



**Health
Information
and Quality
Authority**

An tÚdarás Um Fhaisnéis
agus Cáilíocht Sláinte

Advice to the National Public Health Emergency Team (NPHE)

Wearing of face masks in the community to reduce the transmission of SARS-CoV-2

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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.

Foreword

The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is a highly infectious virus which has caused tens of millions of cases of COVID-19 since its emergence in 2019, with a considerable level of associated mortality. In the context of the ongoing COVID-19 pandemic, SARS-CoV-2 constitutes a significant public health concern due to its high basic reproduction rate, the absence of immunity in the human population, and the current lack of an effective vaccination or treatment approaches.

The National Public Health Emergency Team (NPHET) oversees and provides national direction, guidance, support and expert advice on the development and implementation of strategies to contain COVID-19 in Ireland. Since March 2020, HIQA's COVID-19 Evidence Synthesis Team has provided research evidence to support the work of NPHET and associated groups and inform the development of national public health guidance. The COVID-19 Evidence Synthesis Team which is drawn from the Health Technology Assessment Directorate in HIQA, conducts evidence synthesis incorporating the scientific literature, international public health recommendations, and existing data sources as appropriate.

From September 2020, as part of the move towards a sustainable response to the public health emergency, HIQA provides evidence based advice in response to requests from NPHET. The advice provided to NPHET is informed by research evidence developed by HIQA's COVID-19 Evidence Synthesis Team and with expert input from HIQA's COVID-19 Expert Advisory Group (EAG). Topics for consideration are outlined and prioritised by NPHET. This process helps to ensure rapid access to the best available evidence relevant to the SARS-CoV-2 outbreak to inform decision-making at each stage of the pandemic.

The purpose of this report is to outline the advice provided to NPHET by HIQA regarding the evidence available to indicate that routine wearing of face masks in the community reduces the transmission of SARS-CoV-2. It serves as a rapid evidence update to a previous HIQA evidence summary published in August 2020. The advice takes consideration of results of a scoping review of the research evidence, international recommendations and input from the COVID-19 EAG.

HIQA would like to thank its COVID-19 Evidence Synthesis Team, the members of the COVID-19 EAG and all who contributed to the preparation of this report.

A handwritten signature in black ink, appearing to read 'M. G.', is located at the bottom left of the page.

Dr Máirín Ryan

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The advice is developed by the HIQA Evidence Synthesis Team with support from the Expert Advisory Group. Not all members of the Expert Advisory Group and Evidence Synthesis Team are involved in the response to each research question. The findings set out in the advice represent the interpretation by HIQA of the available evidence and do not necessarily reflect the opinion of all members of the Expert Advisory Group.

Conflicts of Interest

None declared.

Advice to the National Public Health Advisory Team

The purpose of this evidence synthesis is to provide advice to the National Public Health Emergency Team (NPHE) on the following policy question:

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

The response to the policy question is informed by a number of previous HIQA evidence summaries and a rapid evidence update, which followed a HIQA [evidence summary](#) on the use of face masks in the community published on 21 August 2020. Input from the HIQA COVID-19 EAG was further sought and considered within this advice.

Previous HIQA evidence summaries considered

This advice considers three previous evidence summaries and advice provided to NPHE by HIQA pertinent to the transmission of SARS-CoV-2. Specifically:

- An evidence summary by HIQA on [airborne transmission](#) of SARS-CoV-2 via aerosols (published 21 August 2020). While noting the lack of conclusive evidence regarding the viability and infectivity of SARS-CoV-2 in aerosols, the review 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 that indicate such viral particles may represent live virus.

Based on the evidence available at that time, the review concluded that there was some limited, low certainty evidence that SARS-CoV-2 may transmit via aerosols. However, it was not known if this is restricted to specific contexts, such as in enclosed or poorly ventilated environments. A second evidence summary on the relative importance of [direct versus indirect droplet transmission](#) for the spread of SARS-CoV-2 (published 21 August 2020) concluded that it was uncertain what contribution aerosol transmission makes to the COVID-19 pandemic relative to other transmission modes (contact and droplet).

- An evidence summary and advice published by HIQA (18 November 2020) with respect to [settings and activities associated with higher risk of transmission](#) of SARS-CoV-2. These identified that:

- The main factors found to contribute to transmission risk include: indoor environments, crowds, and prolonged and intense contact with others. Other important factors may include the level of ventilation, speaking volume, insufficient use of face coverings, and the viral load of the index case. In particular, activities involving dining, drinking, exercising, singing or shouting, especially in indoor crowded environments, were associated with an increased risk of transmission in several studies.
- While there is consistent evidence that the risk of transmission is substantially lower in outdoor settings, clusters in outdoor environments have been observed, particularly when there are large gatherings, limited social distancing, dense congregation, and mixing among groups.
- The secondary attack rate associated with SARS-CoV-2 is high compared with other pandemic respiratory viruses such as MERS, SARS and H1N1. Given the high risk of transmission, a range of infection prevention control measures, including face masks, are necessary to reduce the spread of infection.
- To mitigate the additional risk of transmission, the required range and or intensity of public health measures may need to differ for activities and settings associated with superspreading.

Current rapid evidence update to HIQA evidence summary on use of face masks

- During the COVID-19 pandemic, the use of face masks by the general public has been recommended by an increasing number of countries, for an increasing number of activities. In Ireland, non-medical face masks are mandatory on public transport, in shops and other retail outlets, and recommended in situations where physical distancing may not be possible.
- 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 those who do not know they are infected)
 - protecting the wearer from droplet splashes or inhaling airborne contaminants including small (aerosol) and large particle droplets.
- HIQA published an evidence summary on the use of face masks in the community on the 21 August 2020, considering SARS-CoV-2 and other respiratory pathogens. The review identified four observational studies specific to SARS-CoV-2. Since its publication, a growing body of evidence has emerged

across the continuum of research design and outcomes of interest. Therefore, a rapid update to this evidence summary was undertaken to synthesise the evidence published since its completion. A scoping methodology was used that considered three elements:

1. A review of the research evidence regarding the effectiveness of face masks for preventing the transmission of SARS-CoV-2, published since the previous evidence summary.
2. An overview of additional considerations which may impact on decision-making for face mask use.
3. A review of the international public health guidance on recommendations for the use of face masks by the general public.

The key points of this rapid evidence update, which informed HIQA's advice, are as follows:

Evidence for effectiveness

- This review of the available research evidence from July 2020 onwards considers a variety of study designs, including: recent rapid reviews to inform policy, systematic reviews, recent randomised controlled trial evidence, observational studies (including ecological studies), and laboratory studies:
 - Recommendations stemming from a recently updated rapid review conducted by the Norwegian Institute of Public Health, including a comprehensive and systematically sourced evidence base, encourages the use of face masks where the incidence is high, increasing, or the spread is uncontrolled; it proposes that 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 to reduce the risk of infection for the wearer. This trial did not consider source control. Furthermore, the trial was subject to significant methodological limitations which impede both the internal and external 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 favour the use of face masks to reduce transmission of SARS-CoV-2.
 - Laboratory-based studies provide evidence of the technical ability of face masks to reduce the outward transmission of virus particles from a wearer (that being, source control) and their ability to reduce the inhalation of

infectious particles 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 SARS-CoV-2 transmission.

- 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. Also, A. 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 such data will become available.

Additional considerations

- A number of additional considerations were outlined which may impact on overall decision-making relating to the use of face masks in the community in the context of the COVID-19 pandemic:
 - Adherence to wearing of face masks: recent public opinion surveys in Ireland appear to indicate a high level of adherence to current recommendations for face mask use by the general population. Evidence appears scarce regarding the extent to which face masks are used correctly. The understanding of socio-behavioural factors was noted as important to understanding and motivating public adherence.
 - Types of face masks: medical grade masks are not currently recommended in Ireland for use by the general public. Notably, there is evidence that face shields or visors are less effective than medical or cloth masks in reducing transmission of SARS-CoV-2. This evidence has been highlighted in recent guidance from the Health Protection Surveillance Centre (HPSC). Also, the National Standards Authority of Ireland has set out minimum requirements for non-medical masks for use by the general public.
 - Potential undesirable effects of face mask use: This scoping review did not note any evidence of significant harm with face mask use. No consistent evidence was found that face mask use leads to a false sense of security or reduced adherence to other public health measures. There are reports in the literature of discomfort and skin irritation related to face mask use, however.

- Face masks as a protective measure for vulnerable groups: the World Health Organization (WHO) recommends the use of medical masks for those groups at higher risk of becoming seriously ill with COVID-19, specifically, those who are over 60 years of age and for people of any age with underlying health conditions, including: chronic respiratory disease, cardiovascular disease, cancer, obesity, immunocompromised patients and diabetes mellitus.

International public health recommendations

- The international review of current public health guidance included 20 countries, 17 of which were within Europe. A summary of the key aspects of this scoping exercise are outlined below:
 - The guidance outlined varies from country to country, but all countries (with the exception of Sweden) recommend the widespread use of face masks in one or more settings. Sweden does not currently recommend face masks in public settings on the basis that the scientific evidence around the effectiveness of face masks is considered to be unclear.
 - The majority of countries specifically refer to the use of face masks on public transport, and in educational settings.
 - All countries providing recommendations on mask use refer to indoor and enclosed spaces or rooms. The detail provided ranges 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 are specifically 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 whilst eating, drinking or sitting at a table.
 - Several countries refer specifically to the use of face masks in outdoor settings, with some noting that this applies where physical distance cannot be maintained. Scenarios include in busy public areas such as streets, parks and squares, or in outdoor gatherings such as parades, or at a school gate, alongside at camps or trainings sessions. Italy currently recommends the use of face masks in all outdoor settings.
 - Several countries identify groups of individuals that are exempt from obligations in relation to face mask use. Children are exempt in many countries; however, the age at which the exemption applies varies

substantially (ranging from those aged less than two years to those aged less than 13 years).

- The majority of countries included do not cite or report in their guidance documents the literature evidence that was used to underpin their recommendations on face mask use. However, it should be considered that the format of many of these guidance documents is that of concise summaries, often one to two-page documents that lay out the key recommendations and which are intended for a lay audience. Therefore, it should be noted that whilst underpinning evidence is often not cited within the text, this does not mean that the evidence does not exist or that it wasn't used to inform the recommendations made.

COVID-19 Expert Advisory Group

- A meeting of the HIQA COVID-19 EAG was convened for clinical and technical interpretation of the evidence provided.
- The EAG found collective consensus that the evidence base supports the ongoing use of face masks by the general public as a measure aimed at reducing the transmission of SARS-CoV-2 in the community.
- The COVID-19 EAG identified additional factors which should be considered to inform both this policy question and potential further research and policy questions. These included:
 - Concerns raised regarding how the results of the DANMASK-19 randomised controlled trial (RCT) have been communicated in the general and scientific media to date. It was acknowledged that the trial results contribute to the overall evidence base surrounding face mask usage. However, communication of the specific outcome assessed within the trial is key (that being, infection of the wearer, under circumstances of low usage of face masks in the community), in order to highlight that the trial results do not address the question of whether face mask recommendations reduce community transmission overall. There were further concerns that if the caveats of this trial are not adequately communicated it may be detrimental to public understanding of the evidence base underpinning face mask usage recommendations.
 - 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 likely 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 study designs, international standards, and expert opinion. There is consistent evidence from epidemiological (including observational studies and community level analyses) and laboratory studies to support the theory that face mask use reduces SARS-CoV-2 transmission.

- On the basis of the available evidence, there may be rationale to extend the advice on use of face masks to all scenarios in which physical distancing cannot be maintained; this may include both indoor and outdoor settings (particularly crowded outdoor areas). However, it was noted that any recommendation should probably be advisory rather than mandated, and be accompanied by clear communication.
- Respiratory droplets are considered to be the primary mode of transmission of SARS-CoV-2 within the COVID-19 pandemic. However, there is a growing level of agreement amongst international bodies that aerosol transmission of SARS-CoV-2 can occur in certain scenarios (such as in high occupancy, poorly ventilated environments). This aspect should be communicated to the public and the scenarios in which such transmission is at greater risk of occurring should be clearly outlined.
- Face masks provide greater protection than visors or face shields in terms of inward (to the wearer) and outward (from the wearer) transmission. Therefore, face masks should be strongly advised over visors, as per recent HPSC guidance, except in limited circumstances.
- Comprehensive product safety guidance for COVID-19 consumer face masks has been published by the Competition and Consumer Protection Commission (www.ccpc.ie)
- The potential for face masks to cause undesirable effects was discussed (for example, psychological effects and difficulties for communication in educational settings). Though very limited evidence of harm was identified in the present review, it was highlighted that more research is required in this area so as to understand and address these concerns.
- The high level of buy-in from citizens with respect to public health recommendations was acknowledged. However, anxiety and resistance to particular measures were also noted.
- There is currently a lack of qualitative research regarding the experience of face mask wearing for the user, and factors associated with adherence and compliance to face mask recommendations. A greater understanding of such factors would be informative.

- Both intermittent use, and incorrect wearing of face masks by the general public, appear to be prevalent. A communication campaign, encouraging the consistent and appropriate use of face masks, was recommended.
- The age of recommended mask wearing in children was highlighted as needing clear and consistent messaging, alongside the rationale for the age bands used. It was acknowledged that age cut-offs differ across countries, and this may give rise to confusion.
- The WHO recommend the use of medical masks for those who are over 60 years of age and for those who are medically vulnerable. It was noted that the adoption of such a recommendation locally would require consideration of the availability of medical masks for healthcare workers and the potential environmental impact of widespread use of disposable face masks.
- Clear messaging with the public is required to accompany recommendations regarding mask use. This messaging should aim to empower people, and emphasise control and personal contribution to the overall pandemic. The Irish public have shown high acceptance of recommendations to date, and the collective efforts of the public to control the pandemic should be greatly commended. It is crucial to maintain the ongoing support of the general public.

Advice

Arising from the findings above, HIQA's advice to the National Public Health Emergency Team is as follows:

- Collectively, the evidence within this rapid evidence update regarding face mask use in the community points towards a:
 - beneficial effect in reducing SARS-CoV-2 transmission
 - lack of evidence of significant harm associated with face mask use.
- Recommendations regarding the use of face masks by the general public in Ireland are largely in line with international public health guidance; however, some countries have further recommended face mask use in outdoor settings, primarily in busy public areas where physical distance cannot be adequately maintained.
- To mitigate the increased risk of transmission, consideration should be given to extending recommendations for face mask use to crowded settings or where physical distancing cannot be maintained; this applies to both indoor and outdoor settings.
- Consideration should be given to exploration of factors affecting appropriate face mask use. Data regarding adherence, extent of appropriate usage, motivating factors and barriers to use, would enable targeted strategies to enhance adherence to recommendations.
- Recommendations regarding the use of face masks by the general public should be accompanied by clear and consistent messaging. The aim of this messaging should be to empower members of the public and support them to make decisions to protect themselves and others, particularly in settings and activities associated with higher risk of transmission.
- Communication campaigns in relation to face mask usage should focus on the following aspects:
 - with respect to children, clarification of the age from which face mask usage is required
 - characteristics of the settings and activities with high levels of SARS-CoV-2 transmission
 - concept of the continuum of risk, that is, that there is currently always some level of risk of SARS-CoV-2 transmission, and that this

risk is greater in certain settings and circumstances, and for certain individuals

- the possibility of aerosol transmission in certain scenarios, including high risk settings
- the potential to mitigate risk through use of face masks, in addition to other public health measures, in settings where there is higher risk of transmission
- importance of adherence to good practice guidelines in terms of appropriate levels of face coverage as well as mask selection, hygiene and disposal.

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