdoor settings.[69] In Czechia, masks must be worn within any urban areas of cities, towns and villages, this includes between buildings, shops, in squares, and everywhere where people can be met in close proximity.[65] In Germany, face masks are compulsory in all public places in inner cities, for example, in front of retail shops and in parking areas.[67, 81] It is necessary in Spain to wear a face mask on a public road or in an outdoor space where interpersonal distance is less than 1.5 metres.[71] In Scotland, while it is not compulsory to wear a face mask outdoors, it is recommended in crowded situations where physical distancing is not always possible, such as at the school gate or at the entrance to a building.[74] Similarly, in Ireland, as of 27 November, face masks are recommended in busy or crowded outdoor settings.

Exemptions to the use of face masks: A number of exemptions were listed in more than half of the included countries, referring to people or groups who are not required to wear face masks as specified for the general. The ages of exemption for children ranged from: Belgium and Switzerland, age < 2; to Netherlands and Ireland, age <13.[64, 68, 82, 83] With respect to other exemptions, in Belgium and Switzerland, exemptions apply for counsellors and their clients (people in need of counselling) are also exempt.[64, 82] In Czechia, face masks do not need to be worn by people who cannot wear a face covering because of a serious mental illness or intellectual impairment.[65] In Ireland, it is noted that face coverings may not be suitable for anyone who has trouble breathing, is unconscious or incapacitated, is unable to remove it without help, or has special needs and who may feel upset or very uncomfortable wearing the face covering.[68] In Italy, people with conditions or disabilities incompatible with the use of a face mask and those who interact with these people, are excluded from the obligation to wear a face mask.[69]

Private cars and visitors to private homes: Several countries refer to the use of face masks when travelling in private cars or visiting a private home; these include Czechia, Ireland, Italy, and the Netherlands.[65, 68, 69, 83]

Evidence cited within international guidance documents

Most countries included in this international review did not cite or report evidence (from either primary research studies or from international agencies) to underpin their recommendation or guidance on facemask use. However, where evidence was not cited, this does not mean that it does not exist or was not used to inform the recommendations made. The following is a case study of how guidance in one country was underpinned by evidence.

Case study of evidence base informing international guidance: CDC

The CDC, in national guidance for the US, recommend the use of masks in the community. The rationale for this recommendation is based on knowledge generated from the following sources, as detailed in a Scientific Brief document:[17]

- study of the ability of masks to block release of fine droplets and particles into the environment ('Source control to block exhaled virus')
- study of the ability of cloth masks to filter fine particles upon inhalation ('filtration for personal protection')
- epidemiological studies of outbreaks or case control studies examining exposures
- ecological studies of incidence of SARS-CoV-2 pre and post mask mandates
- a report modelling the expected impact of masking on economic activity.

The CDC notes that masks are primarily intended to reduce the emission of virus-laden droplets ('source control'), which is particularly relevant for asymptomatic or presymptomatic mask wearers; the CDC further notes that such individuals may represent over 50% of transmissions. The Scientific Brief document was updated on 9 November 2020 to acknowledge that masks, when worn by all, may reduce transmission via both source control and personal protection. CDC's original guidance issued on 3 April 2020 noted that "masks are recommended as a simple barrier to help prevent respiratory droplets from traveling into the air and onto other people when the person wearing the mask coughs, sneezes, talks, or raises their voice."

Of the studies included in the CDC Scientific Brief:

- Fourteen[21-23, 84-94] were laboratory studies examining the potential for source control, that is, the blocking of exhaled virus, seven[21, 22, 84-87, 89] of which were published after 24 June 2020 (the update date for the previous HIQA review of facemasks in the community).
- Sixteen [21, 95-109] studies (including two systematic reviews [97, 98]) assessed the extent to which masks can filter particles to enable personal protection in the mask wearer, 12[21, 95, 96, 98-100, 102-105, 108, 109] of which were published after 24 June 2020.
- among epidemiological studies:
    - Six [20, 27, 32, 110-112] were observational studies examining exposures among individuals, of which two [20, 110] were published after 24 June 2020.
    - eight[34-36, 40-42, 113, 114] studies were ecological studies of the incidence of SARS-CoV-2 infection pre- and post-mask mandates, of which one[113] was a non-academic study reported the expected impact of mask wearing on economic activity. Six [35, 36, 40-42, 114] of the eight studies were published after 24 June 2020.

The CDC Scientific Brief concluded that both experimental and epidemiological data support the use of mask wearing in the community due to the (probable) synergistic effect of source control and personal protection.[17]

Summary of other guidance supported by evidence

Five countries (Australia,[78] Canada[77], Spain,[71] USA,[54] and Wales[75]) within this review explicitly stated the evidence or international guidance underpinning their recommendations. As would be expected, there was considerable overlap in evidence cited across countries, with all referencing as least one evidence review by an international organisational (such as, the WHO, ECDC and CDC). Swedish guidance, in contrast, referred to a lack of evidence to support a face mask

recommendation.[72] Full details on evidence cited by each country is presented in Appendix 3.

Discussion

This rapid evidence update aimed to provide an overview of recent developments in the research evidence and international guidance with respect to the use of face masks in the community to prevent SARS-CoV-2 transmission. It follows a previous HIQA evidence summary on face mask use in the community, published in August 2020 and which included a systematic search of studies published as of 24 June 2020.[6]

The present update, due to the tight timeline required for completion, is not systematic in its search approach and instead adopted a scoping approach to identify relevant literature. However, this update expands upon the scope of the previous evidence summary by considering updates to a wide range of study designs, including recent rapid reviews to inform policy, systematic reviews, randomised controlled trial evidence, observational studies including ecological studies, and laboratory evidence. This update also provides an overview of recent developments with respect to particular considerations in face mask use in the community, for example, evidence for adherence to face mask usage, different face mask types and undesirable effects of face mask use.

A major challenge in controlling the spread of SARS-CoV-2 in community settings is that the viral load is highest among infectees in the period immediately before symptom onset or in the early stages of infection.[115] Individuals at this stage of infection may transmit the virus without recognising that they may be posing a risk. As such, the rationale for face mask use in the community stems from the intention of source control.[116, 117] However, alternative questions may be posed overall:[118]

- firstly, what protection, if any, is afforded to the mask wearer through the act of wearing a face mask?
- secondly, what is the effect of large scale mask use by the population on community-level transmission of SARS-CoV-2?

This update firstly drew on the findings of a recently updated systematic review performed to inform national face mask use guidance in Norway. Studies identified from this review were noted and independently described for the purposes of the present update. The recommendations of the Norwegian review were informed by evidence from a broad range of decision-making domains, and a thorough deliberation by an expert panel. The decision-makers noted the limitations of the

evidence base, and therefore did not recommend general use of face masks in situations where the incidence of COVID-19 is low and controlled. However, the use of face masks was recommended in conditions where COVID-19 incidence is high, increasing, or where the spread is uncontrolled, with face mask use being targeted towards settings where distance cannot be maintained.

Results from a recent randomised controlled trial (DANMASK-19) presented inconclusive results with regard to the use of face masks to reduce the risk of infection for the wearer. Importantly, this trial did not assess the effectiveness of masks for source control, and was conducted within a setting where the majority of the population was not wearing masks. The trial is further subject to significant methodological limitations which hinder the applicability of the trial results overall.

Considering observational studies, conclusions remain relatively unchanged from those made within the previous HIQA evidence summary; there is relatively consistent evidence from observational study analyses performed at the individual level (for example, cohort studies) that favours the use of face masks to reduce transmission of SARS-CoV-2. Furthermore, several ecological studies have emerged in recent months which indicate a probable role for face masks in reduction of transmission of SARS-CoV-2 in jurisdictions which adopted face mask mandates or policies. While ecological studies are traditionally considered to represent a low certainty of evidence in establishing a causal relationship, these studies at a minimum provide hypothesis-forming descriptive data on trends in transmission prior to and following a community-level face mask public health intervention; such information may be considered alongside other forms of evidence.

Recent laboratory-based studies have provided further evidence of the technical ability of face masks to reduce the outward transmission of SARS-CoV-2 from a wearer (that being, source control) and their ability to reduce the inhalation of particles containing SARS-CoV-2 by the wearer (that is, protection). However, this evidence emerges from simulations of infection scenarios in a laboratory setting (for example, using mannequins in biosafety units), as opposed to real-world settings of transmission.

Considering the overall evidence identified within this update and its ability to facilitate decision-making, it is important to recognise that randomised controlled trials traditionally represent the highest quality of evidence in establishing causal relationships, generally. The evidence base for the transmission of SARS-CoV-2 in the community setting now includes one randomised controlled trial of the effects of a mask recommendation. However, this trial only contributes evidence towards the effectiveness of a mask intervention for the wearer, under conditions where widespread community mask use is not in place, and therefore does not contribute to the evidence base for source control of SARS-CoV-2 transmission. Furthermore,

results of this trial were inconclusive. Also, as noted in the editorial accompanying the DANMASK-19 publication,[118] the effect of a mask recommendation depends on more factors than the efficacy of a mask and the appropriate use thereof. These include the background prevalence of the virus, physical distancing behaviours, and the frequency and characteristics of gatherings.

A second, large, community-based trial of face masks is currently underway in Guinea-Bissou; this trial involves 66,000 participants randomised at whole village level.[45] However, in a Cochrane editorial entitled 'Policy makers must act on incomplete evidence in responding to COVID-19', it was noted that this trial, considering similar design aspects to that of DANMASK-19, may also hold little promise in determining the effects of face mask on virus transmission.[119] Such trial results still provide important information regarding face mask uptake or distribution, and self-reported usage,[119] but overall, there remains a lack of robust trial data on the effectiveness of face mask policies in reducing SARS-CoV-2 transmission in the community.

It is unlikely that definitive trial data, with the ability to conclude on the effectiveness of a population-level mask intervention in reducing SARS-CoV-2 in a country such as Ireland, will become available. This is partly due to the significant ethical and methodological challenges for the conduct of such trials; indeed, the authors of DANMASK-19 noted the challenges associated with designing and performing an RCT that would address the question of source control.[120] Furthermore, there are multiple confounding factors which limit the ability to compare the results to real-life settings.

Overall, the available research on this topic includes low certainty results. Those studies which specifically consider SARS-CoV-2 transmission largely comprise observational studies, including ecological studies, and laboratory studies. The transferability of these laboratory-based results to real-world environments is unknown. With respect to measurement of effects of behavioural public health measures, it has been noted elsewhere that there is not, and may never be, high-quality evidence from randomised trials on those effects, and that public health officials must rely on incomplete evidence.[119] As noted by the Cochrane editorial authors[119] in response to the publication of the DANMASK-19 trial, public health officials may draw on the trials summarised in high quality systematic reviews, for example, previous studies from scenarios other than SARS-CoV-2 transmission (such as the use of masks to prevent influenza transmission), but may also consider the observational study data which describe associations with transmission rates, while also recognising the limitations of such data. Furthermore, decision-makers may draw on the findings of basic research, including mechanistic studies demonstrating the effects of face masks in reducing droplet transmission.

Considering the findings of the international review of public health guidance performed for this update, this review summarised recommendations from 20 countries with respect to guidance issued as of 11 December 2020. With the exception of Sweden, all included countries provided recommendations for the use of face masks in one or more settings. The majority of individual countries included did not specifically cite or report literature evidence within their guidance documents to underpin their recommendations on face mask use.

The number and detail of recommendations varied across countries. However, the majority of countries specifically referred to the use of face masks on public transport and in educational settings. All countries providing recommendations on mask use referred to indoor and enclosed spaces or rooms. The detail provided ranged from a general statement on wearing face masks indoors to more detailed lists of indoor settings where face masks must be worn. Cafes and restaurants were specifically listed in guidance from several countries as settings which require face masks for customers and staff, unless while eating, drinking or sitting at a table. Several countries also referred specifically to the use of face masks in outdoor settings, specifically where physical distance cannot be maintained, such as in busy streets, parks or at school gates. Italy currently recommends the use of face masks in all outdoor settings.

The present report was submitted to NPHET in draft version on 25 November 2020. Following this, on 2 December 2020 the WHO published updated Interim Guidance on mask use in the context of COVID-19.[11] Guidance previously issued by the WHO on 5 June 2020[47] recommended the use of face masks by the general population in areas with knowon or suspected widespread transmission and limited or no capacity to implement other containment measures (such as physical distancing or contact tracing); specifically, face masks were recommended in public settings such as shops, workplaces, social gatherings, mass gatherings, schools, and places of worship. in areas with known or suspected widespread transmission and limited capacity to implement other containment measures. Other recommended scenarios for use included settings where physical distancing cannot be achieved, for example, on public transport, or in working conditions involving close contact (such as in shops or restaurants).

In their updated guidance, the WHO recommends use of a non-medical face mask in the following settings, for areas with known or suspected community or cluster SARS-CoV-2 transmission:[11]

- indoor or outdoor settings where physical distancing of at least 1 metre cannot be maintained
- if indoors, unless ventilation has been assessed to be adequate, regardless of physical distancing

- by individuals with higher risk of severe COVID-19 (for example, individuals above 60 years of age), when physical distancing of at least 1 metre cannot be maintained.

The WHO also recommends, in any scenario of possible transmission, the use of medical face masks by caregivers or those sharing living space when in the same room as people with suspected or confirmed COVID-19, regardless of presence of symptoms.[11]

Conclusion

Given the ongoing absence of robust data to inform face mask recommendations, policy-makers and individuals must balance the seriousness of COVID-19, with respect to both individual and societal risk, the uncertainty regarding the degree of source control and protective effect associated with masks, and the tolerability of potential adverse effects of mask use.

While there is currently very limited direct evidence to support the effectiveness of face masks in the community, there is an increasing amount of indirect evidence which suggests that their use may be beneficial. Data on the potential undesirable effects of face masks usage is also limited, however consideration of the potential harms associated with their use must be balanced against the harms associated with COVID-19.

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Appendices

Appendix 1: Summary of DANMASK-19 RCT (Bundgaard et al.)[19]

	DANMASK-19
Study details	Bundgaard et al. 18 Nov 2020 Trial identifier: NCT04337541
Objective	Assess whether recommendation of surgical mask use outside the home reduces wearers' risk for SARS-CoV-2
Setting	Denmark, April and May 2020. Nationwide. Masks uncommon and not among recommended public health measures.
Participants	Adults spending more than 3 hours per day outside the home without occupational mask use.
Intervention	All participants encouraged to follow social distancing. Intervention arm: Recommendation to wear mask when outside the home among other persons. Supply of 50 surgical masks and instructions for proper use.
Outcome	**Primary outcome:** SARS-CoV-2 in mask wearer at 1 month. Assessed by antibody testing, PCR, or hospital diagnosis. **Secondary outcome:** PCR positivity for other respiratory viruses.
Results	Intention-to-treat: Intervention: N=3,030; Control: N=2,994. 80.7% study completion. Primary outcome: Intervention: N=42 (1.8%); Control: N=52 (2.1%) Difference of -0.3% (95% CI, -1.2 to 0.4%, p=0.38) OR = 0.82 (95% CI 0.54 to 1.23, p=0.33) Adherence (As reported by participants): 46% wore mask as recommended; 47% predominantly as recommended; 7% not as recommended.
Limitations	- Inconclusive results - Missing data - Variable adherence - Patient-reported findings on home tests - Lack of blinding - No assessment of source control
Authors' conclusions	Recommendation to wear surgical masks did not reduce the infection rate among wearers by more than 50% in a community with modest infection rates, some degree of social distancing, and uncommon general mask use. The data were compatible with lesser degrees of self-protection.
Additional observations	- During the study period, authorities did not recommend face mask use outside hospital settings and mask use was rare in community settings. Therefore, study participants' exposure was overwhelmingly to persons not wearing masks. - Adherence to mask use may be higher than observed in this study in settings where mask use is common.

	- Some mask group participants (14%) reported adverse reactions from other citizens - No statistically significant interaction was observed between wearers and non-wearers of eyeglasses

Appendix 2: Quality assessment of reporting for Bundgaard et al.[19] randomised controlled trial; CONSORT Checklist

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	Yes
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	Yes 1
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	Yes 2-3
	2b	Specific objectives or hypotheses	Yes 2-3
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Yes 3, 4
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	
Participants	4a	Eligibility criteria for participants	Yes 3
	4b	Settings and locations where the data were collected	Yes 4
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Yes 4
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	Yes 5 (how assessed 4 and Supplement part 8 and page 6)

	6b	Any changes to trial outcomes after the trial commenced, with reasons	No but additional post-hoc analyses p. 8 reasons not given
Sample size	7a	How sample size was determined	Yes p.5
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	Yes 4 and Supplement part 7
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Yes computer algorithm 4
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Yes computer algorithm
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Computer algorithm for random allocation and assignment, enrolled via REDCap software (all p.4)
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	Unblinded
	11b	If relevant, description of the similarity of interventions	N/A
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	Yes 5 for primary and suppl p. 6 for secondary
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	Yes 5 and suppl. p.7
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Yes p.6
	13b	For each group, losses and exclusions after randomisation, together with reasons	Table 1 describes those that

			completed. Suppl. p.5 defines finalised participant. Suppl. p.86 shows table of characteristics of those not completing study. Reasons for losses not given. Exclusion criteria given suppl. p.70
Recruitment	14a	Dates defining the periods of recruitment and follow-up	Yes p.6
	14b	Why the trial ended or was stopped	N/A
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Yes p.7
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Yes p.7
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Yes pp.7-8
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Yes p.8-9 (e.g paragraph commencing ‘ In a per …’)
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	Yes, post hoc described p.8
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	Yes p.10, 11 and suppl. Table 4
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	Yes p.2 and 11
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Yes p.2 abstract and 12 end of discussion
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	Yes

Other information			
Registration	23	Registration number and name of trial registry	Yes p.1 and 3
Protocol	24	Where the full trial protocol can be accessed, if available	Yes p.3 and full protocol suppl. p.65
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Yes p.2 and 5

- PDF copy of report unavailable on Annals of Internal Medicine as of 23 November 2020. Page numbers referenced herein correspond to a Word document containing the article content, as assembled by the reviewer.
- CONSORT comprises 25 checklist items, 11 of which have sub-items 'a' and 'b'. 3 sub-items were not relevant to this RCT. All other checklist items were present as required in the study. Two sub-items were not present.
- The study was un-blinded (item 11(a)). However, the intervention was not possible to blind (face-mask wearing). Also, all participants conducted the PCR and antibody testing themselves and self-reported the results (see page 4).
- Item 13(b) asks whether 'in each group' (mask wearers/non-masks wearers) losses and exclusions, along with reasons are reported. This was partially answered (see below). Table 1 describes those that completed the study. Suppl. p.5 defines finalised participant. Suppl. p.86 shows table of characteristics of those not completing study. Reasons for losses not reported.
- Reporting was considered to be of high quality. Risk of bias concerns are described in the body of this report.

Appendix 3: Review of international guidance on face mask use in the community

Table 1: European Countries

Country EU/EEA countries	Type of face covering	Settings where face covering are required	Exemptions	Underpinning evidence
Austria[63, 121-123]	Mouth and nose protection	Must be worn: ▪ In public and in closed rooms ▪ In the workplace if the minimum distance is less than one metre ▪ Subway stations, platforms and stops, train stations and airports as well as their connecting structures ▪ In the waiting and boarding areas of cable cars, lifts and gondolas ▪ In schools, including outside of classrooms. In school lessons from the age of 10 ▪ In the workplace if the minimum distance is less than one metre	Children <7 years	Not reported
Belgium [64, 124, 125]	Mouth and nose must be covered with a face mask or fabric alternative	Compulsory: ▪ On public transport from entering the airport, the station, on the platform or a bus, metro, tram, train stop or any other means of transport organised by a public authority ▪ For supervisors of camps, training sessions and activities that are allowed ▪ Establishments and places where catering activities are permitted, both for customers and staff, unless while eating, drinking or sitting at a table ▪ In shops and shopping centres ▪ In shopping streets, at markets and in any private or public are with significant footfall, which is determined by the competent local authority and demarcated by a notice specifying the times at which the obligation applies	Children <12 years People living under the same roof People meeting each who have close contact on a regular basis Counsellors and their clients Public transport drivers if well-isolated in a cabin, and a sign indicates to users the reason why the driver is not wearing a mask	Not reported

Country EU/EEA countries	Type of face covering	Settings where face covering are required	Exemptions	Underpinning evidence
		▪ In conference rooms, auditoriums and places of worship & reflection ▪ In libraries, game and multimedia libraries ▪ In places of worship and buildings intended for the public practice of non-denominational moral services ▪ When moving around in public and non-public parts of courthouses and courtrooms and, in other cases, in accordance with the guidelines laid down by the Chairman.	Catering establishments while sitting at a tables When it is not possible to wear a face mask or any fabric alternative due to medical reasons, a face shield can be worn	
Czechia [65, 126]	Mouth and nose must be covered with face mask, respirator or scarf	Obligation: ▪ Any indoor area ▪ Any urban areas of cities, towns and villages including between buildings, shops, in squares, and everywhere where people can be met ▪ While travelling via any public transport, including bus/tram stops, train platforms and waiting rooms ▪ In workplaces ▪ In cars, if travelling with someone who is not a member of a joint household ▪ In publicly accessible places in the built-up area of a municipality, if at that place there are more than two people closer than 2m apart and they are not members of the same household. ▪ By athletes, except for athletes active on sports premises outdoors or, in the case of professional athletes, indoors.	Children <3 years; People who live in the same household People with a serious mental illness or intellectual impairment Teachers may use a protective shield instead of a face mask when it is necessary for a pupil to see teacher's mouth. In such cases, the 2m must be maintained When walking in the nature outside the city, town or village, or when alone away from other people Athletes on sports premises outdoors Professional athletes indoors	Not reported

Country EU/EEA countries	Type of face covering	Settings where face covering are required	Exemptions	Underpinning evidence
Denmark [79, 80, 127]	Face mask or visor	By law: ▪ When travelling by public transport ▪ When not seated at the table in indoor sit-down restaurants, cafés, fast food restaurants, pastry shops, bakeries etc. ▪ In all shops, for example supermarkets, grocery shops, shopping centres, department stores, bazaars, arcades, etc. to which the public has access ▪ In indoor spaces such as canteens, corridors and communal areas at universities, secondary and further education, music schools, driving schools, folk high schools, day colleges and evening schools, for example ▪ Teachers and educators in primary and secondary schools must wear a visor ▪ Indoors at museums, galleries, entertainment venues and sports facilities and fitness centres ▪ In churches or other places of worship when not seated ▪ In hospitals, clinics, doctors' office, nursing homes, etc. unless an inpatient or resident Recommended: ▪ If infected or at risk of being infected with novel coronavirus and have to leave home, for example to be tested ▪ If at higher risk of severe illness from COVID-19 and in situations where it is difficult to keep a distance of 2m, for example at a party ▪ If visiting someone at higher risk, for example a person in a nursing home when a distance of at least 2 metres cannot be maintained ▪ In large crowds, for example demonstrations or parades, where it can be difficult to keep distance	Classrooms Auditoriums When seated in restaurants, the cinema or theatre or participating in a sport or performing, in churches and places of worship Hospital inpatients, certain residents in nursing homes, homeless hostels etc. (but the local management can introduce restrictions)	Not Reported

Country EU/EEA countries	Type of face covering	Settings where face covering are required	Exemptions	Underpinning evidence
France [66]	Facemasks	Compulsory: ▪ In schools ▪ In all open shops ▪ On all public transport ▪ If social distancing cannot be maintained.	Children <6 years	Not reported
Germany [67, 81]	Facemasks/Mouth and nose covering	Compulsory: ▪ Closed rooms that are accessible to the public or where there are visitors or customers ▪ All public places in inner cities (e.g. including in front of retail shops and in parking lots) ▪ Public transport ▪ Work and production facilities, unless a distance of 1.5m to other people can be safely maintained ▪ For all persons on school premises where social distance is not observed and in lessons in secondary schools from grade 7, in regions with an incidence of more than 50 new infections per 100,000 inhabitants.		Not reported

Country EU/EEA countries	Type of face covering	Settings where face covering are required	Exemptions	Underpinning evidence
Ireland [68, 128, 129]	Face covering	Must be worn: ▪ While using public transport. ▪ In shops, including pharmacies; supermarkets; shopping centres; libraries; cinemas and cinema complexes; theatres; concert halls; bingo halls; museums; nail salons; hair salons and barbers; tattoo and piercing parlours; travel agents and tour operators; laundries and dry cleaners; betting shops and bookmakers. ▪ In restaurants and cafes (including pubs that serve food and hotel restaurants), face coverings must be worn by staff in customer facing roles where no other protective measures are in place, for example: protective screens and where physical distancing of 2 metres is not possible. They must also be worn by customers when arriving to and leaving their table. Recommended: ▪ when visiting the homes of those over 70 or who are medically vulnerable ▪ by those who are over 70 or medically vulnerable when being visited ▪ when travelling with someone not from the same household ▪ in busy or crowded outdoor areas ▪ in places of worship ▪ in crowded workplaces.	In restaurants and cafes when seated Children <13 years Anyone who has trouble breathing, who is unconscious or incapacitated or who is unable to remove a face mask without help Anyone who has special needs and who may feel upset or very uncomfortable wearing the face covering	Not reported

Country EU/EEA countries	Type of face covering	Settings where face covering are required	Exemptions	Underpinning evidence
Italy [69]	Facemask	Mandatory to wear a face mask at all times, which must be worn: ▪ in closed spaces accessible to the public ▪ in indoor spaces other than homes ▪ in all outdoor spaces. Recommended: ▪ in private homes if non-residents are visiting.	Where characteristics of the place or the actual circumstances, the condition of being isolated from non-residents is guaranteed Children <6 years People with disabilities or pathologies incompatible with use of a facemask and those who interact with the latter During any sports activity.	Not reported
Netherlands [83]	Non-medical facemask	Mandatory: ▪ in all indoor public spaces (including municipal offices, hospitals, shops, museums, petrol stations, theatres and other entertainment venues, restaurants) ▪ education institutions (except primary schools and schools for special education) ▪ contact-based professions (e.g. hair and beauty or professions involving physical contact) ▪ public transport (buses, trains, trams metros) ▪ on coaches ▪ on aircrafts ▪ if more than one passenger in a taxi ▪ in all public and covered areas, in education and for contact-based professions ▪ in some designated areas at Amsterdam Schiphol Airport.	Children <13 years Personal drivers belonging from a different household. Schools for special education. People who have a disability or health condition that makes them unable to wear a face mask (or carers of people who become extremely distressed by wearing a mask). People who are dependent on non-verbal communication.	Not reported

Country EU/EEA countries	Type of face covering	Settings where face covering are required	Exemptions	Underpinning evidence
		Advised: ▪ Travelling in a private vehicle with people you do not live with.		
Portugal [70, 130, 131]	Facemask	Mandatory: ▪ in closed public spaces, such as commercial establishments and public transport ▪ in the workplace.		Not reported
Spain [71, 132]	Facemasks	Required: ▪ On a public road or outdoor space where interpersonal distance is less than 1.5m ▪ In closed spaces where interpersonal distance is less than 1.5m ▪ On public transport	Children <6 years People with respiratory illness or difficulty People with disabilities or dependency who do not have the autonomy to remove the mask or who have behavioural disorders that make it unfeasible In a case of force majeur or situation with which face covering is incompatible	WHO[47] ECDC[133] CDC[47, 54]
Sweden[72, 134]	Facemasks	While facemasks are not recommended in public setting due to the lack of clarity in scientific evidence, there may be some situations where they are considered useful. In dialogue with the County Medical Offices, these situations will be decided upon and may include, for example, crowded public transport or opticians visits. Facemasks should be seen as		

Country EU/EEA countries	Type of face covering	Settings where face covering are required	Exemptions	Underpinning evidence
		complimentary to other recommendations (i.e. to stay at home if experiencing symptoms, to wash hands regularly and to keep a distance from others)		
UK countries				
England[135, 136]	Face covering	Must wear: ▪ On public transport (aeroplanes, trains, trams and buses), taxis and private hire vehicles, transport hubs (airports, rail and tram stations and terminals, maritime ports and terminals, bus and coach stations and terminals). ▪ In shops and supermarkets (places which offer goods or services for retail sale or hire), shopping centres (malls and indoor markets), auction houses. ▪ In premises providing hospitality (bars, pubs, restaurants, cafes), except when seated at a table to eat or drink. ▪ In post offices, banks, building societies, high-street solicitors and accountants, credit unions, short-term loan providers, savings clubs and money service businesses, estate and lettings agents. ▪ In theatres, exhibition halls and conference centres, public areas in hotels and hostels. ▪ In premises providing personal care and beauty treatments (hair salons, barbers, nail salons, massage centres, tattoo and piercing parlours). ▪ In premises providing veterinary services ▪ In visitor attractions and entertainment venues (museums, galleries, cinemas, theatres, concert halls, cultural and heritage sites, aquariums, indoor	In premises providing hospitality (bars, pubs, restaurants, cafes), when seated at a table to eat or drink	Not reported

Country EU/EEA countries	Type of face covering	Settings where face covering are required	Exemptions	Underpinning evidence
		zoos and visitor farms, bingo halls, amusement arcades, adventure activity centres, indoor sports stadiums, funfairs, theme parks, casinos, skating rinks, bowling alleys, indoor play areas including soft-play areas). ▪ In libraries and public reading rooms. ▪ In places of worship, funeral service providers (funeral homes, crematoria and burial ground chapels). ▪ In community centres, youth centres and social clubs. ▪ In storage and distribution facilities ▪ In indoor places not listed here where social distancing may be difficult and where you will come into contact with people you do not normally meet.		
Northern Ireland [73, 137]	Face coverings	Required: ▪ In certain indoor settings including shops, shopping centres, public, private and school transport services, taxis, airplanes, public transport stations and airports, banks and some government offices.		Not reported
Scotland [74, 138, 139]	Face covering	By law: ▪ In certain indoor settings including shops, shopping centres, on public transport and public transport premises such as railway and bus stations and airports, and in certain other indoor public places such as shops, restaurants/cafes including canteens (including in workplaces and when not seated), libraries and places of worship. ▪ In workplaces communal areas indoors, unless exempt. Advised:	Restaurants, cafes, canteens when seated Early learning and school settings	Not reported

Country EU/EEA countries	Type of face covering	Settings where face covering are required	Exemptions	Underpinning evidence
		▪ Other indoor places and where physical distancing is difficult and where there is a risk of being within 2m of people who are not members of own household (including, for example, when attending an appointment at any healthcare setting such as GPs' surgeries, dentists, optometrists and hospitals). ▪ In crowded situations where physical distancing is not always possible, such as at the school gate or at the entrance to a building.		
Wales [75, 140]	Face coverings	Must be worn: ▪ In all indoor public places (including public transport and taxis, and in places where food and drink is served, other than when you are seated to eat or drink). Applies to staff working in indoor public areas and to members of the public entering those public areas.	In places where food and drink is served, when seated to eat or drink Children <11 years	[141]
Non-EU/EEA or UK countries				
Switzerland [76, 82]	Masks	Mandatory: ▪ Note: Masks need not be worn in large rooms if distancing rules and restrictions on capacity apply and ventilation is assured ▪ In publicly accessible indoor spaces as well as in public transport waiting areas and railway stations and airports ▪ When queuing for and travelling on ski lifts and all other forms of transport at ski resorts ▪ In indoor and outdoor areas of establishments and businesses such as shops, zoos, theatres, cinemas, concert and event venues, restaurants, bars and markets ▪ In fitness centres	Children <12 years Persons who are unable to wear a mask for medical reasons In restaurants and bars when seated at a table	Not reported

Country EU/EEA countries	Type of face covering	Settings where face covering are required	Exemptions	Underpinning evidence
		▪ Outdoors in busy pedestrian areas of town and village centres and as soon as there is a gathering of people where it is not possible to keep the required distance (for example busy streets, squares and parks) ▪ In schools from upper secondary level ▪ In the workplace unless the distance between workspaces can be maintained (e.g. in individual offices).		

Table 2: Australia, Canada, USA

Country	Type of face covering	Settings where face coverings are required	Exemptions	Underpinning evidence
Australia [78]	Mask	May choose or be required as determined by jurisdictional public health authorities: ▪ where there is significant community transmission ▪ if physical distancing is difficult to maintain, for example on public transport ▪ for those at increased risk of severe COVID-19 themselves - because of older age or chronic illness, when physical distancing cannot be maintained.	Where there is low community transmission of COVID-19, wearing a mask in the community and when the person is well	1 academic review (2013) of international evidence and policy gaps for the use of cloth masks in infection control [142] 6 experimental studies[88, 107, 143-146] 3 clinical studies[32, 147, 148] 1 WHO document[47] 1 ECDC document [149] 1 CDC document[150] 1 Royal Society document[151]
Canada[77]	Non-medical mask or face covering	Recommended: ▪ in public and where close contact with others is likely ▪ in shared indoor spaces with people from outside immediate household ▪ when advised by local public health authority. Mandatory: ▪ in some jurisdictions, the use of masks is now mandatory in many indoor public spaces and on public transit. (Check with your local public health authority)	Children <2 years Children 2-5 years depending on their ability to tolerate it as well as put it on and take it off	WHO [152]

Country	Type of face covering	Settings where face coverings are required	Exemptions	Underpinning evidence
		▪ children 2-5 years depending on their ability to tolerate it as well as put it on and take it off ▪ children older than 5		
USA[54]	Mask	Should wear a mask: ▪ In public settings and when in contact with those who do not live in own household. ▪ When caring for someone who is sick with COVID-19 (whether at home or in a non-healthcare setting). ▪ If sick or suspected of being sick and when around other people or animals, even in own home. ▪ Outdoors in localities where mandated by local authorities.	Children <2 years In specific instances when wearing a mask may not be feasible. In these instances, consider adaptations and alternative Anyone who has trouble breathing Anyone who is unconscious, incapacitated or otherwise unable to remove the mask without assistance People with sensory, cognitive, or behavioural issues. If are unable to wear a mask properly or cannot tolerate a mask should not wear one, and adaptations and alternatives should be considered.	▪ (90, 112, 145, 153-176)

Published by the Health Information and Quality Authority (HIQA).

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