



**Health
Information
and Quality
Authority**

An tÚdarás Um Fhaisnéis
agus Cáilíocht Sláinte

Protocol

Use of respirator masks by persons who are at higher risk from COVID-19

Published: 21 December 2021

Purpose and aim

The purpose of this protocol is to outline the process by which the Health Technology Assessment (HTA) directorate in the Health Information and Quality Authority (HIQA) will identify and present information as part of a facilitated discussion involving HIQA's COVID-19 Expert Advisory Group (EAG), on a topic relating to the public health response to COVID-19. This facilitated discussion will inform advice provided to the National Public Health Emergency Team (NPHET) in their response to the COVID-19 pandemic.

The following policy question was outlined by NPHET:

"Should there be a recommendation for persons who are classed as at higher risk from COVID-19 ('high risk' or 'very high risk', according to HSE classification) to wear respirator masks (FFP2 or equivalent, or respirator masks with higher filtration efficacy), with the goal of their personal protection?"

Background

Respirators, or 'filtering facepiece respirators' (FFR) (for example, 'FFP2', or 'N95' masks) are single-use, disposable respiratory protective medical devices intended primarily for use in healthcare settings or certain clinical scenarios. They are personal protective equipment which filters at least 95 percent of airborne particles,⁽¹⁾ and are designed to tightly fit the face and reduce exposure of the wearer's airway to airborne contaminants such as particles, gases or vapours.⁽²⁾

Interim guidance on infection prevention and control for the Health Service Executive (HSE)⁽²⁾ states that sound scientific principles support the use of fit-tested and fit-checked FFP2 respirators to prevent airborne transmission of pathogens when:

- there is a high probability of airborne transmission due to the infectious microorganism
- performing procedures on infectious people (for example, bronchoscopy on a patient with suspected or confirmed infection).

In the context of COVID-19, the HSE recommends that healthcare workers should have access to a well-fitted respirator mask (FFP2) and eye protection when in contact with possible or confirmed COVID-19 cases and COVID-19 contacts.⁽³⁾

As of 11 November 2021, no recommendation is in place for any member of the public to wear respirator masks outside of the healthcare setting. From February 2021, NPHET recommended that medical grade face masks should be worn by

vulnerable, high-risk, and very high-risk cohorts, and older age groups when in crowded outdoor spaces or confined indoor community spaces.⁽⁴⁾

Approach to addressing question – facilitated discussion format

A facilitated discussion was considered the most appropriate format for informing the generation of advice for this policy question. This is due to the following factors:

- the importance of considering a range of topics (for example, acceptability and feasibility) relevant to decision-making
- acknowledgement of the limited research evidence available to inform a number of the relevant topics
- the context of a limited timeframe in which to provide advice to NPHE.

Conduct of facilitated discussion

A standardised approach to conduct facilitated discussions has been developed by HIQA and is documented to allow for transparency and to aid in project management:

1. drawing up a list of topics for consideration
2. identification of external experts to provide presentations on specific topics
3. identification by HIQA of literature evidence relevant to the topics for consideration
4. presentations to the EAG of evidence and national and international practice relevant to the topics for consideration, and discussion to clarify any questions that arise in relation to the material presented
5. facilitated discussion among members of the EAG in relation to the topics for consideration relevant to the policy question
6. drafting of advice and submission of advice to NPHE.

1. Drawing up a list of topics to be considered within a facilitated discussion

In order to structure the facilitated discussion, a list of topics of importance to the policy question was drawn up, as follows:

1. The current and projected burden of SARS-CoV-2 within the community setting
2. Anticipated risks associated with the emergence of new variants
3. The degree to which individuals who are at higher risk from COVID-19 are currently protected by vaccination, including 'booster' or additional vaccine doses

4. Contextual factors which may alter the current level of risk (for example, behaviours within the current context)
5. The effectiveness and safety of respirator masks versus medical masks
6. Barriers and enablers to the use of respirator masks within this population:
 - a. Feasibility of use, in terms of fit, acceptability, and tolerability
 - b. Availability and equity of access, and guidelines around use and re-use
7. Examples of international recommendations regarding the use of respirator masks by the general population.

2. Identification of external experts to provide presentations on specific topics

Due to the range of topics for consideration, the importance of local data, and the need for external expertise, a number of external experts will be requested to provide presentations on the Irish experience with respect to these specific topics. These topics include:

- The current and projected burden of SARS-CoV-2 within the community setting
- Anticipated risks associated with the emergence of new variants
- The degree to which individuals who are at higher risk from COVID-19 are currently protected by vaccination, including 'booster' or additional doses.

3. Identification by HIQA of literature evidence relevant to the topics for consideration

For topics where the evidence base will primarily be presented by HIQA, (for example, with respect to evidence regarding the effectiveness and safety of respirator masks), a pragmatic approach to searching the literature will be adopted.

This approach will draw on [previous evidence reviews performed by HIQA](#) on the effectiveness of face mask use as well as previous facilitated discussions performed by HIQA in relation to the use of face masks by children, and will aim to identify guidance and literature published primarily in the context of the COVID-19 pandemic. Evidence specific to respirator use (versus other mask types) will be prioritised. Where literature has not undergone peer review (preprint studies), this will be noted, and caveats associated with study design will be outlined in the presentation.

The following points are additionally noted for the general conduct of identification of published information by HIQA for presentation as part of a facilitated discussion:

- Evidence will be sourced from a range of sources, involving date-limited searches of Google Scholar, PubMed, preprint servers such as PubMed Central, Google (in order to capture recent grey literature) and COVID-19

research databases as appropriate. Forms of evidence may include, but are not limited to, the following:

- evidence reviews (systematic reviews or reviews, particularly those performed by health policy organisations such as the World Health Organization) which consider the effectiveness, safety, barriers to and/or enablers of the use of respirator masks in the context of COVID-19 prevention
- relevant and methodologically robust interventional and observational studies, particularly those performed within the population under consideration, which examine the effectiveness, safety, barriers to and/or enablers of the use of respirator masks in the context of COVID-19 prevention
- methodologically robust quantitative or qualitative studies of the feasibility, acceptability and tolerability of respirator mask use (for example, surveys of mask-wearing experience), particularly those in which the population under consideration provide their experience of using respirator masks
- policy documents from authorities or position statements from stakeholders (for example, representative groups for the population under consideration) describing barriers and enablers to the use of respirator masks by the population under consideration.

Conduct of review of international recommendations regarding the use of respirator masks by the general population

A review of international recommendations in place will be performed for a selection of countries, which are listed in Appendix A. The list of countries to be reviewed will include all countries included in HIQA's previous international reviews of public health measures and strategies to limit the spread of COVID-19; the protocol informing this work is available [here](#). These predominantly comprise European countries (including EU/EEA and UK countries). Singapore, Hong Kong, Taiwan, Japan, the US Centers for Disease Control and Prevention (CDC), the European Centre for Disease Control and Prevention (ECDC), and the World Health Organization (WHO) will also be examined. The countries and regions of Singapore, Hong Kong, Taiwan, Japan and Singapore will be included as it is anticipated that such countries and regions may provide recommendations on the use of respirator masks, and represent locations relatively comparable to European countries with respect to health system composition. As per the approach used in HIQA's previous international reviews of public health measures and strategies to limit the spread of

COVID-19, countries where decision-making on public health measures has been broadly devolved to individual states, regions, or provinces (such as in Australia, Canada, China, and the US) will not be included, though national guidance for the US will be captured through review of the US CDC recommendations.

The review will extract relevant information as per the data extraction table depicted in Appendix B.

4. Presentations to the EAG of information relevant to the topics for consideration, and facilitated discussion among members of the EAG

Presentation material will be circulated to members of the EAG in advance of the facilitated discussion to be held on 15 November in order to allow for preparation and background reading as appropriate. Following the delivery of presentations on each of the relevant topics, a question and answer session will be held to allow clarification on any of the information presented.

5. Facilitated discussion among members of the EAG in relation to the topics for consideration relevant to the policy question

The facilitated discussion among the members of the EAG will be moderated by a Deputy Director of the HTA directorate within HIQA. The discussion will be conducted to obtain expert interpretation of the available evidence and the broader context in which the policy question is being considered. Points of discussion will be noted in order to inform the drafting of advice.

6. Drafting of advice and submission of advice to NPHET

A summary of the content of the presentations will be developed and forwarded to the presenters for a factual accuracy check. Points raised by members of the EAG during the facilitated discussion will be noted and summarised. Following the EAG meeting, HIQA HTA team members will draft advice informed by the presentations and the facilitated discussion. The advice report comprising the summary of the material considered, the feedback from the EAG and the advice will be submitted to NPHET.

Review and update

Given the rapidly changing environment, this protocol may be regarded as a live document and amended when required to ensure it reflects any changes made to the outlined processes.

References

1. US Food and Drug Administration. Face Masks, Barrier Face Coverings, Surgical Masks, and Respirators for COVID-19 2021 [updated 15 September 2021. Available from: <https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/face-masks-barrier-face-coverings-surgical-masks-and-respirators-covid-19>.
2. Health Service Executive. HPSC Interim Guidance on Infection Prevention and Control for the Health Service Executive 2021 v1.3 2021 [updated 11 Jan 2021. Available from: <https://www.hpsc.ie/a-z/microbiologyantimicrobialresistance/infectioncontrolandhai/guidelines/Interim%20HSE%20Guidance%20on%20IPC.pdf>.
3. Health Protection Surveillance Centre. Current recommendations for the use of Personal Protective Equipment (PPE) for Possible or Confirmed COVID-19 in a pandemic setting v2.4 [updated 06.07.2021 Available from: <https://www.hpsc.ie/a-z/respiratory/coronavirus/novelcoronavirus/guidance/infectionpreventionandcontrolguidance/ppe/Current%20recommendations%20for%20the%20use%20of%20PPE.pdf>.
4. Department of Health. NPHET COVID-19 Meeting Minutes - 25 February 2021 2021 [Available from: <https://assets.gov.ie/129786/3cc1fa5e-b3f6-4075-815f-b8e09757963a.pdf>.

Appendix A: List of countries and associated resources searched

EU/EEA countries

- Austria
 - <https://www.sozialministerium.at/en.html>
 - <https://metropole.at/coronavirus-updates-in-english/>
- Belgium
 - <https://www.info-coronavirus.be/en/faq/>
 - <https://www.info-coronavirus.be/en/covid/>
 - <https://www.info-coronavirus.be/en/>
- Czech Republic
 - <https://www.vlada.cz/en/media-centrum/aktualne/measures-adopted-by-the-czech-government-against-coronavirus-180545/>
- Denmark
 - <https://coronasmitte.dk/en>
 - <https://coronasmitte.dk/en/rules-and-regulations>
 - <https://coronasmitte.dk/en/overview>
- Finland
 - <https://stm.fi/en/frontpage>
 - <https://thl.fi/en/web/thlfi-en>
- France
 - <https://www.gouvernement.fr/info-coronavirus>
- Germany
 - <https://www.bundesregierung.de/breg-en>
- Greece
 - <https://www.moh.gov.gr/>
 - <https://eody.gov.gr/en/category/covid-19-en/>
- Hungary
 - <https://www.nnk.gov.hu/index.php/jarvanyugyi-es-infekciokontroll-foosztaly/lakossagi-tajekoztatok/koronavirus>
- Ireland
 - <https://www.gov.ie/en/>
 - <https://www.gov.ie/en/publication/e5175-resilience-and-recovery-2020-2021-plan-for-living-with-covid-19/>
 - <https://www.gov.ie/en/campaigns/resilience-recovery-2020-2021-plan-for-living-with-covid-19/>
- Italy

- o <http://www.salute.gov.it/portale/nuovocoronavirus/dettaglioFaqNuovoCoronavirus.jsp?lingua=english&id=230#11>
- Malta
 - o <https://deputyprimeminister.gov.mt/en/health-promotion/covid-19/Pages/landing-page.aspx>
- Netherlands
 - o <https://www.government.nl/topics/coronavirus-covid-19>
- Norway
 - o <https://stm.fi/en/frontpage>
 - o <https://www.fhi.no/sv/smittsomme-sykdommer/corona/>
- Poland
 - o <https://www.gov.pl/web/coronavirus>
- Portugal
 - o <https://covid19estamoson.gov.pt/>
 - o <https://www.visitportugal.com/en/node/421175>
- Slovakia
 - o <https://www.health.gov.sk/Clanky?tlacove-spravy>
- Spain
 - o <https://english.elpais.com/news/society/>
 - o <https://www.lamoncloa.gob.es/lang/en/Paginas/index.aspx>
 - o <http://www.exteriores.gob.es/Portal/es/Paginas/inicio.aspx>
- Sweden
 - o <https://www.government.se/government-policy/the-governments-work-in-response-to-the-virus-responsible-for-covid-19/>
 - o <https://www.folkhalsomyndigheten.se/smittskydd-beredskap/utbrott/aktuella-utbrott/covid-19/>
 - o <https://www.krisinformation.se/>

Non-EU/EEA and UK countries

- England
 - o <https://www.gov.uk/coronavirus>
 - o <https://www.gov.uk/guidance/new-national-restrictions-from-5-november>
 - o <https://www.gov.uk/government/publications/coronavirus-outbreak-faqs-what-you-can-and-cant-do/coronavirus-outbreak-faqs-what-you-can-and-cant-do>
- Northern Ireland
 - o <https://www.nidirect.gov.uk/campaigns/coronavirus-covid-19>
 - o <https://www.nidirect.gov.uk/articles/coronavirus-covid-19-regulations-guidance-what-restrictions-mean-you>

- Scotland
 - <https://www.gov.scot/>
 - <https://www.gov.scot/coronavirus-covid-19/>
 - <https://www.gov.scot/collections/coronavirus-covid-19-guidance/>
- Wales
 - <https://gov.wales/coronavirus>
 - <https://gov.wales/coronavirus-firebreak-frequently-asked-questions>
- Hong Kong
 - <https://www.chp.gov.hk/en/healthtopics/content/24/102466.html>
- Israel
 - <https://www.gov.il/en/Departments/Guides/ramzor-cites-guidelines?chapterIndex=1>
- Japan
 - <https://www.mhlw.go.jp/stf/covid-19/mask.html>
- Switzerland
 - https://www.bag.admin.ch/bag/en/home/das-bag/aktuell/medienmitteilungen.html?dyn_startDate=01.01.2016
- Taiwan
 - <https://www.cdc.gov.tw/En/Bulletin/Detail/8OPsSOdaLyYs5xknjevufw?typeid=158>

Appendix B: Data extraction table for review of international recommendations

Table 1: Data extraction table for review of international recommendations

Country Endorsing authority	Recommendations for high risk individuals and the general public regarding the use of respirator masks	Previous advice	Information on use and reuse of mask	Type of face mask		Considerations relating to VoCs	Supports available to enable mask use	Evidence base
				Adult	Child			

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

For further information please contact:

Health Information and Quality Authority

George's Court

George's Lane

Smithfield

Dublin 7

D07 E98Y

+353 (0)1 8147400

info@hiqa.ie

www.hiqa.ie

© Health Information and Quality Authority 2021