

The following information resources have been selected by the National Health Library and Knowledge Service Evidence Virtual Team in response to your question. The resources are listed in our estimated order of relevance to practicing healthcare professionals confronted with this scenario in an Irish context. In respect of the evolving global situation and rapidly changing evidence base, it is advised to use hyperlinked sources in this document to ensure that the information you are disseminating to the public or applying in clinical practice is the most current, valid and accurate. For further information on the methodology used in the compilation of this document—including a complete list of sources consulted—please see our National Health Library and Knowledge Service Summary of Evidence Protocol.

YOUR OUESTION

What is the evidence around the relative effectiveness of surgical masks to properly fitted respiratory protective equipment such as FFP2 and FFP3 masks against airborne droplet viruses: SARS, MERS, influenza, and SARS-CoV-2?

IN A NUTSHELL

This evidence summary incorporates general international guidance on the use of surgical masks and respirators; it also cites a recent evidence summary prepared by the Centre for Evidence Based Medicine (CEBM)⁶ which was updated in April 2020 and concurs with the findings of a systematic review conducted by the Chinese Cochrane Centre¹. In view of the fact that both of these papers have conducted literature searches that include previous pandemics, our summary provides references to trials and reviews published since March 1, 2020, and which are not included in either the review by the Chinese Cochrane Centre or the CEBM summary.

National guidance from the HPSC² and international guidance from the WHO³ and ECDC⁴ regarding the use of surgical masks vs respirators is mainly in agreement that surgical masks provide sufficient protection for all encounters with COVID-19 confirmed or suspected cases, and that N95 respirators should be reserved for situations that involve or may involve the generation of aerosols [aerosol generating procedures or AGPs]. The guidance from CDC differs insofar as it recommends more widespread use of N95 respirators⁵. However, widespread use of N95 masks may result in limited PPE for those healthcare workers exposed to AGPs.

International literature is also, for the most part, in agreement with international guidance. The CEBM summary concludes that standard



surgical masks are as effective as respirator masks such as N95, FFP2 and FFP3 for preventing infection of healthcare workers in outbreaks of viral respiratory illnesses such as influenza, except in situations involving AGPs⁵. Most of the studies highlight the fact that the epidemiological study of COVID-19 is still in its infancy and there has not been sufficient time or organisational capacity to organise robust, properly constructed cohort studies. Opinions are also divided as to whether COVID-19 is preferentially spread in droplet or aerosol form, although fluid and droplet dynamic models suggest that influenza transmission models can be applied to COVID to better illustrate the dynamics of person-to-person transmission.

More recent studies draw a similar conclusion, while at the same time acknowledging that although respirators may offer better protection, the evidence base is so uncertain that definitive conclusions cannot be deduced. 8.9.10.11. MacIntyre et al note that although laboratory testing shows that N95 masks are superior to surgical masks, the outcomes of studies in the clinical setting show no significant difference in effect. 11.

In summary, surgical masks, according to the available evidence, have been shown to provide similar protection against COVID-19 as N95 respirators in routine patient contact in a clinical setting. However, N95 masks are recommended for use in all procedures that risk generating aerosols due to the greater level of fit of the mask to the individual's face: the robust barrier effectively prevents the inhalation of aerosolised secretions from an infected patient. It is important to stress at this point that the definition of an aerosol-generating procedure will differ from setting to setting and therefore there should be flexibility to allow the use of N95 masks if an individual clinician, following a clinical risk assessment, determines that there is a risk of generation of aerosol from any procedure or patient encounter.

Most authors agree that more research is needed; and trials comparing the effectiveness of surgical masks vs respirators have been registered, an example of which is included below.



IRISH AND INTERNATIONAL GUIDANCE

What does the Health Protection Surveillance Centre (Ireland) say?

<u>Current recommendations for the use of Personal Protective Equipment</u> (PPE) for Possible or Confirmed COVID-19 in a pandemic setting²

Updated to reflect Decision by NPHET dated 22nd April 2020 in relation to use of surgical masks in healthcare settings:

- Surgical masks should be worn by healthcare workers when they are providing care to people and are within 2m of a person, regardless of the COVID-19 status of the person.
- Surgical masks should be worn by all healthcare workers for all encounters of 15 minutes or more with other healthcare workers in the workplace where a distance of 2m cannot be maintained.
- An FFP2 facemask is recommended for patients with respiratory symptoms or suspected or confirmed COVID-19 who require an aerosol generating procedure. In situations where staff are in the room with a patient and there is a significant risk that an unplanned aerosol generating procedure may need to be performed urgently—eg accidental extubation—it may be appropriate to wear an FFP2 mask while in the room.

What does the World Health Organization say?

Advice on the use of masks in the community, during home care and in healthcare settings in the context of the novel coronavirus (COVID-19) outbreak: interim Guidance 5 June 2020³

This document provides advice on the use of masks in communities, during home care, and in health care settings in areas that have reported cases of COVID-19. It is intended for individuals in the community, public health and infection prevention and control (IPC) professionals, health care managers, health care workers (HCWs), and community health workers. This updated version includes a section on Advice to decision makers on the use of masks for healthy people in community settings.

Their recommendation is as follows:

— In the absence of AGPs, WHO recommends that health workers providing direct care to COVID-19 patients, should wear a medical mask [in addition to other PPE that are part of droplet and contact precautions];



— In care settings for COVID-19 patients where AGPs are performed [eg COVID-19 intensive and semi- intensive care units], WHO recommends that health workers should wear a respirator: N95 or FFP2 or FFP3 standard, or equivalent.

What does the European Centre for Disease Prevention and Control say? Infection prevention and control and preparedness for COVID-19 in healthcare Settings: second update 31 March 2020⁴

The relative role of droplet, fomite and aerosol transmission for SARS-CoV-2, the protection provided by the different components of personal protective equipment (PPE) and the transmissibility of the virus at different stages of the disease remain unclear. Caution should therefore be exercised when considering these elements. With the exception of AGPs, it is unclear whether facial filtering piece (FFP) respirators [class 2 or 3] provide better protection than surgical masks against other coronaviruses and respiratory viruses such as influenza. Therefore, in the event of widespread community transmission leading to shortages of PPE, a rational approach would necessitate prioritising use of FFP2/3 respirators for care activities involving a higher perceived risk of transmission such as during AGPs or in intensive care.

Management of Residents with Symptoms of COVID-19

- If a resident in a long-term care facility displays clinical signs or symptoms of COVID-19, contact public health authorities/healthcare services for notification, assessment and instructions on testing and possible transfer to an acute care hospital.
- Residents displaying signs or symptoms of COVID-19 that do not require hospitalisation should be isolated in single rooms with a separate bathroom.
 If there are more than a few cases, consider placing the residents in a separate ward or section of the facility with dedicated staff.
- Ensure that all long-term care facility staff are aware of the residents displaying symptoms compatible with COVID-19 or having tested positive for the disease.
- If appropriate, consider posting information detailing IPC precautions on the doors of all residents' rooms, especially in those areas that have suspected or confirmed COVID-19 cases.
- Healthcare and other workers coming into contact with residents who have respiratory infections should wear a surgical mask or an FFP2 respirator if available, eye protection [ie visor or goggles], a gown and gloves.



- Healthcare workers should strictly follow the procedures for putting on and safely removing PPE in the correct sequence.
- Hands should be washed immediately after removing PPE.

What do the Centers for Disease Control and Prevention (United States) sav?

Personal Protective Equipment: Questions and Answers⁵

The document address frequently asked questions about personal protective equipment (PPE), including respirators and the difference between respirators and surgical masks.

- A surgical N95 is recommended only for use by healthcare personnel who need protection from both airborne and fluid hazards: ef splashes, sprays. These respirators are not used or needed outside of healthcare settings. In times of shortage, only HCPs who are working in a sterile field or who may be exposed to high velocity splashes, sprays or splatters of blood or body fluids should wear these respirators such as in operative or procedural settings. Most HCPs caring for confirmed or suspected COVID-19 patients should not need to use surgical N95 respirators and can use standard N95 respirators.
- If a surgical N95 is not available for use in operative or procedural settings, then an unvalved N95 respirator may be used with a faceshield to help block high velocity streams of blood and body fluids.

INTERNATIONAL LITERATURE

What does the international literature say?

Greehalgh T, et al (2020) What is the efficacy of standard face masks compared to respirator masks in preventing COVID-type respiratory illnesses in primary care staff?⁶

Standard surgical masks are as effective as respirator masks such as N95, FFP2 or FFP3 for preventing infection of healthcare workers in outbreaks of viral respiratory illnesses such as influenza. No head to head trial of these masks in COVID-19 has yet been published, and neither type of mask prevents all infection. Both types of mask need to be used in combination with other PPE measures. Respirator masks are recommended for



protection during aerosol generating procedures. Rapid reviews on wider PPE measures, and what counts as an AGP, are ongoing.

Bartoszko JJ, et al. (2020) Medical masks vs N95 respirators for preventing COVID-19 in healthcare workers: A systematic review and meta-analysis of randomized trials⁷

Background: Respiratory protective devices are critical in protecting against infection in healthcare workers at high risk of novel 2019 coronavirus disease (COVID-19); however, recommendations are conflicting and epidemiological data on their relative effectiveness against COVID-19 are limited.

Purpose: To compare medical masks to N95 respirators in preventing laboratory-confirmed viral infection and respiratory illness including coronavirus specifically in healthcare workers.

Data synthesis: 4 RCTs were meta-analyzed adjusting for clustering. Compared with N95 respirators the use of medical masks did not increase laboratory-confirmed viral [including coronaviruses] respiratory infection (OR 1.06; 95% CI 0.90-1.25; I2 = 0%; low certainty in the evidence) or clinical respiratory illness (OR 1.49; 95% CI: 0.98-2.28; I2 = 78%; very low certainty in the evidence). Only one trial evaluated coronaviruses separately and found no difference between the two groups (P = .49).

Limitations: Indirectness and imprecision of available evidence.

Conclusions: Low certainty evidence suggests that medical masks and N95 respirators offer similar protection against viral respiratory infection including coronavirus in healthcare workers during non-aerosol-generating care. Preservation of N95 respirators for high-risk, aerosol-generating procedures in this pandemic should be considered when in short supply.

Chu DK, et al (2020) Physical distancing, face masks, and eye protection to prevent person-to-person transmission of SARS-CoV-2 and COVID-19: a systematic review and meta-analysis⁸

Background: Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) causes COVID-19 and is spread person-to-person through close contact. We aimed to investigate the effects of physical distance, face masks, and eye protection on virus transmission in health-care and non-health-care settings.

Methods: We did a systematic review and meta-analysis to investigate the optimum distance for avoiding person-to-person virus transmission and to assess the use of face masks and eye protection to prevent transmission of viruses. We obtained data for SARS-CoV-2 and the betacoronaviruses that



cause severe acute respiratory syndrome, and Middle East respiratory syndrome from 21 standard WHO-specific and COVID-19-specific sources. We searched these data sources from database inception to May 3, 2020, with no restriction by language, for comparative studies and for contextual factors of acceptability, feasibility, resource use, and equity. We screened records, extracted data, and assessed risk of bias in duplicate. We did frequentist and Bayesian meta-analyses and random-effects meta-regressions. We rated the certainty of evidence according to Cochrane methods and the GRADE approach. This study is registered with PROSPERO, CRD42020177047.

Findings: Our search identified 172 observational studies across 16 countries and six continents, with no randomised controlled trials and 44 relevant comparative studies in health-care and non-health-care settings (n=25 697 patients). Transmission of viruses was lower with physical distancing of 1 m or more, compared with a distance of less than 1 m (n=10 736, pooled adjusted odds ratio [aOR] 0.18, 95% CI 0.09 to 0.38; risk difference [RD] -10·2%, 95% CI -11·5 to -7·5; moderate certainty); protection was increased as distance was lengthened (change in relative risk [RR] 2.02 per m; pinteraction=0.041; moderate certainty). Face mask use could result in a large reduction in risk of infection (n=2647; aOR 0·15, 95% CI 0·07 to 0·34, RD -14·3%, -15·9 to -10·7; low certainty), with stronger associations with N95 or similar respirators compared with disposable surgical masks or similar (eg reusable 12-16-layer cotton masks; pinteraction=0.090; posterior probability >95%, low certainty). Eye protection also was associated with less infection (n=3713; aOR 0.22, 95% CI 0.12 to 0.39, RD -10.6%, 95% CI -12.5 to -7.7; low certainty). Unadjusted studies and subgroup and sensitivity analyses showed similar findings.

Interpretation: The findings of this systematic review and meta-analysis support physical distancing of 1 m or more and provide quantitative estimates for models and contact tracing to inform policy. Optimum use of face masks, respirators and eye protection in public and health-care settings should be informed by these findings and contextual factors. Robust randomised trials are needed to better inform the evidence for these interventions, but this systematic appraisal of currently best available evidence might inform interim guidance.



Iannone P, et al (2020) The need of health policy perspective to protect Healthcare Workers during COVID-19 pandemic. A GRADE rapid review on the N95 respirators effectiveness⁹

Protecting Health Care Workers during routine care of suspected or confirmed COVID-19 patients is of paramount importance to halt the SARS-CoV-2 pandemic. The WHO, ECDC and CDC have issued conflicting guidelines on the use of respiratory filters (N95) by HCWs. We searched PubMed, Embase and the Cochrane Library from the inception to March 21, 2020 to identify randomized controlled trials comparing N95 respirators versus surgical masks for prevention of COVID-19 or any other respiratory infection among HCWs. The grading of recommendations, assessment, development, and evaluation (GRADE) was used to evaluate the quality of evidence. Four RCTs involving 8736 HCWs were included. We did not find any trial specifically on prevention of COVID-19. However, wearing N95 respirators can prevent 73 more (95% CI 46-91) clinical respiratory infections per 1000 HCWs compared to surgical masks (2 RCTs; 2594 patients; low quality of evidence). A protective effect of N95 respirators in laboratory-confirmed bacterial colonization (RR = 0.41; 95%CI 0.28-0.61) was also found. A trend in favour of N95 respirators was observed in preventing laboratory-confirmed respiratory viral infections, laboratory-confirmed respiratory infection, and influenza like illness. We found no direct high quality evidence on whether N95 respirators are better than surgical masks for HCWs protection from SARS-CoV-2. However, low quality evidence suggests that N95 respirators protect HCWs from clinical respiratory infections. This finding should be contemplated to decide the best strategy to support the resilience of healthcare systems facing the potentially catastrophic SARS-CoV-2 pandemic.

MacIntyre CR, et al (2020) human coronavirus data from four clinical trials of masks and respirators¹⁰

There are few published data on the protection of masks or respirators against coronavirus infections. This is an important research question to inform the response to the COVID-19 epidemic. The transmission modes of human coronaviruses are similar, thought to be by droplet, contact and sometimes airborne routes. There are several randomised clinical trials of masks and respirators, but most used clinical endpoints or tested only for influenza. In four trials which we conducted, we tested for human coronaviruses, but only composite viral endpoints were reported in the trials.



We reviewed and analysed the coronavirus data from four of our trials. Laboratory-confirmed coronavirus infections were identified in our community household trial [1 case], health worker trials [8 cases] and trial of mask use by sick patients [19 cases]. No coronavirus infections were transmitted in households to parents who wore P2 or surgical masks, but one child with coronavirus infection transmitted infection to a parent in the control arm. No transmissions to close contacts occurred when worn by sick patients with coronavirus infections. There was a higher risk of coronavirus infection in HCWs who wore a mask compared to a respirator, but the difference was not statistically significant. These are the only available data on coronavirus infections associated with mask or respirator use. More clinical trials are needed to assess the efficacy of respiratory protection against coronavirus infections.

MacIntyre CR, et al (2020) A rapid systematic review of the efficacy of face masks and respirators against coronaviruses and other respiratory transmissible viruses for the community, healthcare workers and sick patients¹¹

Background: The pandemic of COVID-19 is growing, and a shortage of masks and respirators has been reported globally. Policies of health organizations for healthcare workers are inconsistent, with a change in policy in the US for universal face mask use. The aim of this study was to review the evidence around the efficacy of masks and respirators for healthcare workers, sick patients and the general public.

Methods: A systematic review of randomized controlled clinical trials on use of respiratory protection by healthcare workers, sick patients and community members was conducted. Articles were searched on Medline and Embase using key search terms.

Results: A total of 19 randomised controlled trials were included in this study 8 in community settings, 6 in healthcare settings and 5 as source control. Most of these randomised controlled trials used different interventions and outcome measures. In the community, masks appeared to be effective with and without hand hygiene, and both together are more protective. Randomised controlled trials in health care workers showed that respirators if worn continually during a shift were effective but not if worn intermittently. Medical masks were not effective; and cloth masks even less effective.

Conclusion: The study suggests that community mask use by well people could be beneficial, particularly for COVID-19, where transmission may be



pre-symptomatic. The studies of masks as source control also suggest a benefit, and may be important during the COVID-19 pandemic in universal community face mask use as well as in health care settings. Trials in healthcare workers support the use of respirators continuously during a shift. This may prevent health worker infections and deaths from COVID-19, as aerosolisation in the hospital setting has been documented.

<u>Viswanath A, Monga P. Working through the COVID-19 outbreak: Rapid review and recommendations for MSK and allied heath personnel¹²</u>

The coronavirus (COVID-19) pandemic has caused the world to undergo unprecedented change in a short space of time. This disease has devastated the economy, infringed personal freedom, and has taken a toll on healthcare systems worldwide. This review aims to highlight aspects of this pandemic with a specific emphasis on musculoskeletal work within the secondary care setting.

Surgical face masks are not designed for personnel protection and do not closely fit around the face and mouth. Their design is intended for preventing contamination of the surgical wound from the aerosols generating by the surgical team. When tested for personal protection in lab settings, they provide a 35% protection against a standard lab aerosol challenge. There are no clinical studies comparing N95/P2 masks to surgical masks for prevention against coronavirus but studies have compared these two masks in the setting of influenza virus which is a similar sized virus and is also airborne. Despite the differences we have seen in the lab settings, there seem to be no difference in infection rates between these two groups in the clinical setting [2 randomised trials]. It is apparent that in the lab setting N95/P2 masks are superior but in the clinical setting such a difference is not seen.

OTHER

McMaster University (2020) Medical Masks vs N95 Respirators for COVID-19: RCT, not yet recruiting¹³

A randomized controlled trial in which nurses will be randomized to either medical masks or N95 respirators when providing medical care to patients with COVID-19. This Canadian multi-centre randomized controlled trial will assess whether medical masks are non-inferior to N95 respirators when nurses provide care involving non-aerosol generating procedures. Nurses





will be randomized to either use of a medical mask or to a fit-tested N95 respirator when providing care for patients with febrile respiratory illness. The primary outcome is laboratory confirmed COVID-19 among nurse participants.



National Health Library and Knowledge Service | Evidence Team Summary of Evidence: COVID-19 CURRENT AS AT 10 JUNE 2020 VERSION 1.0

Produced by the members of the National Health Library and Knowledge Service Evidence Team[†]. Current as at 10 June 2020. This evidence summary collates the best available evidence at the time of writing and **does not replace clinical judgement or guidance**. Emerging literature or subsequent developments in respect of COVID-19 may require amendment to the information or sources listed in the document. Although all reasonable care has been taken in the compilation of content, the National Health Library and Knowledge Service Evidence Team makes no representations or warranties expressed or implied as to the accuracy or suitability of the information or sources listed in the document. This evidence summary is the property of the National Health Library and Knowledge Service and subsequent re-use or distribution in whole or in part should include acknowledgement of the service.



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The following PICO(T) was used as a basis for the evidence summary:



The following search strategy was used:

(COVID-19 OR CORONAVIRUS OR "CORONA VIRUS" OR WUHAN NEAR/3 VIRUS OR (("2019-NCOV" OR "2019 NCOV")) OR "SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2" OR "2019 NOVEL CORONAVIRUS" OR "2019 NEW CORONAVIRUS" OR "SARS-COV-2")

AND

('SURGICAL MASK' OR 'SURGICAL MASKS' OR 'MEDICAL MASK' OR 'MEDICAL MASKS' OR BFE1 OR BFE2 OR 'TYPE R') AND TOPIC: (RESPIRATOR OR RESPIRATORS OR RPE OR FFP1 OR FFP2 OR FFP3 OR N95 OR N99 OR N100 OR NIOSH OR FFR OR 'FILTERING FACEPIECE' OR 'FILTERING FACE PIECE')

FROM MARCH 2020

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National Health Library and Knowledge Service | Evidence Team









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⁵ Centres for Disease Control and Prevention. Personal Protective Equipment: Questions and Answers. https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirator-use-faq.html [Accessed 09 JUNE 2020]

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⁷ Bartoszko JJ, et al. (2020) Medical masks vs N95 respirators for preventing COVID-19 in healthcare workers: A systematic review and meta-analysis of randomized trials [published online ahead of print, 2020 Apr 4]. Influenza Other Respir Viruses. 2020;10.1111/irv.12745. doi:10.1111/irv.12745

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¹⁰ MacIntyre CR, et al (2020) human coronavirus data from four clinical trials of masks and respirators [published online ahead of print, 2020 Jun 1]. Int J Infect Dis. 2020;51201-9712(20)30399-4. doi:10.1016/j.iiid.2020.05.092

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