Subject to EAG advice

National Public Health Emergency Team (NPHET)

Suggested way forward re use of face masks/coverings in the community during the COVID-19 crisis as an aid to infection prevention

1 May 2020

Action required

☐ For noting
☒ For discussion
☐ For decision

TO NPHET – for consideration

Suggested way forward re use of face masks/coverings in the community during the COVID-19 crisis as an aid to infection prevention

Proposal for consideration by NPHET:
On foot of advice and guidance of international bodies and consideration of actions taken by other countries, and subject to EAG advice, the following is proposed for consideration by NPHET in respect of use of face masks/coverings in the community:

(1) That the public be advised (rather than mandated) to wear community face masks/coverings in enclosed spaces where physical distancing of two meters is difficult, as an act of solidarity, the purpose of which is to limit the spread of the virus from the wearer to others (This is subject to the wording of the EAG);

(2) That the public be advised that medical masks i.e. surgical masks and respirators be reserved for use by healthcare workers (HCWs). A national communication strategy should be prepared to ensure that the correct message is received by the general public in this regard ie a clear explanation of the different types of face masks available and who should wear what type of mask and in what setting;

(3) To ensure a strong supply line of non-medical masks, that the MDCAG support the work of DBEI and its agencies in its engagement with relevant stakeholders on the manufacture of cloth and paper masks, including support for indigenous companies;

(4) Consideration be given to non-medical mask standards established in other jurisdictions for non-medical masks (such as the French ANFOR criteria) to determine whether and how these could be considered in the Irish context;

(5) That a national information campaign be prepared to advise persons on the use and self-manufacture of masks, e.g. how to apply, remove, safely dispose or clean of non-medical cloth and paper masks/face covering, with advice and guidance of EAG/HPSC as appropriate.

1. Background

As we move towards gradually easing the restrictive measures introduced to slow the transmission of COVID-19 and begin to consider the resumption of normal social and economic activity, consideration is being given to the use of face masks by members of the public.

An increasing number of countries are recommending or making compulsory the use of masks in the community to complement SD. These include a number of EU countries. (See Appendix I).

A recommendation is awaited by the EAG in respect of use of masks in Ireland. In advance of that, the NPHET asked that consideration be given to an approach to support the use of face masks in

Ireland in the community, mindful of the need to ensure this does not undermine the supply of medical (surgical and respirator) facemasks required for health service staff. [1]

NPHET has identified the need to ensure a ready supply of medical (surgical and respirator) masks for healthcare workers by limiting their availability to HCW, other essential workers and possibly persons who are deemed vulnerable.

The matters in this paper were considered by a group comprising Darina O'Flanagan, Máirin Ryan, HIQA; Breda Smyth, HSE; Eibhlin Connolly, DCMO; Máire Connolly, NUI Galway; and officials of the Department, Mary Hyland and Karen McNamara Medicines and Pharmacy Legislation Unit, Rosarie Lynch (NPSO) and Siobhán Kennan.

2. Types of facemasks available

Different masks perform different functions – to protect the wearer from acquiring disease, or to prevent the wearer from spreading disease.

1. A respirator face masks (FFP2 and FFP3), classified under EU law as personal protective equipment, are designed to protect the wearer from exposure to airborne contaminants. They are mainly used by healthcare workers, especially during aerosol-generating procedures. Respirators comply with requirements defined in European Standard EN 149:2001+A1:2009.

2. A medical face mask (also known as a surgical or procedure mask), classified under EU law as a medical device, and used by healthcare workers to prevent large respiratory droplets and splashes from reaching the mouth and nose of the wearer, and also reduce and / or control the spread of large respiratory droplets from the wearer. Medical masks comply with requirements defined in European Standard EN 14683:2014.

3. Non-medical masks or face coverings:
    a. Cloth non-medical face masks (or community masks), either self-made or commercial (not standardised under EU law, and not intended for use in healthcare settings or by healthcare professionals)
    b. Paper non-medical face masks (or community masks), either self-made or commercial (not standardised under EU law, and not intended for use in healthcare settings or by healthcare professionals).

[1] The HPSC, following consideration by NPHET, issued new advice recommending that all healthcare workers should wear surgical masks when within two metres of a patient, regardless of the COVID-19 status of the patient and for all encounters, of fifteen minutes or more, with other healthcare workers in the workplace where a distance of two metres cannot be maintained. Understandably, this has had a significant impact on the national requirements for surgical masks and it is now forecasted that over 1.2 million masks will be required, per day, by the health service, in light of this new guidance.

3. ECDC , WHO and HIQA evidence review

The **ECDC report** *Reducing COVID-19 transmission from potentially asymptomatic or pre-symptomatic people through the use of face masks*[2] 8 April 2020 provides the ECDC opinion on the suitability of face masks and other face covers in the community by individuals who are not ill in order to reduce potential pre-symptomatic or asymptomatic transmission of COVID-19 from the mask wearer to others.

It finds that there is increasing evidence that persons with mild or no symptoms at the pre-symptomatic and early stages of infection can contribute to the spread of COVID-19. **It states that the use of face masks in public may reduce the spread of infection in the community by minimising the release of respiratory droplets from infected people from people who may not even know they are infected and before they develop any symptoms.** In this respect, mask use by . asymptomatic persons can be regarded as an extension of the current practice of face mask use by symptomatic individuals.

On the 6th April the World Health Organisation provided interim guidance on the use of masks in the context of COVID-19[3]. WHO advised that wearing a medical mask is one of the prevention measures that can limit the spread of certain respiratory viral diseases, including COVID-19. WHO advised that persons with symptoms should wear a medical mask. Those with suspected COVID-19 or mild symptoms being managed at home should wear a medical mask as much as possible. Caregivers should wear a medical mask when in the same room as the affected person. The wider use of masks by healthy people in the community was not supported by current evidence and carries uncertainties and critical risks. However, WHO offers advice to decision makers so they apply a risk-based approach on the use of masks in the community settings. Importantly, the purpose for which the mask is to be worn is to be made clear – whether it is to be used for source control (used by infected persons) or prevention of COVID-19 (use by healthy person). The WHO identifies reducing potential exposure risk from infected person during the asymptomatic or "pre-symptomatic" period as a potential advantage of the use of masks by healthy people in the community setting. In addition, the wearing of masks by the community reduces the stigmatization of infected individuals wearing masks for source control.

Personal communication received from WHO Health Emergencies Programme Director Michael Ryan on 28 April confirmed that he has made statements on at least two occasions, to clarify the guidance of 6 April, to say that "*it is up to countries to weigh the evidence (which is inconclusive) against the utility in specific circumstances (e.g public transport) where physical distancing is not possible. People with symptoms should never use a mask and go out, go to work or otherwise engage in social activity regardless of mask use. Community mask use should never cause a shortage of masks for HCWs. Mask use does not mean that physical distancing should be ignored where it can be done. Mask use should be associated with continued hand hygiene, safe donning and doffing and appropriate disinfection or disposal. Mask use in young children should be carefully considered especially for the above and for any choking hazard*."

[2] https://www.ecdc.europa.eu/en/publications-data/using-face-masks-community-reducing-covid-19-transmission

[3] https://www.who.int/publications-detail/advice-on-the-use-of-masks-in-the-community-during-home-care-and-in-healthcare-settings-in-the-context-of-the-novel-coronavirus-(2019-ncov)-outbreak

The **HIQA report** *Evidence summary for face mask use by healthy people in the community 21 April 2020* looked at what evidence is available to indicate that routine wearing of face masks by healthy persons in the community reduces the transmission of respiratory pathogens spread via droplet transmission. HIQA noted that it is difficult to reach a definitive conclusion on the effectiveness of face masks in the community. Current evidence is inconclusive, and mainly based on low quality studies of influenza and influenza-like illness; influenza is substantially less infective than SARS-CoV-2 and therefore the evidence may not be applicable to COVID-19. HIQA did not identify any randomised control trials that had been conducted during a pandemic and considered the use of face masks for healthy individuals in the community; it included one household trial partially conducted during the 2009 H1N1 pandemic. There is some low-quality evidence from observational studies during the SARS pandemic that the regular use of face masks in community settings may reduce the risk of infection. No studies examined the effectiveness of reusable cloth masks worn in the community. Recommendations for the wearing of face masks in the community are based on the mechanical and physiological plausibility regarding the potentially protective effects of face masks, which could plausibly act as a source control measure in pre-symptomatic and asymptomatic COVID-19 cases. There was no evidence from the included studies that face masks introduce a false sense of security and lead wearers to neglect hand hygiene. **The HIQA report concluded that** *the current evidence on whether the use of face masks in community settings can reduce transmission of respiratory pathogens is inconclusive, and mainly based on low quality studies of influenza and influenza-like illness, which may not be applicable to COVID-19. While better quality evidence is required, findings from some studies suggest that compliance with wearing face masks may play an important role in determining the efficacy of face mask use.*

4. Policies adopted in other countries in relation to face mask use in the community:

While recognising the need to ensure an uninterrupted supply of surgical and respirator masks for healthcare workers and other medical first responders, a number of countries have either mandated or recommended the use of cloth face coverings/masks to help slow the spread of COVID-19 (see table at Appendix 1). Information available to us is not always clear on whether countries distinguish between the type of masks or covering to be worn, beyond the fact that one should be worn.

Germany, Austria, Portugal, Czech rep, Luxembourg, Spain, Slovenia, France, Italy, Poland, Hungary, Bulgaria, Slovakia and others have announced or introduced public face masks wearing. Routes taken by countries which advocate the use of face masks have differed in a number of respects: compulsory or recommended/encouraged face mask use; use at all times in public (public transport, taxis, the workplace, eg in shops, for restaurant workers or in offices where the SD limit cannot be observed); provided by the Government (eg Spain); provided free at point of entry to shops); with information provided on a number of websites on how to make your own mask (eg US Centers for Disease Control and Prevention (CDC))[4].

The UK government has so far resisted calls to make it compulsory for people to wear face masks in some public situations. It is understood that the experts have concluded that cloth masks could help stop an asymptomatic person from infecting others in a closed environment, such as offices or public transport. But they do not believe that cloth masks would be of much use in parks or other public

[4] https://www.cdc.gov/

spaces. The Scottish Government announced on Tuesday 28 April 2020 a recommendation that the public wear face coverings in enclosed spaces where social distancing is difficult to achieve, eg shopping or public transport.

5. Consideration in Irish context

To not undermine the supply line of surgical masks and FFP3 for those who need it, in particular healthcare workers, the following issues need to be considered in any decision to recommend the use of face masks in the community in Ireland. These are:

- Management of the existing supply line of surgical and FFP2/3 masks to ensure they are available for those who need them and not diverted
- Possible introduction of regulations if deemed necessary to protect the existing supply to those who need surgical masks
- Provision of non-medical face mask covering for the public
- Communication to the public

In light of new guidance arising from a decision of the NPHET that surgical masks should be worn more widely in the healthcare sector, with a forecasted daily need of over 1.2 million masks required by the health service, a key concern is to ensure that this will not have an impact on the availability of surgical face masks for healthcare workers.

Medicines Unit was consulted on what might be done in order to protect the supply of surgical masks to healthcare workers, including the possibility of introducing regulations to control the supply of surgical masks to healthcare workers and possibly others, eg people with specific illnesses. It in turn, discussed the matter informally with a relevant contact in both HSE and HPRA. Its views are reflected in the text below.

Managing the existing supply line

- The **global demand** for PPE has created a very competitive and difficult market. It is important to note that most traditional supply sources are no longer available and the major supply line we have from China is essential to maintain. The HSE has secured a contract with an established Chinese supplier for ongoing provision of PPE.
- **Surgical masks are defined** as a medical device under EU law [5], with HPRA being the body responsible for overseeing and enforcing this piece of legislation. FFP2 and FFP3 masks, as PPE, fall under the PPE Regulation (EU) 2016/425, with the Health and Safety Authority, an agency governed by DBEI, being the market surveillance authority body responsible.
- Currently, the **HSE is a large-scale purchaser** of PPE and surgical masks given the national demand and their purchasing power, and has **enhanced existing and opened** new supply chains. Many of these new supply chains are confirmed, in as much as possible given the volatility of the global marketplace and are well managed.
- The **HSE does not provide all surgical masks and PPE;** a smaller volume of items come into the system outside of the HSE's much larger supply lines to meet some local demand by some healthcare workers and other essential and non-essential workers for PPE. It is the understanding of the Medicines unit that the HSE has not tried to purchase these supply lines, given that they are too small scale to meet national demand on an ongoing basis and rather, are happy for local purchasers to continue to manage their existing supply lines in order to meet this local demand.

[5] subject to subject to Directive 93/42/EEC on General Medical Devices (MDD)

- **The HSE has established a central allocation system that incorporates the State's entire healthcare setting requirements** including nursing homes (public and private), NAS, and Section 38 and 39 service providers. This is in line with WHO guidance on coordinating PPE supply in the guidance document 'Rational use of personal protective equipment (PPE) for coronavirus disease'. PPE and surgical masks received into the country are held and are not distributed until a suitability assessment is conducted by National Infection Prevention and Control Team. **Drawdown is rationed by the HSE**, using a clinically based algorithm and is distributed via a scheduled delivery service.

Legislative options for controlling supply of medical masks

- The Minister for Health has power under the Irish Medicines Board Act to make regulations controlling the supply or use of medical devices, in this case, **surgical masks**. However, any regulations would need to ensure that they did not have unintended consequences in relation to existing supply chains. Issues of concern and which would need significant further consideration include:
    - Ensuring that there is no incentive for manufacturers to cease classifying their devices as medical devices as a result of the State limiting to whom these can be supplied.
    - Ensuring that there is no disincentive to manufacturers continuing to supply medical devices and PPE to Ireland by limiting to whom they can supply product.
    - Ceasing or affecting existing supply lines: introducing supply restrictions could interfere with smaller volume supply chains to pharmacies etc which are still in operation and serve local supply lines.
    - The HPRA, which would be required to enforce the legislation, advised that it may prove difficult to enforce a supply restriction, given that there is no register of distributors and importers of medical devices in Ireland.

- The Government can make an emergency order under the Consumer Protection Act 2007 to allow for **price control only**, in the case of **respirator masks**. There is no power to control supply by means of regulation, and primary legislation would be required. However, DBEI has indicated that the matter to restrict the sale of FFP2 and FFP3 masks to consumers could be approached from a consumer policy perspective rather than a safety perspective.

Provision of face coverings for the public

While it is not recommended to make wearing of masks compulsory, as evidence base is not strong, it is expected that in time mask use will increase in an act of social solidarity, such as we have seen in observance of social distancing.

The Covid-19 Medical Devices Criticality Assessment Sub-Group (MDCAG) was established as a subgroup to the NPHET on 3rd March 2020 to assess and anticipate potential medical device supply issues related to the Covid-19 outbreak, the priority being availability of PPE and medical devices used in diagnosis of Covid-19, treatment of Covid-19, supportive treatments, and treatments of secondary infections. PPE and medical devices identified by the WHO as essential to the prevention of transmission of Covid-19 has formed the basis of the work carried out by the MDCAG to date.

The availability of non-medical or cloth masks has not been considered by this group. However, in light of recent discussions with them, Medicines Unit have initiated dialogue with Enterprise Ireland who have had some engagement with some manufacturers in relation to the production of reusable

non-medical material masks, surgical masks, and respirator masks. To date they have not had any engagement in relation to disposable non-medical paper masks.

Paper masks

It is noted that in some countries paper masks (disposable) are being provided free at entrance to supermarkets, public transport and other outlets to supplement SD measures. Further discussion on the practicality of such a measure in Ireland is warranted. While there are a number of benefits to such a measure there are a number of considerations that must be addressed before a formal recommendation from NPHET is appropriate.

Potential benefits to introducing such a measure could include increased compliance and control and oversight of supply. However if this option is progressed consideration should be given to establishing a new group to address implementation issues such as funding, procurement of millions masks to be used daily, identifying and managing potential infection, prevention and control issues i.e. practical issues such as hand cleaning, dispensing and disposing of masks. In addition, strategic decisions in relation to the length of time the government should and could run the service, whether the service should be run by the Department of Health considering that non-medical masks are classified as consumer items, whether individual outlets should be responsible for this service, identification of appropriate sites and mechanisms for distribution, will all need to be addressed.

Cloth masks

Some countries have asked the public to wear cloth coverings in certain circumstances. The question arises as to whether there is value in ensuring a production and availability of such masks such that persons are not required to make their own, and can use them in as safe a way as possible. In that context, it is noted that a new standard has been developed by AFNOR in France with regard to the production of cloth masks. The AFNOR certification is the official national standardization and certification body in France under the French Ministry of Industry. AFNOR has produced a reference document that anyone can use to make "barrier masks". Intended for both mask manufacturers and the public, guidance on how to make masks for all healthy individuals has been published. This guidance document includes; the minimum requirements for mass-produced and homemade masks, the tests to ensure that barrier masks are effective, tips on how to use and clean masks, the preferred materials, dimensions and types of straps, among other information. The guidance document is updated as suggested improvements are approved by the 150 experts who were involved in the first version published on 27 March 2020.[i]

In the context of our current situation, in order to ensure sufficient availability of masks to meet increased national demands as a result of NPHET recommendations, and given the lack of evidence of any specific standard for non-medical masks' coverings, it may be worth further considering whether or not standards are necessary or of overall benefit at this time. As an alternative strategy, it may be helpful to consider if existing standards should be used as helpful guidance rather than statutory obligations.

This is not withstanding however, the importance of safety standards in relation to general consumer products, such as non-medical face masks, that are placed on the Irish market, either by indigenous producers or via importers, such as use of toxic chemicals, potential choking hazards, etc. Further engagement with the CCPC and NSAI may be required in this regard.

It is proposed that consideration to the question of production etc of cloth masks be advanced, supported by the Medicines Unit in conjunction with DBEI and bringing on board as required the necessary advisors, stakeholders, and other Government departments and agencies.

Noting that standards could be introduced or adapted over time as more clinical data becomes available, in line with any standards system, the following should be considered:

- Whether the introduction of defined standards provide any additional clinical benefit or whether the standards impose an additional burden that may limit supply of non-medical masks going forward.
- Examine the benefit of having set standards vs the risk of stunting supply, especially where there is no clinical evidence to support standards.
- Whether the imposition of standards would be in conflict with the broader idea of 'face coverings'.

The Communications message

A strong risk communication strategy is required, which will include messaging on the following:

- The wearing of masks by healthy persons in the community is an additional public health measure for situations where physical distancing of two metres is difficult to maintain eg supermarkets or public transport.
- Wearing of masks supplements existing guidance on hand washing which must continue to be implemented.
- Medical masks (ie surgical and respirator) are to be reserved for healthcare workers [and others].
- As we prepare to enter a "new normal," wearing a mask in enclosed spaces where it is difficult to maintain social distancing is an act of solidarity in our unified action in the fight against this common threat and reinforces the importance of social distancing measures. (Wearing masks reduces the transmission of the virus from the wearer, by catching droplets of sneezes or coughs).
- The requirement to wear a mask does not affect the existing direction for persons who have been diagnosed with COVID-19 or who are displaying symptoms of COVID-19; they must self-isolate.
- The HSPC and HSE website should provide guidance regarding the use of facemasks: how to apply, wear and remove the mask; disposal; cleaning/washing. Guidance can be drawn from a number of websites already in use, eg the CDC describes in clear terms how to make, wear, remove and clean a cloth face mask.

Appendix 1 - International Overview

Information available re position of certain countries in relation to face masks by the public

Country	Settings	Provided by whom
Hungary	Every shop, food store, market. From 27 April, masks/face covering mandatory for public transport and in shops.	Several municipalities buy face masks and distribute them among their residents (an increasing trend). HU has bought a mask production line from China.
Austria	Restaurant workers. In larger shops, taxis and public transport. Re-opening of non-essential businesses is conditional on staff and customers wearing face masks	Available free at entrance of shops.
Belgium	Phase 1 (from 4.05): shops selling fabric and materials for making homemade masks reopen. Masks mandatory on public transport and strongly advised elsewhere Phase 2 (from 18.05): masks mandatory for all pupils over 12 and all staff.	
Bulgaria:	All public places until 26 April	
Cyprus:	When in public (professional or homemade)	
Germany:	Cities in 10 of 16 states in certain areas, e.g. shopping, public transport and workplaces where SD of 1.5 metres not possible (In Berlin, obligation restricted to public transport.)	
Portugal	Expectation that, in plan yet to be announced, wearing of face masks will be mandatory in schools and on public transport	
Spain:		Govt has distributed 10 million protection masks on public transport across the country since 13.04
Czechia (Czech Republic)	Facemasks remain obligatory – and will remain obligatory to June and beyond People must wear masks (professional or homemade) when in public to cover mouth and nose while outside of their residence.	
Luxembourg	Facemasks to be mandatory wef 20.04 for people to wear a mask in all situations where a minimum of 2m distance from other people not guaranteed. E.g. at work, in shops and supermarkets, at outdoor markets, on public transport. Govt. to further evaluate in 3 weeks	Surgical masks to be distributed to all households in the coming days.
Slovenia	In indoor public spaces, use of masks and gloves, mandatory. (There is also information to suggest that *Medical masks and gloves should be worn in public*.)	
France	The wearing of masks in public may become required in certain areas, such as in public transport, from May 11.	From May 11, France will provide masks to the general public, particularly for the professions most at risk.
Italy	In Lombardy, a new decree obliges all citizens to	

	wear a mask when in shops and out on the street. Tuscany to introduce similar.	
Poland	From 16 April, the public will be obliged to cover their mouth and nose in public…will apply at all stages of exit strategy	Govt. has launched "Polish sewing rooms" to produce 100 million affordable masks by end of June
Slovakia	Wearing Face masks or similar compulsory outside of the home. *Exemptions for children under 2, walking in nature if nobody else within 20m distance, public transport drivers if in separate cabins.*	
Lithuania	Compulsory to wear facemask (or scarf/similar to cover face) when going outside.	
Romania	After 15 May when State of Emergency ends everyone will be required to wear protective masks in enclosed public spaces and on public transport.	
Switzerland		The Federal Council does not envisage a general obligation to wear a mask Notwithstanding, the Government will supply 1 million hygiene masks daily to leading retailers for 2 weeks.
USA		The US Centers for Disease Control and Prevention (CDC) recommends wearing cloth face coverings as an **additional, voluntary public health measure** in public settings where other social distancing measures are difficult to maintain (e.g., grocery stores and pharmacies), especially in areas of significant community-based transmission.

[i] https://masques-barrieres.afnor.org/home/telechargement?culture=en-GB