



**Health
Information
and Quality
Authority**

An tÚdarás Um Fhaisnéis
agus Cáilíocht Sláinte

Advice to the National Public Health Emergency Team

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

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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, Equality, Disability, Integration and Youth, 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

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is a highly infectious virus which has caused hundreds of millions of COVID-19 cases since its emergence in 2019, with a considerable level of associated morbidity and mortality. Despite high uptake of the COVID-19 vaccine in Ireland, and the roll-out of booster vaccination to certain populations, SARS-CoV-2 remains a significant public health concern due to its high basic reproduction rate, the limited evidence of effective treatments, the waning of vaccine effectiveness over time, the risk of reinfection in those recovered from COVID-19, and emerging variants of concern.

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.

Since September 2020, 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 policy question: "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". This advice reflects the findings of a facilitated discussion with the HIQA COVID-19 EAG considering key issues regarding this policy question.

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 'Máirín Ryan'.

Dr Máirín Ryan

Deputy CEO & Director of Health Technology Assessment

Health Information and Quality Authority

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- Prof Philip Nolan, Chair of Irish Epidemiological Modelling Advisory Group (IEMAG)
- Dr Joan O'Donnell, Specialist in Public Health Medicine, Health Protection Surveillance Centre (HPSC)
- Dr Pete Lunn, Associate Research Professor and Research Area Coordinator for the Behavioural Economics area, Economic and Social Research Institute (ESRI)
- COVID-19 Data Briefing team, Department of Health
- Product Safety Division, Competition and Consumer Protection Commission
- Engineering and Market Surveillance Unit, Health and Safety Authority
- Sourcing and QA Team, National PPE Procurement Team, HSE.

Membership of the Expert Advisory Group involves review of evidence synthesis documents and contribution to a discussion which informs the advice from HIQA to NPHET. It does not necessarily imply agreement with all aspects of the evidence synthesis or the subsequent advice.

The membership of the EAG was as follows:

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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

Background

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

"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?"

At the request of NPHET, the COVID-19 EAG was convened to discuss this policy question on 15 November 2021. A number of presentations were delivered to provide information and to summarise the evidence with respect to key issues relating to this policy question, including:

- description of the relevant population and the proposed intervention
- the current and projected burden of SARS-CoV-2 within the community setting
- anticipated risks associated with the emergence of new variants
- current morbidity and mortality due to COVID-19 within the population at higher risk from COVID-19
- vaccine effectiveness within the population at higher risk from COVID-19
- effectiveness and safety of respirator masks
- barriers and enablers to the use of respirator masks within this population
- examples of international recommendations regarding the use of respirator masks by the general population.

The approach to gathering information for these presentations, and the conduct of the facilitated discussion that followed, is outlined in a separate protocol document, which may be accessed [here](#).

Key points from presentations

Description of the relevant population and the proposed intervention

- A summary description of the target population relevant to the policy question was provided. The [HSE classification](#) of those considered at higher risk ('high risk' and 'very high risk') from COVID-19 was detailed. Individuals with certain medical conditions that are considered to place them at 'high' or 'very high' risk are identified in this classification. Additionally, all individuals aged 60-69

are classed as 'high risk' and those aged 70 years or above are classed as 'very high risk'.

- There are no national data available for the number of people that meet the classification for being at high or very high risk. However, data are available from the HSE on the number of people who have been fully vaccinated within each risk cohort; given the high proportion (>90%) of the eligible population fully vaccinated, these data approximate the number of people within these risk categories. Based on data provided to HIQA via the Department of Health, the following were fully vaccinated as of 10 November 2021:
 - age 70+: 526,508 people
 - age 60-69: 479,578 people
 - age 12-59, and 'high risk', 'very high risk', or 'immunocompromised': 142,983 people.
- A brief overview of respirator masks ('filtering facepiece respirators') was provided with visual depictions of different mask types. FFP2, N95 and KN95 masks represent examples of respirators which are designed to achieve a filter performance of $\geq 94-95\%$ and are in accordance with regulatory standards in place in the EU, the US, and China, respectively, while FFP3, N99, and KN99 masks are designed to achieve a filter performance of $\geq 99\%$. While requirements for filter performance may be relatively comparable across mask types such as FFP2 and N95, they cannot be considered to be interchangeable.
- Respirator masks, in contrast with medical masks (or 'surgical masks')¹, fall under specific EU and Irish regulations for the use of personal protective equipment, and the relevant competent authorities for surveillance are the Health and Safety Authority (occupational settings) and the Competition and Consumer Protection Commission (consumer settings).
- Respirator masks are available under different brands and in various shapes and sizes. As a tight seal is essential for effectiveness, healthcare workers typically sample more than one brand of mask in order to determine an optimal fit. Design components include use of ear loops versus head straps, which may influence fit. Masks also vary in terms of the presence of exhalation valves; such valves may improve breathing comfort, but are not suitable for source control of virus exhalation.
- A summary of current face covering and face mask guidance in Ireland was provided. Department of Health and HSE guidance for use of face masks in the community to date has largely focused around the use of cloth face

¹ The terms 'medical mask' and 'surgical mask' are used interchangeably within this document to refer to a mask primarily intended for medical purposes that covers the user's nose and mouth and provides a physical barrier to fluids and particulate materials.

coverings with the intention of source control. In March 2021, guidance was issued relating to medical mask use by persons at higher risk from COVID-19; such masks are recommended to be worn by vulnerable, high-risk, and very high-risk cohorts, when in crowded outdoor spaces or confined indoor community spaces. Currently available guidance documents, including posters and HSE website guidance, describe the correct type of face covering to use, the appropriate fit, and explain how to remove and dispose of single-use masks.

- Guidance documents made available for healthcare workers ([issued by the Health Protection Surveillance Centre](#)), focus on the type of mask to use and note that healthcare workers should have access to a well-fitted respirator mask (FFP2) when in contact with possible or confirmed COVID-19 cases and COVID-19 contacts.

The current and projected burden of SARS-CoV-2

The **Irish Epidemiological Modelling Advisory Group (IEMAG)** presented recent data:

- Daily count data from Ireland and 7-day rolling average case numbers were presented for the burden of cases of SARS-CoV-2 within the community setting (excluding data from long-term residential care facilities and hospital outbreaks).
- Based on incidence data to 15 November 2021:
 - The most recent 7-day average number of cases was 3,962.
 - Case numbers have risen rapidly in the preceding six weeks.
 - Incidence has risen particularly rapidly in the 19-24 year age-group, increasing almost threefold over the last two weeks, along with an increase across all adult age-groups up to 75 years of age. The only age group in which incidence was declining is those aged 80 and over; this decline was attributed to the impact of recent booster vaccination.
- Considering hospital admission data:
 - There was a decrease in the rate of case hospitalisation from February 2021 to November 2021 in all age-groups.
 - The rate of admissions fell from approximately 50 admissions per 1,000 cases in January 2021 to approximately 20-30 admissions per 1,000 cases in August-September 2021. However, the overall number of admissions has increased in recent weeks in line with the increase in the incidence of SARS-CoV-2 infection.
 - The hospital data suggest vaccination-conferred protection against severe outcomes has been relatively well preserved, despite waning

protection against overall infection (as evident by increasing incidence).

- Susceptible-Exposed-Infectious-Removed (SEIR) prediction models were presented illustrating various scenarios for the burden of cases through Q4 2021 – Q1 2022. It was noted that the future trajectory is very uncertain and will be influenced by factors such as the extent of infection-induced immunity within the population (currently unknown) and the waning of vaccine-induced immunity, along with the ongoing roll-out of booster and additional dose vaccination campaigns. However, the current growth rate in cases is in the order of 3-5% per day and may be explained by increased adult social contact and decreased levels of mitigation. These conditions suggest a sharp rise in cases will occur which may peak in December 2021. The associated high risk of exposure to the virus is likely to result in a large number of hospital admissions and thus pressure on hospital (and ICU) capacity.

Anticipated risks associated with emergence of new variants

- Data from the **National Virus Reference Laboratory** were presented. The Delta variant (B.1.617.2) has been dominant in Ireland since July/August 2021. An increasing number of cases of the AY4.2 (“Delta plus”) sublineage have been identified, though incidence is presently low (between 1% and 2% of cases).
- Considering data emerging from the UK, the [UK Health Security Agency Technical Briefing 28](#) provides information on the current status of the AY4.2 sublineage.
 - the Delta sublineage AY4.2 accounted for approximately 15% of all cases in England as of 6 November 2021.
 - the [most recent UK Health Security Agency risk assessment](#) for the AY4.2 sublineage noted that there is a small increase in the secondary attack rate and in the household transmission risk associated with AY4.2 versus Delta. Early data show no evidence of increased disease severity (hospitalisation and deaths).
 - vaccine effectiveness analysis does not suggest a significant relative reduction in vaccine effectiveness for AY.4.2 compared to other circulating Delta sublineages in England. Data on the AY4.2 sublineage are provisional and further assessment is ongoing.

The degree to which individuals who are at higher risk from COVID-19 are currently protected by vaccination, including 'booster' or additional vaccine doses

The **Health Protection Surveillance Centre (HPSC)** presented recent data including trends in the extent of morbidity and mortality due to COVID-19 among those who are at higher risk from COVID-19.

- The number of deaths occurring in those with COVID-19 has increased in September, October, and November 2021. The majority of these deaths have occurred in the older population. The majority of the deaths in younger age groups during this time period have occurred among those who were unvaccinated.
- Overall, the percentage of hospitalisations among COVID-19 cases fell at the end of wave 3 and during the early part of wave 4, but has been steadily increasing since mid-to late-August 2021. ICU admissions have also been increasing since August 2021.
- Among those admitted to ICU with COVID-19, the most commonly reported underlying conditions are hypertension, chronic heart disease, chronic respiratory disease, diabetes mellitus, medical conditions and treatments resulting in immunodeficiency, chronic kidney disease, and cancer.
- The proportion of cases with underlying conditions admitted to ICU has differed between different waves of the pandemic (wave 1, 88%; wave 2, 92%; wave 3, 90%; wave 4, 81% - date to 6 November 2021). The difference in wave 4 may relate to differences in the age profile of those admitted to ICU during this wave; the age profile of the patients admitted to ICU with COVID-19 was younger, hence their having fewer underlying conditions.
- The biggest risk factors for death among those admitted to ICU are older age and male sex.
- Among all reported COVID-19 deaths, 86% had documented underlying medical conditions.

A presentation was given, by a representative of the **National Immunisation Advisory Committee (NIAC)**, summarising evidence recently considered by NIAC on the effectiveness of COVID-19 vaccination, including booster vaccination, particularly among those who are at higher risk from COVID-19.

- Data were presented for all of the COVID-19 vaccines administered in Ireland, showing the high vaccine efficacy against symptomatic infection and hospitalisation as demonstrated initially in clinical trials: [BNT162b2 \(Comirnaty/Pfizer-BioNTech\)](#); [mRNA-1273 \(Spikevax/Moderna\)](#); [ChadOx1](#)

([Vaxzevria/Astra-Zeneca](#)); [Ad26.Cov2.s\(COVID-19 Vaccine Janssen/Johnson and Johnson\)](#)). Data were also presented from a [recent \(4 November 2021\) publication](#) demonstrating the safety and efficacy of the BNT162b2 vaccine (Pfizer–BioNTech) at six months post-vaccination.

- The 'real-world' vaccine effectiveness against symptomatic infection has been confirmed in the short term in observational studies (for example, by [Andrews et al.](#)), with high levels of vaccine effectiveness against severe disease and hospitalisation sustained for at least six months, including in the context of the Delta variant.
- Studies are, however, consistent in identifying greater and more durable vaccine effectiveness against severe disease, hospitalisation and mortality than against infection and symptomatic disease. Vaccine effectiveness against infection and symptomatic disease, although high in the short term, wanes over time (see, for example, [Tartof et al.](#))
- Overall, lower levels of protection are achieved with the adenoviral vector vaccines (that is, ChadOx1 (Vaxzevria/Astra-Zeneca) and Ad26.Cov2.s (COVID-19 Vaccine Janssen/Johnson and Johnson)).
- There is a slight reduction in vaccine effectiveness against infection with the Delta variant versus the Alpha variant (B.1.1.7). (See, for example, [Andrews et al.](#)). US data have shown a reduction in effectiveness against hospitalisation over time, which may be contributed to by the rise of the Delta variant. [Havers et al.](#) (preprint study of adult population) found that across all age groups, cumulative hospitalisation rates were 17 times higher in unvaccinated than in vaccinated persons, but that the difference in hospitalisation rates was smaller (≥ 10 times higher) during the period when the Delta variant became dominant.
- UK studies by [Pouwels et al.](#) and [Andrews et al.](#) were presented which also showed that vaccine effectiveness is reduced over time and particularly among those who are older and clinically extremely vulnerable. For the ChAdOx1-S (Vaxzevria, AstraZeneca) and Pfizer-BioNTech (BNT162b2/Comirnaty®) vaccines, [Andrews et al.](#) reported that vaccine effectiveness against symptomatic disease peaked in the early weeks after the second vaccine dose and then fell to 47% and 70%, respectively, at greater than 20 weeks post follow-up, in the context of the Delta variant.
- Studies have shown that age and immune status are the most important determinants of vaccine effectiveness and of risk of severe outcome in the event of a breakthrough infection. The evidence regarding the impact of other underlying medical conditions, independent of age or immune status, on the reduction on vaccine effectiveness against infection is less robust. However, in

the event of a breakthrough infection, those with underlying conditions are at risk of a more severe outcome.

- In studies from Israel, [Bar-On et al.](#) reported that booster doses were effective in further reducing the risk of infection and severe disease. The effect was apparent within seven days of administration and largely involved a reduction in infections overall, which occurred across all age-groups.
- There has been substantial uptake of booster doses in the over 80 age-group in Ireland, with increasing uptake in the over 70 age-group. Reductions in the incidence of SARS-CoV-2 infection have been observed in the over 80 age-group in Ireland since the administration of booster doses commenced. However, it is important to consider that additional public health measures are needed in parallel with vaccination and the administration of booster doses.
- The main aim of the Irish vaccination programme is to reduce severe disease, hospitalisation and death related to COVID-19. The currently available vaccines will not eliminate onward transmission of SARS-CoV-2. The addition of booster vaccines where needed will be an important part of, rather than the full solution to, reducing cases of SARS-CoV-2 infection. Global equity remains a concern regarding the provision of booster doses, with low numbers of healthcare workers fully vaccinated in some countries.

Contextual factors which may alter the current level of risk (for example, current behaviours)

- It was noted that, additional to national trends in SARS-CoV-2 incidence, Europe overall is currently considered to be at the epicentre of the pandemic.
- The current surge of COVID-19 cases is occurring against a context of what can be referred to as 'winter pressures' on the health system, that is, the pressure that faces the hospital system over the winter period due to increases in demand resulting largely from circulating respiratory viruses and acute exacerbations of chronic respiratory conditions. This context poses an additional risk for those who are at higher risk from COVID-19, and represents a potential additional benefit associated with mask use (that is, the potential reduced likelihood of other respiratory infections).
- Data provided by the **Economic and Social Research Institute (ESRI)** from the Social Activity Measure (SAM) were presented. The SAM, a collaboration between the Department of the Taoiseach and the ESRI's Behavioural Research Unit (BRU), is a behavioural study which records the public response to the risk of SARS-CoV-2 infection over time; 1,000 adults are surveyed on a fortnightly basis. The presented data were derived from results collected up to and including the latest survey ([results published 5](#)

[November 2021](#)). The most recent data reflected a period of increasing case numbers, loosened restrictions and the October Bank Holiday weekend and depicted trends in behavioural measures since the beginning of the survey (results from the week beginning 25 January 2021).

- There has been an increase in the numbers of locations visited during 2021, with more recent data suggesting an increase in visits to indoor locations and events, alongside an increase in the numbers of people met and the number of close contacts.
- The proportion of people engaging in mitigating behaviours (for example, mask wearing, social distancing) decreased earlier in 2021 and has remained relatively stable since late summertime. However, although rates of mask-wearing and distancing when visiting other homes are low, the most recent data indicated a slight increase.
- In considering current face mask use among those who are at higher risk from COVID-19, the data suggested that older people are somewhat more likely to wear face masks in indoor locations outside of homes. However, they do more socialising in homes (both visiting other houses and hosting visitors), and once this is factored in they are less likely to wear a face mask when meeting others indoors. These patterns have been relatively stable over recent months.
- Considering intentions to take a booster vaccine if offered (among those already vaccinated), no survey participants aged over 70 expressed hesitancy over the vaccine, while 6.4% of those aged 60-69 expressed hesitancy.

Effectiveness and safety of respirator masks

- The policy question relates to the effectiveness of respirator masks, versus medical masks, for the personal protection of those who are at higher risk from COVID-19. This question therefore relates to a different body of evidence than that used for the question of face mask use by the general population as source control to prevent transmission of SARS-CoV-2.
- A Summary of Evidence document [published by the HSE](#) in June 2020 reviewed the relative effectiveness of medical masks (surgical masks) versus respirators against airborne droplet viruses including SARS, MERS, influenza and SARS-CoV-2. This report was focused on the healthcare setting and concluded that medical masks have been shown to provide similar protection to respirators against COVID-19 in the context of routine patient contact in a clinical setting.
- Since 2021, overviews of systematic reviews have been published by several international agencies. Examples include an [overview review](#)

[published by the UK Health Security Agency](#) (October 2021) and an [update of a review published by the National Collaborating Centre for Environmental Health, Canada](#) (May 2021). These overviews have concluded that the evidence for the effectiveness of respirator masks in the community setting is not clear.

- One systematic review, highlighted in the overview reports for its high quality, is the [living review by Chou et al.](#), for which the sixth update was published in September 2021. This update concluded that the strength of the evidence for the effectiveness of respirator mask use versus medical mask use in preventing respiratory infections remains insufficient.
- The majority of the evidence base for the effectiveness of respirators is derived from their use by healthcare workers within the hospital setting. This evidence is unlikely to be transferable to the general population, and particularly to those within the general population who are at higher risk from COVID-19 due to age and morbidity. Recent studies specific to the healthcare setting include:
 - a randomised controlled trial (Loeb et al., NCT04296643) that is underway to assess whether medical masks are non-inferior to respirators for the prevention of COVID-19 in nurses engaged in routine clinical practice (non aerosol-generating scenarios).
 - a preprint study by [Ferris et al.](#) which examined the effectiveness of FFP3 respirators, versus medical masks, in staff working on COVID-19 wards in England. This study used data from an NHS healthcare worker testing programme and modelled the occupational versus community-derived risk of infection among workers. Respirator use was concluded to have conferred close to 100% protection against infection from patients with COVID-19.
- Considering adherence, there is a lack of recent and relevant data on adherence to use of respirator masks within the community setting. A systematic review by [Bakhit et al.](#) included a meta-analysis of four studies reporting on adherence with medical masks compared with respirators. Adherence was found to be significantly higher (26%, 95% CI 8% to 46%, $p < 0.01$) in the medical mask group.
- Many factors may influence mask effectiveness. A study by [Sickbert-Bennett et al.](#) demonstrated that:
 - filtration efficiency of respirator masks was decreased for respirators which were not officially approved, used ear loops (as opposed to head ties), or were inappropriately sized.
 - filtration efficiency was also lower in medical masks secured with ear loops versus those secured with head ties.

- From a safety perspective, there can be a reasonable expectation that some members of the community who are at higher risk from COVID-19 may experience breathing difficulty when using respirator masks. In 2020, the Global Initiative for the Diagnosis, Management, and Prevention of Chronic Obstructive Lung Disease published a [report on COVID-19 and Chronic Obstructive Pulmonary Disease](#), which emphasised the importance of mask use within the COPD population, but which also highlighted a study by Kyung et al.. [This study](#) identified that respiratory rate, peripheral oxygen saturation and exhaled CO₂ levels were adversely effected in patients with COPD who had been wearing a respirator mask at rest followed by six minutes of walking. The US [FDA has issued guidance](#) stating that people with conditions which make breathing difficult should check with their healthcare provider before using a respirator mask.

Barriers and enablers to the use of respirator masks within this population

- Acceptability of mask use, including respirator mask use, to the wearer is affected by community trends (social norms) and characteristics of the individual person.
 - A cross-sectional study by [Carbon et al.](#) found that acceptance of specific mask types was higher when it was perceived that others in society would also be wearing them.
 - A review by [Haraf et al.](#) found that underlying conditions such as anxiety were found to be predictive of the probability of experiencing respiratory distress while wearing a mask during exercise.
 - Regarding respirator masks, [Haraf et al. \(2021\)](#) suggested that higher resistance masks may have a greater magnitude of psychological impact on the wearer despite minimal to no effect on actual breathing resistance.
- Tolerability of mask use is reported to be lower among those wearing respirator masks compared to either medical or cloth masks.
 - A systematic review by [Bakhit et al.\(2021\)](#) and rapid review by [Sharpe et al.\(2021\)](#) both reported higher levels of facial discomfort for respirator masks, compared to other types of masks, when used by health care workers. These reviews also identified breathing issues, facial discomfort or rashes, and psychological distress associated with respirator use.
 - A study by [Foo et al.](#) found that among healthcare workers using N95 masks in Singapore during a SARS outbreak in 2003, 60% reported acne, 51% reported facial itch and 36% reported rash.

- A study by [MacIntyre et al.](#) reported that among healthcare workers wearing N95 masks in Beijing, 52% experienced facial irritation or discomfort, 19% reported difficulty breathing, and 13% reported headache.
- Correct mask fit is highly important for realising the benefit of respirator mask use and is influenced by various factors.
 - A review by [Regli et al.](#) of the importance of fit testing for respirators stated that correct respirator fit is far more important for airborne protection than the filtration capacity of the material.
 - This review also noted that factors influencing respirator fit include sex (poorer fit observed in women), ethnicity (poorer fit observed in Asian healthcare workers), age, weight, and facial dimensions.
 - [FDA guidance](#) notes that a proper fit cannot be achieved in children and in people with facial hair and that in these cases, a respirator may not provide full protection.
- [Guidance is provided by the HPSC](#) for respirator mask use in the healthcare setting. This guidance refers to the type of respirator mask to use, how to check the fit of the respirator mask, and tips for when the wearer should remove the respirator mask (for example, if breathing becomes difficult). Corresponding guidance is currently unavailable in Ireland for the use of respirators by members of the general population.
- Respirator masks are a high cost item considering that they are intended for single use. Prices vary from approximately €0.60 - €0.80 per item when purchased in bulk but cost approximately €2 - €3 for individual mask purchase. Respirators may be purchased in pharmacies, hardware stores and other retailers, in addition to online purchase, depending on availability of supply.
- Many respirators fail to meet requirements of EU and Irish [PPE Regulations](#). [In a European Coordinated Activity on Safety of Products \(CASP\) project \('CASP Corona 2020'\)](#), 85% (63/74) failed tests:
 - Many respirators had inadequate labelling for consumers to be certain that they were selecting an appropriately approved respirator.
 - There was a high proportion of instances where the mask did not fit the user's face, outlining that the face mask size and fit design were not suitable for facial proportions for a wide population of adult users within the EU.
 - Within Ireland, four of five respirators sampled failed to meet the EN 149 standard required for respirator masks in the EU and the

remaining respirator failed to meet the formal compliance requirements of the PPE regulations.²

- Should a recommendation be issued for persons who are at higher risk from COVID-19 to wear respirators:
 - guidance would likely need to be provided on the effective use of respirator masks, the potential for re-use of such masks, their appropriate disposal
 - in the absence of directly providing a supply to the population, guidance would likely be required to support individuals in the acquisition of these masks
 - it is possible that competition for access to respirator masks may occur between private providers of healthcare (for example, dentists), purchasers within industry (for example, the construction industry), and those to whom the recommendation for use would be issued. The stability of the supply chain for these items is unclear
 - those who consider themselves to be at higher risk of occupational exposure to COVID-19 may perceive that they would also fall under a recommendation for respirator masks to be used, which may lead to pressure on the supply chain for respirator masks
 - there may be concerns regarding equity of access, particularly under conditions of respirator mask supply shortages.

Examples of international recommendations regarding the use of respirator masks by the general population

A review of international guidance from the WHO, ECDC, US CDC, FDA, and 29 countries was presented. Details of the list of countries included in this review are outlined in the protocol document informing the conduct of the overall facilitated discussion. This document is available [here](#).

- The ECDC published a technical report in [February 2021](#) on the effectiveness of face mask use in the community setting for the reduction of transmission of COVID-19. In considering the use of respirators, this report stated that the anticipated added value of the universal use of respirators in the community was considered to be very low at the time of writing. Furthermore, taking into account the potential costs and harms, the ECDC stated that a recommendation for the use of respirators in place of other types of face masks in the community was not considered justifiable at that time. For people vulnerable to severe COVID-19, such as the elderly or those with

² Communication with a representative of the Competition and Consumer Protection Commission

underlying medical conditions, the use of medical face masks was recommended as a means of personal protection in confined public spaces and, as a consideration, in crowded outdoor settings.

- The WHO, [as of December 2020](#), recommends the use of medical masks by people with a higher risk of severe complications from COVID-19 (individuals above the age of 60 and those with underlying conditions) when physical distancing cannot be maintained.
- The [US CDC](#), as of October 2021, states that respirator masks should be prioritised for healthcare personnel. The [FDA](#) notes that N95 respirators are not designed for children or for people with facial hair.
- Guidance from several countries and regions (for example, Belgium, Denmark, Finland, France, Greece, Malta, Norway, Hong Kong) states that respirator masks are not recommended for use within the community setting and are primarily intended for healthcare personnel. Guidance from Israel states that respirator masks are suitable for use by the general public but that these masks are not specifically required.
- A number of countries specify that medical masks should be worn in certain public settings, such as public transport, crowded places, or healthcare settings.
- Medical masks are recommended specifically for those at high risk from COVID-19 in France, Ireland, Netherlands, Portugal and Spain. Four countries (Austria, Czech Republic, Germany, Slovakia) were identified as having official mandates or recommendations in place for the use of respirator masks by the general population.
 - In Austria, the wearing of FFP2 masks has been mandatory in the workplace since 2 November 2021. Additionally, tourist areas have implemented the use of FFP2 masks in certain settings.
 - In the Czech Republic, the wearing of FFP2 or N95 masks is mandatory in indoor settings (shops, service provision outlets, outpatient healthcare facilities, public transport). The guidance now additionally states that 'it is necessary to wear the given respiratory protection outdoors, if there is an accumulation of persons in the given area (concerts, sports matches, etc.) and several other situations'.
 - In Germany, the wearing of respirator masks (FFP2, N95 or KN95) is mandatory when using local public transport and when shopping. The mandate is implemented differently within different states.
 - In Slovakia, FFP2 masks are recommended generally for a wide range of indoor settings and on public transport.
 - For context, it was noted that each of the above countries which have recommended respirator mask use have, as of November 2021,

achieved lower COVID-19 vaccination uptake within their individual populations than in Ireland.

- Among countries that have specifically recommended or mandated the use of respirators, facilitators of access to respirators have included the following:
 - In Austria, in December 2020 and January 2021, ten free FFP2 masks were sent to people over 65.
 - In the Czech Republic, VAT on respirator products was temporarily waived from February 2021 to June 2021 and free FFP2 masks were provided to people and households who qualify for social security benefits.
 - Throughout Germany, a distribution scheme was set up to make 15 FFP2 masks available free of charge between December 2020 and April 2021 for those aged 60 years or older or who had certain medical conditions³. Also, in November 2021, FFP2 masks were made available in schools and daycare settings.
 - In Bremen, Germany, in February 2021, all adults aged 15-59 were sent five FFP2 masks by post.
 - In Berlin, Germany, in March 2021, certain population subgroups (low income, homeless, and refugee groups) were provided with FFP2 masks free of charge.

COVID-19 Expert Advisory Group Discussion

The COVID-19 Expert Advisory Group (EAG) engaged in a facilitated discussion to address the policy question under consideration. The discussion took consideration of the presentations described above. The following points were raised:

- It was acknowledged that the policy question is complex in nature with respect to the evidence required to inform a decision.
- It was agreed that the epidemiological situation in Ireland as of 15 November 2021, whereby there has been a sharp escalation in case numbers and a corresponding increase in the numbers of hospitalisations and ICU admissions, presents a high degree of urgency with respect to the risks to the population under consideration. On this basis, it was suggested that the current focus needs to be on what effective interventions can be achieved in the short term (within three to four weeks).

³ Asthma, chronic heart or kidney failure, stroke, type 2 diabetes, active or metastatic cancer, cancer therapy that weakens the immune system, organ or stem cell transplantation, or women with a high-risk pregnancy

- The evidence for the effectiveness of respirator masks in the community setting, compared with medical masks, was not found to be sufficiently convincing to support a population-level recommendation for respirators to be used. It was also noted that the highest risk of exposure to COVID-19 for those at higher risk is likely to be the household setting, where masks are less likely to be worn.
- Potential barriers to the implementation of respirator use among this population were discussed and highlighted in the context of the need for a clear, simple and immediate message to the public. These include:
 - difficulties in ensuring correct fit and usage of respirators by members of the public. Given the importance of appropriate fit and consistent use of respirator masks, and the barriers in ensuring that appropriate fit is achieved by the general population in the community setting, it is possible that any potential additional filtration benefit provided by respirators relative to medical masks may not be realised in this setting
 - specific difficulties associated with the experience of wearing respirator masks. These include the suggestion that those who are at the highest risk from COVID-19 might also find it the hardest to access or tolerate respirator masks
 - potential confusion among the public regarding who is considered to be at higher risk from COVID-19, and in particular with respect to messaging to those aged 60 and over
 - the potential reluctance of some individuals to wear a respirator as it may signal an underlying condition
 - difficulty in access to respirators for members of the public, particularly as some forms of masks have been noted by members of the HSE procurement team to be in short supply
 - the difficulty in enabling access to respirators in an equitable way and the risk of further exacerbating inequalities. In particular, the high cost to the individual or state of purchasing respirators for the target population, was noted.
 - the lack of a clear international model for the equitable supply of respirator masks. It was highlighted that the international review presented demonstrated that individuals in some countries have been issued with a limited supply of masks free of charge, but that these

quantities of masks are likely to be insufficient given the intended single use of respirators

- difficulty in enabling the public to obtain and use an appropriately fitting respirator mask.
- The potential impact of a recommendation on respirator use in the community setting on expectations and demand for access to respirators from other groups was noted.
- The onus of the responsibility for protection from infection being placed on those who are at higher risk was discussed. It would be preferable for messaging to reflect collective responsibility rather than to further increase the burden of personal responsibility, and the associated costs of a protective intervention, for those who are at higher risk from COVID-19. However, emphasis was also placed on the importance of ensuring protections are in place for those who are at higher risk from COVID-19; such protections include the person at higher risk wearing, where possible, a highly protective face mask, their close contacts wearing masks, and both the person who is at higher risk and their close contacts having been fully vaccinated.
- Considering the barriers to the implementation of effective respirator use and despite the urgent need for an increase in mitigation, a population-level recommendation for the use of respirator masks by those who are at higher risk from COVID-19 was not deemed to be a timely or effective intervention. The next four to six weeks were identified as being critical given the current and predicted high force of infection in the community, highlighting the immediate need for a clear and simple message to the public regarding mask use.
- There was agreement that improved compliance with existing guidance would be a better alternative than introducing a new recommendation to wear respirators, as the latter would require time for implementation and uptake by the public, is of uncertain additional benefit and may contribute to additional confusion regarding current public health guidance.
- It was agreed that a decision not to advise a population-level recommendation for the use of respirators does not preclude their use by individuals at higher risk of COVID-19, particularly where there is an opportunity to discuss with their healthcare provider to what degree they are likely to benefit from the use of a respirator mask, and to obtain advice on appropriate usage.

- The importance of adherence to the existing mitigation measures, which are recommended as part of public health guidance, was highlighted. In particular, the perceived under use of masks within the general population was noted, and the importance of reinforcing and clarifying the existing public health recommendations. It was also considered that there may be a lack of awareness among the public as to who is classified as being at higher risk from COVID-19 and the specific recommendation for those who are within this group to wear medical masks for their personal protection. Access to data on compliance with mask-wearing guidance, broken out according to mask type, would be beneficial in informing future policies on mask use.
- With regard to the current recommendation for the use of medical masks in those who are at higher risk from COVID-19, there may be a need to increase access to medical masks in some areas. It was suggested that targeted interventions could be introduced, for example, medical masks could be provided free of charge in locations such as pharmacies or in community centres in areas that are disadvantaged or at sites where individuals receive additional or booster doses of vaccines. The current reported provision of free face masks at COVID-19 test centres was described as useful but was discussed as being variable in practice. It was also suggested that the provision of masks in such a way may be beneficial in serving as a signal to the population of the importance of mask use. Support was expressed for expanded access to masks generally, for example, under a government subsidy model.
- Given the current high force of infection, it was suggested that a review of the existing policies on face mask use may be required. Such policies include the minimum age at which face masks are required and recommendations as to the type of face coverings (medical or cloth) to be used by the general population.
- Particular emphasis was placed on the importance of ensuring public awareness of the:
 - age groups and medical conditions which are considered to represent a higher risk
 - appropriate settings and circumstances for mask use, and particularly within the context of visiting homes of those who are at higher risk from COVID-19 or receiving such visitors in the home

- type of mask that is recommended to be worn if at higher risk from COVID-19
- correct approach to wearing a mask.
- The impact of poor health literacy and language barriers on understanding and accessibility of public health guidance was noted. Communication should be clear and consistent in emphasising the above points relating to mask use, should involve visual messaging and multiple modes of messaging and should be issued in multiple languages.

Advice

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

- There was a general consensus among EAG members that the evidence does not support a population-level recommendation for persons who are classed as at a 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. The existing recommendation for the use of medical masks, in place of cloth masks, in this cohort should instead be reinforced.
- In the context of the current and predicted epidemiological situation over the weeks leading into December, a policy of reinforcing current public health and mask guidance (that is, medical mask use by those who are at higher risk from COVID-19 and face covering use by the general population) was identified as the most efficient and appropriate means of managing the current situation.
- The advice against a population-level recommendation for the use of respirators by those who are at higher risk from COVID-19 does not preclude their use at an individual level, for example, where there is an opportunity for individuals to discuss with their healthcare provider to what degree they are likely to benefit from the use of a respirator mask, and to obtain advice on appropriate usage.
- Given the current high force of infection, there is an urgent need to provide a strong message, in a clear and simple manner, communicating the current public health guidance, including the guidance on face masks and face coverings. Communication should involve visual messaging, multiple modes of

messaging and should be issued in multiple languages. The following should be emphasised:

- continued compliance with the existing public health guidance and the range of mitigation measures that all should adopt
- the groups at higher risk from COVID-19 (that is, everyone aged 60 years and older, and those with specified health conditions)
- the recommendation for those at higher risk to wear medical masks rather than cloth masks for their personal protection
- the correct way to wear a mask, and the circumstances in which masks should be worn.

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