

# STRATEGIC USE OF MASKS AS AN ELEMENT OF A NON-PHARMACEUTICAL MEASURES SET FOR A PANDEMIC

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# **STRATEGIC USE OF MASKS AS AN ELEMENT OF A NON-PHARMACEUTICAL MEASURES SET FOR A PANDEMIC**

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## Technical Sheet

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## Executive Summary

The technical report hereby presented consists of two parts. The first part, the Technical report, is the scientific literature review. The review features epidemiological, virological and clinical evidence as well as sociological, educational and economic and industrial sources.

The second part is ASPHER's recommendations related to the use of masks and potential implementation. We set out a protocol for the management and use of masks. This Protocol aims to replace the usual operational approach to the use of mask recommendations by a strategic one. This strategic mask management aims to assist decision-making and management on stock management of the various types of mask, to ensure that all citizens have access to the best mask available on a given time according to personal specific needs; preserving the best technical quality masks for the priority groups, as a mask stock management based on a forecast over the best possible fit according to the pandemic curve; including the economical dimension in the global issue of the generalized mask use by the population. The Protocol also provides a different reading on the management and use of masks by the population depending on the specific moments of the epidemic period.

To produce both parts, a mixed production method was followed, between the writing of a technical report made by the Unit of Public Health of the Health Sciences Institute of the Catholic University of Portugal (USP/ICS-UCP), and continued peer-review and other contributions of the work development by the monitoring group appointed by ASPHER and its Board.

The COVID-19 pandemic has raised debate on the use or non-use of masks by the general public in almost all European countries. Decision-making should be based on scientific knowledge, but where knowledge is incomplete as in the current pandemic, principles of precaution, and pragmatism, become increasingly important; political and professional judgements have played an increasing role.

ASPHER, follows the principle that decisions that affect the health of whole populations should be based on the best scientific evidence available. Our aim is to contribute a

critical reading of the evidence so that decisions made by National or International Health Authorities may be more informed and effective with these contributions.

Public Health science is not exclusively a clinical or epidemiological enterprise. It involves also social, psychological and behavioural sciences in understanding individual and collective behaviours and beliefs. It recruits as well from ethics, economics and political science. In the context of mask use, we need to understand industrial processes, production, procurement and fairness in distribution. Public health insight and practice is central to an effective response to the threat posed by COVID-19 (SARS-COV-2 virus).

The ASPHER COVID-19 Task Force has concluded:

1. **The use of masks is not a panacea** to prevent viral transmission during an epidemic. It only makes sense as one element alongside other non-pharmaceutical measures (NPMs) (personal hygiene, physical distancing, and so on).
2. **The need and function of masks differs at various phases of the epidemic.** What is available from the evidence suggests that recommended mask use should change over the course of an epidemic:
  - The widespread use of masks has not been verified prior to community transmission when it is still possible to identify the active transmission chains.
  - Use of masks in the epidemic growth phase may mitigate viral transmission by asymptomatic patients and thus limit the epidemic's growth rate. However, at this point in the outbreak, isolation and physical distancing are most important to control transmission; social mixing with masks should be discouraged.
  - After the consolidated start of the decline in contagion processes and if economic activity is intended to re-start by the end of the confinement period, we do recommend use of masks. This is due to the intensification of the number of people in circulation and the return of citizens to living with older family members and populations at higher risk. At this stage, we recommend that, in addition to the portability of masks in public spaces, protective materials should be used when in contact with social groups vulnerable to COVID-19.
  - No evidence was found for the widespread use of masks in the final phase of the epidemic.
3. **ASPHER calls for the principle of a hierarchy of access to masks** to be respected according to the degree of exposure risk. Namely by reserving FFP2 and FFP3 masks for health professionals caring for COVID-19 patients, other health

professionals who may contact the virus and other workers playing critical roles to combat the epidemic

4. **There is a worldwide shortage of professional masks. Non-medical grade “social” masks will have to be used, if the aim is to recommend or require mask use for the entire population.** If not, there will be an aggravated shortage for health and other critical service workers and others at high risk, who need masks of adequate quality.
5. **Imposing the use of masks has implications beyond viral transmission.** Covering the face has sociological, personal image, religious and human rights implications. In taking a decision on mandatory or recommended use in public places, policymakers must evaluate freedoms and guarantees, aggravation of social inequalities and loss of normal human social interaction.
6. **The use of masks does not prevent viral transmission by other means,** namely through the hands when touching a contaminated mask. **If widespread use of masks is implemented, this decision must be accompanied by a strong public training campaign by health authorities with quality assurance processes.**
7. Only adequately produced masks can provide protections outweighing the risks of use. **The option to use social masks requires immediate training for the public** regarding which masks can present a barrier to viral transmission. Especially in homemade/DIY masks, clear instructions on the mask’s technical requirements must be made available and respected.
8. **Non-clinical advantages can be invoked in favor of the use of social masks by the population,** such as reduced demand for professional masks directed at health services; visual reinforcement of the need for physical distance; potential anticipation of economic activity.
9. **Personal Protective Equipment (PPE) has become an element of potential geopolitical interest and even national security.** It is essential that lessons are learned and shared, and that **countries and economical regions adequately strengthen manufacturing capacities, productive scalability, storage and distribution.** In Europe, there is a risk for the pandemic to worsen if the few current PPE suppliers are unable or unwilling to continue supplying PPE. Masks are among the critical materials to safeguard.
10. **States and Health Authorities must guarantee that legal and distribution control mechanisms are created to ensure the best and fairest possible use of the available masks at all times.**



11. The public health community is heavily involved in seeking to address inequalities in health. The COVID-19 pandemic is widening inequalities and creating greater health problems for people in poorer social circumstances. **The use of social masks may help to relieve situations of great poverty and social and mental distress. In countries without the capacity to have extended periods of confinement, the use of social masks can support, to some extent, a survival driven economic recovery by freeing up more activities.**
12. **There is a considerable absence of research and scientific knowledge** on many analytical dimensions related to masks, including:
- a. Knowledge of the physical and mechanical properties of non-medical grade “social” masks.
  - b. Availability of new classes of masks produced using new materials or new technologies.
  - c. Psychological aspects related to the use of masks, including persuasion, impact, stigmatization, etc.
  - d. Clinical effectiveness and efficiency of the use of masks alone and in conjunction with other NPMs.
  - e. Specificities related to the use of masks in non-hospital practice/activities, with people with dementia or other psychological problems, and with young children.

ASPHER calls on the Faculties and Research Centers throughout Europe to contribute to fill the knowledge gaps that have been identified in almost every aspect relating to masks and their use.

**Keywords:** Masks, COVID-19, Risk Mitigation, DIY, Non-Pharmaceutical Measures

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## **Part A – Scientific Review**

**UNMASKING THE POTENTIAL VALUE OF THE USE OF MASKS BY  
THE COMMUNITY IN THE CONTEXT OF THE COVID-19 PANDEMIC**

## 1. Introduction

The development of the COVID-19 pandemic has led to the hypothesis of implementing the widespread use of masks by the population in most countries, especially in the Western. The scarcity of PPE, namely masks (sometimes even for professionals), forced countries to consider the hypothesis of the population to resort to social masks. Social masks will hereby be designated as masks made of fabric and other materials, but not subject to medical device classification, nor subject to certification and traceability processes.

Social masks can be of two types: those made as a garment by the clothing industry and those made with fabrics or other materials commonly found at households, by do-it-yourself.

In contrast to Eastern countries, until now there was no socially widespread knowledge regarding the use of social masks, on the production of these masks in adequate quantity and quality or on the general population's knowledge regarding their production. Moreover, there is a diminished scientific and technical response on the mechanical properties of the materials used to produce social masks and especially its use as a filter for SARS-CoV-2, among many other issues identified below.

The discussion of generalized mask use (surgical or social masks) by the community goes beyond the scientific debate, into the mass media, social networks and political debate on many countries.

This discussion has been sparked around the experience in Asian countries who have implemented widespread mask use measures to control the epidemic, stating<sup>(1,2)</sup> (South Korea, China, Taiwan, Singapore, etc.) that it was instrumental in bending the epidemic expansion curve<sup>(3)</sup>, an opinion which has been reinforced when comparing the evolution in those countries with the epidemic curves found in European countries.

Based on what is currently known regarding the independent effect of each measure, it is impossible that the sole use of masks was capable of having such a great impact in bending the epidemic curve, which does not invalidate that this specific measure may have contributed, in some way, to this final result.

The debate on this issue is no longer under the umbrella of science and is currently led by social agents, the general population, politicians and journalists. Some local or national governments have radically changed their position without explaining why,

possibly through the pressure of citizen groups or lobbies in response to fear and panic. These situations were also either not well received by citizens and in some cases with measures being requested to be implemented. Those governments have gone from strongly discouraging the use of masks for apparently asymptomatic people, as based on the WHO recommendations, to imposing the use of the same masks for all people in public places<sup>(4)</sup>.

This was not necessarily consistent with the WHO's advice. Up to the moment of this article's writing, WHO has consistently stated that masks should be reserved for health care workers and persons with symptoms<sup>(1,5,6)</sup>. This indication was not due to clinical reasons, as seen in the U.S. General Surgeon statement<sup>(3)</sup>, but being based on the need to concentrate the masks stock available to health professionals in many countries and on the hierarchy of risks. On the other hand, for the general population the recommendation is that "masks may be worn in accordance with local customs or in accordance with advice by national authorities in the context of COVID-19"<sup>(4)</sup>.

Health professionals are also in need of other PPE, as they are the ones who deal with COVID-19 positive patients, being in great need of shoe protection, aprons, face shields, glasses, among other materials, whereas the general population is in principle excluded from this need, being only referred to repeated hand washing, physical distancing and the use of masks (in some populations at higher risk).

The situation that now arises about whether masks should be used, or not, by the population, exposed Health Services and Authorities along with the absence of an immediate and substantiated scientific response from the public health and research community. Therefore, it is of the utmost importance that the issue is recaptured to the public health realm, to provide debate and decision-making processes with a multidisciplinary scientific-based approach guidance, ranging from virologic, environmental, clinical to epidemiology, social sciences and public health ethics. In addition, the multidisciplinary approach needs an understanding of design, ergonomics and modern production, and procurement capabilities using sustainable materials.

Beyond the context surrounding the use of masks, it is important to consider which set of Non Pharmaceutical Measures (NPM) should be adopted to protect the population<sup>(7)</sup> as a whole. Redundancy is an engineering systems design consideration not often appreciated by the public or professionals. It describes the checks or extra overlapping steps built in to avoid known risk in a sequence of events. Most people see it as a waste, duplication, pointless bureaucracy. But it is normal engineering practice. It is vital in any system we are designing to reduce risk and harm, while also being extremely complex so we cannot know all that can go wrong.

Each measure is only fit to protect people from part of the contamination process and that there should be protection from redundancy between measures to cover situations where any of these interventions may fail. The general idea of the NPM is that each piece has a function for protecting one part of the body, but to have if possible a second barrier if the principle fails. For example: the plastic visor should retain all droplets. PPE clothing, although complete and closed, must be complemented with a disposable apron; gloves on contact with positive COVID must be two layers. In China they use 3 layers of gloves. Therefore, the idea is to have successive layers of equipment in a logic of redundancy.

The focus of the discussion should weigh the advantages and disadvantages of generalized mask use, its appropriate use and the different implementation levels, according to specific contexts (e.g. different countries, different prevalence rates, etc.) and dynamic changes in pandemic's features.

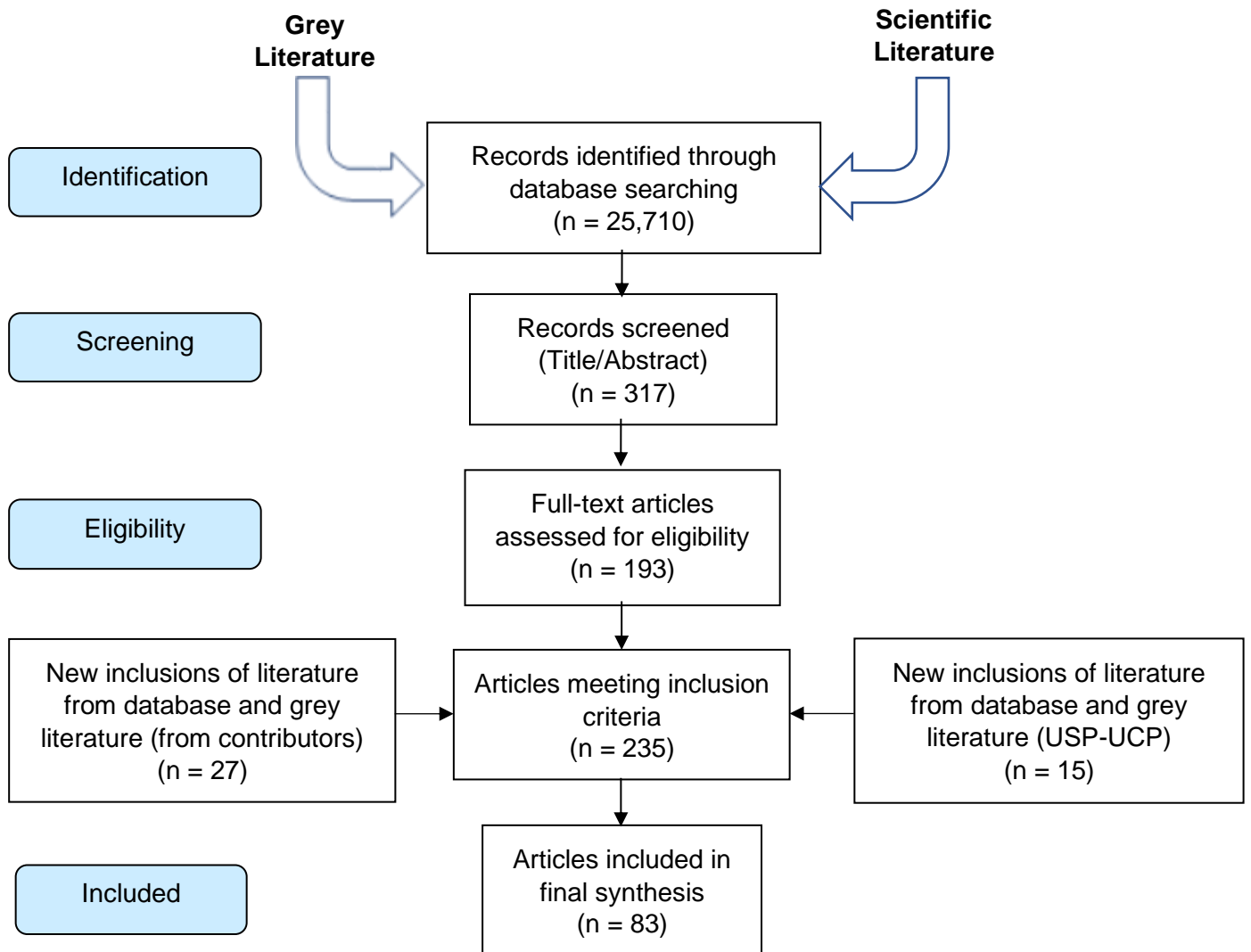
## **2. Methodology**

For the production of this work, bibliographical references related to the use of both professional and social masks (industrial and DIY) were surveyed. Given the emergent need for a response, indexed bibliographical bases were consulted and extended to Research Gate preprints and grey literature to capture publications from international health organizations (European Centre for Disease Control (ECDC), World Health Organisation (WHO), Centers for Disease Control, (CDC) and other national agencies ). This survey aimed to collect critical information about the evolution of policies and interventions in countries towards the pandemic and the experience that is being recorded with the use of masks.

After data collection and following work, aiming to shorten the production time, the first draft of this document was submitted to a monitoring group (described in the technical sheet) that carried out a peer review work and provided/requested the inclusion of new references, mostly produced in the previous days of writing this document.

The following flowchart describes the bibliographic survey process, as presented below:

**Figure 1: Flow diagram of the study selection aggregated over the topic areas reviewed.**



**Table 1: Inclusion and exclusion criteria of articles in the literature review survey**

<p><b>Inclusion criteria:</b></p> <ul style="list-style-type: none"> <li>• Present in the results from the searches focused in “COVID-19 Mask use”;</li> <li>• Publication and information collection performed after 2007;</li> <li>• Aim of the study must be about the use of masks, in aspects from sociological to technical, management, implementation phases, mask characteristics, and other related aspects.</li> </ul> <p><b>Exclusion criteria:</b></p> <ul style="list-style-type: none"> <li>• Publications or data from the publication before 2007.</li> </ul>
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Experts were also consulted for the collection of qualitative information in the areas considered to be lacking, or most difficult in the scientific domain by the team. This hearing cannot be classified as structured interviews, as there was no creation of a previous and discussed script. There were only discussions with the duration of one to two hours with each person to clarify technical and scientific aspects after the first bibliographic collection. When necessary, the discussion was repeated, with a much shorter duration, after the second bibliographic inclusion from the monitoring group.

**The following experts were heard:**

Prof. Doctor Edgar Fernandes: issues related to air turbulence and the use of masks, mechanical resistance of masks, sprays and aerosol particle properties.

Eng. Alexandre Guedes: the use of masks by immunosuppressed patients, mask ergonomics, patients' relationship with this new medical device.

Eng. Noélia Duarte: mask certifications and related processes.

Based on the collected material and discussions with the Peer Reviewers, a literature review was written that sought:

- a) To highlight the main dimensions regarding the adoption of widespread mask use by the population.
- b) In each dimension, to identify the main reference (if found) and point out the areas in need of research, in what may be seen as a call of research.
- c) Based on the literature review, to develop three guidelines, covering the following areas considered to be the most urgent:
  - Protocol for stock management and use of masks.
  - Guideline for the production of social masks.
  - Guideline for the use and elimination of social masks.

### **3. Background on the use of masks by the community**

The tradition of mask use in eastern countries' public health is historically active, contrary to what is verified in western countries. For example, mask use is a common measure in influenza seasons in the eastern countries (particularly in Asia), being

associated with more positive health behaviors and other personal hygiene practices (handwashing, respiratory hygiene, etc.)<sup>(8)</sup> and is well accepted in the community for its potential to protect against air pollution, to lessen the contagion chain in transmitting illness and as a collective courtesy to others<sup>(3,9)</sup>. On the other hand, the use of masks in western countries was only associated with the 1918 pandemic, as an infectious respiratory illness threat especially in Europe and in the USA. Since then and at least for the last few decades, the perception of the use of masks has been radically different since it has a stigmatizing connotation. This has been due to masks being associated with a sick person one must avoid for their contagious potential<sup>(10)</sup>.

Many historical factors (religious, cultural, legal, aesthetical, technical, etc.) have been contributing to hindering mechanisms linked to avoiding the use of masks in viral epidemics. For example, the measure has been previously discussed in a European context<sup>(11)</sup>, but not considered as a widespread measure in case of epidemic due to the lack of data regarding the mask's effectiveness in preventing respiratory infections. However, it should be noted that not having scientific data regarding the mask's effectiveness does not mean that they are not effective.

The use of masks from the contextual perspective of relationships between citizens, along with the social spaces aesthetics takes on many more dimensions than those strictly related to Public Health. The following stand out: the political, socio-ethnological, psychological, efficacy and efficiency management for hospital supplies, and the management of industrial production, among others.

### **3.1. Scientific reasons among different sciences**

#### **3.1.1. Political science reasons**

Politics may be associated with positive connotations (when we speak as "the art or science of government", and "the art of the possible") or negative ones (such as "the dirty game of playing politics"). The generalized use of masks by the community has been set on the public agenda in many countries, not only for noble political purposes but also to expose for criticism those who had not implemented these measures. This confrontation has been amplified by journalists, and other political and social actors, who often convey their ideas solely based on the immediate thinking and public pressure, and without proper background on Public Health sciences.

This issue must be redirected and led (or at least strongly influenced) by the Public Health professional community (Schools and researchers). Otherwise, by the principle

of political vacuum, which can also be applied to the professional context in power relationships between different professions, the ecological niche will be occupied by any other social actor, who will merely express opinions that fulfill the gap regarding this issue, with the inherent risk of leading the discussion without a scientific approach, and the cumulative risk of using populist arguments.

### **3.1.2. Socio-ethnological scientific reasons**

In the Public Health domain, the analysis must be taken to understand the sociological and ethnological phenomena in which outbreaks exist, to enhance the acceptance and integration of guidelines that may be provided beyond the administrative and clinical sphere.

Each person has a different inter-body distance (the measurement of chest distances between two people who are talking) which is culturally determined as stated in the international negotiation's theory and psychiatry. Knowing that the physical distance of communication is one of the factors assumed as a contagion mediator, we should also take this into account in our approach. People of Anglo Saxon, German or Scandinavian culture maintain 100-110cm of distance during their interaction. For people from Southern Europe, the natural position between the bodies is about 90 cm. In Latin American people and some people from Africa and South Asia, the distance between chests is around 80cm<sup>(12)</sup>. The natural proximity of communication must therefore be considered regarding what is known about contagion mechanisms, representing one of several socio-ethnological factors that must be explored.

In Japan and other Asian countries, mask-wearing became a socially accepted and applauded protective practice after the exposure to commercial, corporate and political pressures which encouraged individual responsibility for health protection, particularly after 1990<sup>(13)</sup>.

Individuals in different cultures have different behavior patterns, such as touching their faces several times per hour, as well as on the body of the person with whom they speak.

The fact is that cultural differences can be (or can become) a risk factor, with positive or negative directions that also involves many other complex cultural dimensions<sup>(13)</sup>.

This subject, and especially the use of masks by the population should be an object of future polycentric research, due to the cultural dimension playing a very relevant role in incorrect compliance rates and therefore in association with contagion risk. In other

words, very scarce multidisciplinary research was made to evaluate masks' efficacy on the field for any type of mask.

### **3.1.3. Psychological scientific reasons**

The condition (COVID-19) tends to be portrayed in the media as being treated by health care professionals wearing conspicuous PPE. This tends to scare the population<sup>(14)</sup> because this was not so clearly seen in previous respiratory epidemics. There is only social memory of the use of this equipment during the Ebola, SARS and MERS outbreaks, and yet there is still a latent fear of illness and death present in the community<sup>(14)</sup>.

Naturally, people may question if they are being left unprotected if no protection material is recommended for their use<sup>(15)</sup>. Moreover, since the virus is an invisible aggressor, it makes it impossible to physically perceive the threat which generates psychological rejection, being necessary to tailor measures that address these socially shared feelings. It should also be considered that these negative psychological effects have even been increased by extended periods of confinement.

Therefore, Public Health must consider the integration of the psychological dimension, and present holistic proposals capable of providing meaning to the sacrifices made by individuals and collectively, by populations. Only meaning provides sense to sacrifices to reinforce behaviors, with the use of masks representing a tangible way of dealing with this fear, by using something tangible to combat the danger. In a complementary way, and from the opposite perspective, we must consider the psychological and physical error that the false security of using masks can imply, especially if they are not properly used. For these reasons of strong psychological impact, countries have developed solutions in which, alongside Public Health and medical measures, psychological responses have been integrated to respond to fear<sup>(13)</sup>.

### **3.1.4. Epidemiological impact over mask technologies**

The number of unknown factors regarding SARS-Cov-2 transmission pathways is still broad<sup>(18)</sup>, which has hindered a full scientific discussion or even epidemiologically modeling the impact of the adoption/non-adoption of masks by the community. We also have poor understanding of the effect of meteorology on COVID-19- for example, effects of ultra-violet light, humidity, temperature<sup>(19)</sup>.

These factors seem to have some impact degree on the disease's epidemiological behavior and will certainly have it on the mask's mechanical behavior (possibly

including non-waterproof masks), representing the creation of new mechanical risks to breathing and permeability damage, among others<sup>(20)</sup>.

A great portion of these aspects is yet to be theorized, with elements already published being very partial and in small numbers.

It must also be noted that there is a lack of theories regarding mechanical behaviors of the materials constituting masks<sup>(20)</sup>, of airflow turbulence, and mainly with importance for the epidemiology, of the mechanical and biological behavior of all masks (especially DIY) in each of the major human activities.

The sparse existing theories are focused on the behavior of professional masks in a hospital or industrial environment contexts for which they were created and studied. Virtually all knowledge is very limited regarding the behavior of professional masks and social masks in activities such as sports, work activity usually not subject to the use of a mask, use in transports with airflow.

Furthermore, scarce literature has shown the variance of the capacity of efficiency and effectiveness of each mask according to the developed activity. In most cases, masks were designed for hospital situations or for professions that deal with toxic products. Considering the identified resistance which determines its classification, there is always a loss for most activities. There is also a lack of research on this issue to cover many other activities and to inquire about the possible needs in the future to develop masks for specific activities other than those for which the current masks were designed.

Finally, there is an almost total absence of literature on the application of social masks in children and young people. For example, no theoretical or even empirical framework is defined on the age limits for types of masks, children's activities and their impact on masks use and efficacy, among other operational aspects. It is only known that for professional and social masks, effectiveness and efficiency drops abruptly for children and youth groups<sup>(21)</sup>. The same issue must be considered for other groups: people with dementia and disturbed psychologic capacities/behaviors, among other aspects.

This lack of knowledge has led to very simplified discussions on the mask issue, with dichotomous options: use or non-use, for which the public health domain must also bring to the debate in-between states such as use by risk groups; use of certain masks; training in the use of masks; when (and whom) to use masks according to the epidemiologic curve.

### **3.1.5. Public Health principles about the use/non-use of masks by the community**

Whatever the approach from the public health community, it is essential to be explicit about our principles that are informing our recommendations.

Where there is insufficient and unclear evidence from binary randomized trials or systematic reviews, we are of necessity, forming judgements, based on a range of sources and applying pragmatic, and precautionary approaches. Where the ‘best is the enemy of the good’ we should apply the ‘good’.

Events such as the current COVID-19 pandemic will repeat itself in history and possibly more frequently due to the degradation of the environment, in particular with the disruption of ecosystems as a result of the climatic breakdown, inequalities, literacy/numeracy, poverty, among others.

In these situations, there must be a clear answer from the Schools of Public Health and public health professionals regarding a strategic vision providing scientific answers when needed, with a reasoned appraisal of arguments for or against the measures currently in use. The literature that was found is mostly directed to very specific professionals and not for the general population.

The rapidly evolving position of the main Health Authorities about masks and rules from governments shows that much work is still to be achieved to create a public health scientific doctrine about generalized use of masks.

## **4. Countries measures and evolution of health entities recommendations**

Until recently, the CDC-USA shared a common recommendation with WHO regarding the use of masks only by people who have symptoms of respiratory infection who are in contact with other individuals and by those who are providing health care. However, the CDC’s position shifted towards recommending the widespread wearing of cloth face coverings in the community<sup>(22,23)</sup>.

Below there are presented some countries among those most affected by COVID-19 and respective recommendations on the widespread use of masks by the population.

**Table 2: List of countries with most infected COVID-19 cases in the world and their recommendations on the widespread mask use**

Country	Recommendation on the widespread use of social masks and other	Country	Recommendation on the widespread use of social masks and other
USA	Yes <sup>(3,22)</sup>	UK	No <sup>(3)</sup>
Spain	Partially <sup>(24)</sup>	Switzerland	No <sup>(33,34)</sup>
Italy	Partially <sup>(25,26)</sup>	Turkey	Yes <sup>(35)</sup>
Germany	Partially <sup>(27-29)</sup>	Belgium	No <sup>(36)</sup>
China	Yes <sup>(3)</sup>	Netherlands	?
France	Partially <sup>(30,31)</sup>	Canada	Partially <sup>(37,38)</sup>
Iran	Yes <sup>(32)</sup>	Austria	Yes <sup>(39)</sup>

The same position shift regarding the widespread of masks by some Western States<sup>(40)</sup>. In Europe, up to the moment of the document's writing, only the Czech Republic, Austria, Slovakia, the city of Jena (in Germany) and the Lombardy/Tuscany regions (in Italy), have implemented the mandatory use of mask by all the population, differing in some aspects regarding its application<sup>(41)</sup>. For example, in the Czech Republic, DIY masks began to be produced by the general population. In Austria, this measure is mandatory to enter facilities such as supermarkets, with millions of masks expected to be distributed at the entrance of such settings. In Slovakia, all individuals must wear masks on public spaces, with the same being achieved in Jena by using DIY masks in addition to masks that offer better protection.

In Asia, mask use by the community is widespread, such as in China, Taiwan, Mongolia, Singapore, South Korea, Hong Kong and Vietnam<sup>(42)</sup>.

## **5. Widespread use of masks by the community as a part of a NPMs set**

Masks or any other isolated NPMs cannot be a panacea against the spread of the disease but only as a piece of a whole set of NPMs, based on the complementarity of protections and the redundancy of barriers.

Different people in different social contexts need different degrees of NPM barriers. Professionals may require a whole specific PPE set, but the same professional at home no longer needs it. The NPM set is defined by the activity performed concerning the disease, by the health context in which the person is, and the set must be considered as a tailored protocol.

Its most basic form is that in which the citizen is healthy, until proven otherwise, and is outside a hospital context, which implies the application of NPMs focused on respecting physical distancing, hand washing, breathing protocol and eventually the use of masks.

### **5.1. Mask use as a complementary contagion barrier**

Despite not being yet possible to determine the widespread use of mask isolated gains and of those in association with other NPMs <sup>(43,44)</sup>, it is suggested<sup>(42,45)</sup> that it had a central effect in controlling the epidemic of the aforementioned Asian countries, by suppressing the number of infections and managing to bend the epidemic curve.

The general public must be trained for the idea of creating successive and complementary barriers, in which each measure loses meaning if not employed appropriately and with the complementary measures, thus opening a gap to contagion risks. For example, the use of masks in no way reduces the contagion by hand contact, droplets contamination through the eyes or by other means that are known or are yet to be known.

Therefore, the use of masks by the population as opposed to triggering the Principle of Risk Perception<sup>(46)</sup>, on which the WHO initial position is based, can be by the contrary an element of reinforcement of the complementary measures that form the preventive structure.



The Principle of Risk Perception<sup>1</sup> works when there is no training for the user of the safety device because when feeling protected by any protective measure it alleviates safety practices. The key is always information and training as prevention measures, as it was applied with huge success in driving and industrial safety devices and vaccination campaigns. Good communication is vital in enabling understanding preventive measures and using them.

## **5.2. Mask types and characteristics**

For this discussion, it is important to know the types of masks that are available, their characteristics and for whom should they be prioritized. According to the literature, there are different degrees of protection against respiratory infections depending on the specificities of each type of mask, such as: particulate and/or medical respirators, of the FFP3/FFP2 type (N95) and similar, have a filtering efficiency up to 99%, while surgical masks have the potential to reduce the number of droplets that are found inside the mask by a quarter when comparing to the ones found on the outside of the mask; this difference was found to be around a third for DIY masks<sup>(47)</sup>.

In an experimental study conducted in 2008<sup>(48)</sup>, the transmission reduction potential of the aforementioned PPE was assessed. Results appointed for the use of any mask allowing a decrease of viral exposure and infection risk, while also considering factors such as incorrect use or imperfect fits. Therefore, despite no masks appointing for clear effectiveness in preventing COVID-19 infections<sup>(49)</sup>, it is possible to infer that some protection is better than no protection<sup>(7)</sup>.

## **5.3. Which mask should be recommended?**

The issue of which masks should be recommended is complex and fundamentally conditioned by socio-industrial factors rather than the clinical dimension. When resources are scarce and there is a moment of great restriction on its distribution, it may affect the adequate protection of health professionals. There may be the need of guaranteed safety masks (in Europe called FFP3/FFP2, following the “filtering facepiece” standards, equivalent to what in America is called N95, which follow the standards managed by the American National Institute of Occupational Safety and Health (NIOSH), surgical masks, air pollution masks, and others<sup>(16)</sup>. When this is the case, it is clear that the priority must be to ensure that the hospital environment and

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<sup>1</sup> According to this principle, when people are provided with an additional protection device, they tend to relax their safety behaviors due to feeling that they no longer need them so much.

the basic needs of the community (out-of-hospital) health care are met. But the situation is not clear cut and priorities need to be determined with good judgment. To address this issue, a risk mitigation protocol is proposed (See Recommendation 1).

In a situation of surgical masks abundance on the market, these would be the ideal type of masks. FFP2/FFP3 are unaffordable for mass-use due to price. These are also not desirable for mass use because they are medical devices which are certified and have mandatory traceability documents<sup>(50)</sup>.

Solely considering this scenario of surgical masks, in European terms, with a single average daily use (below the daily recommendations), it would represent more than 500 million masks a day. This means that several issues arise: economical, supply-chain and waste disposal/treatment. Even if there was government interest in investment and waste management, there is no short-term productive capacity, thus impossible to achieve. Countries that have implemented the widespread use of masks have targeted this issue by opting for the use of washable social masks.

#### **5.4. Use of social masks**

Considering the PPE worldwide shortage, the use of scarfs was recommended by health authorities<sup>(51)</sup>, if necessary, and now the use of social masks as a last-resort option, if no other mask is available for the community<sup>(30,52)</sup>. In many countries, these masks are also used by healthcare professionals due to lack of adequate materials, but it is hereby considered as a practice to be utterly avoided. Therefore, the approach of this document is only to consider the use of social masks by the community.

If a strategy of social mask use is implemented for the entire community, the correct procedure is to change masks when they become moist or wet. Ideally, everyone should have several masks that allow for daily changes and elimination when damaged, with each mask having to be immediately isolated after use (e.g. putting in a plastic bag) to avoid hand contamination and washed at temperatures higher than 50°C with appropriate detergents<sup>(23)</sup>.

These masks may be easily produced, by following specific instructions on the shape, dimensions and other production technical details, usually consisting of three to four layers and two types of fabric (quilting fabric, cotton sheets, etc.)<sup>(2,23)</sup>.

Moreover, it is also possible to produce social masks with other materials besides cloth, which eventually may provide a better protective ability than surgical masks<sup>(35)</sup>.

Currently, thousands of solutions are available on YouTube and other social networks, and hundreds of companies have become available to face this production as a new

business opportunity. Information related to social masks production and compliance is currently being disseminated at a small scale<sup>(53,54)</sup>, which does not mean that the total set adding all these small scales does not form a large scale. This flourishing opens new problems of parameterization of technical characteristics and therefore heterogeneity in production, particularly in DIY masks. For example, in a brief survey, solutions were found based on magical thinking (e.g. cotton fabric boiled in turmeric, assuming that the spice will kill SARS-CoV-2 particles that go through the outer layer of the mask). However, there are immense doubts regarding its success in the field where people in western countries are not trained in its production and use.

There are new ways of developing massive Adult Learning Education (ALE) through social networks, by an education system (that in the East is mobilized to spread this knowledge to families), by television content, among others, keeping in mind that it would always be favorable if these tutorials were supervised by professionals (ideally public health professionals) to optimize and ensure the best available form of these home solutions. In Part 2 a proposal of Guideline development about this issue is presented.

### **5.5. Swift massive production of masks**

To obtain an adequate number of masks to supply the technical needs of the entire population, as it will consist in massive quantities, options for its production must be considered, such as mobilizing the clothing industry or home-made production.

The clothing industry is not yet heavily mobilized in its productive capacity for the current crisis. On the contrary, the vast majority of the industrial park is at a standstill.

However, this industry is familiar with mass production procedures, for which producing millions of washable masks will be very easy, swift and guaranteeing the use of appropriate fabrics. Considering the costs of raw materials and production can allow introducing masks in the market with costs below 1€, possibly below 0.5€ per unit<sup>(47)</sup>.

The home-made production option is also viable, as anyone can easily produce a cloth mask in a few minutes by following specific instructions. The necessary fabrics are very easy to find, and one can even recycle used garments. However, it must be noted that not everyone has access to the capacities of producing a social mask due to not knowing how to sew fabrics, not having appropriate fabrics, among other operational issues.

## 6. Disadvantages of the mass use of masks by the community

### 6.1. The mandatory vs. non-mandatory use of masks

The widespread application of mask use measures must contemplate the discussion on its mandatory dimension, from which several main issues are identified.

#### 6.1.1. Mask stock supply

With the race (especially if mandatory use of masks is implemented) to buy the masks that offer the best quality of protection, the stock of FFP3, FFP2 and surgical masks will be very limited in places where those are mostly needed: the health care workers and patients. In this specific point, it is important to have in mind the aforementioned issues in point 6.3. regarding the supply and management of masks, the production of industrial or social masks and the geostrategic importance of masks.

An additional issue concerning the mask supply chain is the limited nature of produced masks as a medical device (those that are subject to “EN 149:2001 + A1:2009 Respiratory protective devices” and “EN 14683:2019 + AC:2019 Medical face masks” certifications)<sup>2</sup>, which requires that the answer is given essentially by two industrial subsectors.

Professional mask solutions that use diversified materials and technologies are lacking, an answer to this matter is important so that, in critical moments, pronounced dependence on industrial sectors and the supply of very specific materials are not aggravated. Equally, the solutions for social masks, although much wider and easier

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<sup>2</sup> European Committee for Standardization (CEN), European Norms:

- EN 149:2001 + A1:2009 Respiratory protective devices – Filtering half masks to protect against particles - Requirements, testing, marking (commonly referred to as ‘FFP masks’).
- EN 14683:2019+AC:2019 Medical face masks - Requirements and test methods.

In addition, ASTM presents a list of standards for masks, namely:

- ASTM F2299/F2299M-03(2017) Standard Test Method for Determining the Initial Efficiency of Materials Used in - Medical Face Masks to Penetration by Particulates Using Latex Spheres
- ASTM F2101-19 Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus (EN 14683)
- ASTM F2100-19 Standard Specification for Performance of Materials Used in Medical Face Masks
- ASTM F1862/F1862M-17 Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)
- ASTM F1494-14 Standard Terminology Relating to Protective Clothing

to supply, are also highly dependent on the virtues and defects of the fabrics' actions as a filter.

### **6.1.2. Equity in access to Health**

People with higher financial capacity will have a higher availability to acquire the best masks (FFP2/FFP3 and surgical), either legally or illegally. All the remaining population cannot afford these masks and neither do hospitals and other health facilities due to capital capacity.

In the application of a management and use protocol for masks, concentrating the materials with the best quality in the groups in most need of risk containment will certainly help countries to improve equity problems. However, it will not resolve the issues of illegal access to masks. There is a full proposal for solving this issue in Part 2: Recommendation 1.

### **6.1.3. Religion**

In some religions it may be considered sinful to use a face mask either in public or private settings, posing ethical and moral issues to those who share specific religious principles.

The situation also arises in countries where the burka and similar clothes can make difficult the use of masks, although these elements also theoretically possess a minimum degree of defense themselves.

Therefore, mandatory action regarding mask use can transform a health precaution into a human rights issue.

## **6.2. Collapse risk of the PPE supply chain in the competition to acquire professional/non-professional masks**

As stated above, the supply of masks and all other PPE material intended for healthcare professionals is experiencing significant supply restrictions<sup>(3)</sup>. Masks are among the main resource under stress demand and currently in shortage<sup>(57)</sup>.

It is foreseeable that the difficulty in replenishing hospital stocks will worsen if the worldwide number of patients is aggravated or if countries that export materials proceed to its restriction/suppression. This situation is aggravated by considering that

fear also leads the population to seek supplies of all types of masks, depleting stocks of those in hardware stores to pharmacies.

Moreover, it is possible to observe the price inflation due to the supply-demand market curve on medical device products<sup>(55)</sup> and non-ethical competition among countries for medical device supply<sup>(56)</sup>. This is a major potential threat for all countries, especially those with fewer resources.

The use of professional masks by the entire population, if not compensated by an alternative aggravates the supply-demand equilibrium point by establishing a new higher price difficult to afford by those with less wealth, increases the black market and diminishes the stock directed to professionals, eventually contributing for the collapse risk of the mask market. In general, any mask with clinical value that is removed from the health care circuit (e.g. black market, mask theft, etc.)<sup>(58)</sup> is yet another difficulty to overcome in providing adequate health and care to patients.

Therefore, it is important to create alternative paths for mask supply to reduce the competition of these market segments and in this way reduce final prices and protect stocks. Social masks are a preventive measure for avoiding the collapse of the professional mask market and in reducing the supply-demand equilibrium point that defines the price of masks.

### **6.3. Self-production mask risks**

There are thousands of fabrics and each one is very different in its behavior as a respiratory filter. There are cottons, wools, fibers, the latter very often and with better behavior because they are much less hydrophilic. So what makes a fabric more or less efficient as a mask filter is to be hydrophobic and to have the weave knots as close as possible. So a social mask must have several layers. At least one with hydrophobic properties facing the face, a hydrophilic intermediate to absorb the moisture that passes and a hydrophobic layer facing the outside to prevent the entry of moisture which is where the virus can be transported.

In South Korea they recommend that instead of 1 layer of hydrophilic cotton inside there are two.

A study for SARS CoV-1 carried out at that time determined that starting from this number of layers, what is gained in efficiency is lost in resistance to breathing, which can cause an increase in respiratory fatigue and therefore an increase in blood pressure.

It is important to consider the specific worldwide context in which industrial production is either at a standstill or seriously reduced. There must also be a clear orientation of which sectors should be mobilized in the production of PPE for the population.

To worsen the supply chain issue regarding these materials, it must be noted that the concentration of its production is mainly based in China. This leads to every country depending on its production at the moment, allowing the creation of situations that pose enormous risks either through the potential use of the supply-chain as a geostrategic political weapon or due to the resurgence possibility of a second pandemic wave in China, which may lead to the captivation of a significant part of PPE to supply their domestic needs.

To reinforce the reading on the use of the PPE supply-chain as a geopolitical weapon, there is the recent example of Russia, which has sent fifteen cargo planes loaded with PPE and ventilation material supplies, through the mediation of the German party AfD and the Italian party Lega Nord.

For the security of populations and the independence of States, it is essential that international cooperation mechanisms for materials critical to fighting COVID-19 are strengthened, as well as the capacitation of industrial sectors for training and production scalability in countries and economic regions, such as, for example, the European Union.

Governments need to know which sectors of activity should be given priority in opening or maintaining operations. The fact that a type X mask is recommended instead of type Y, means mobilizing different technologies and, therefore, different factories. The general mask use would have to resort to the production by the clothing industry or by self-produced tissue masks (DIY). These masks have (depending on the fabric) the potential issue of not being impermeable and contaminated particles can go through the fabric<sup>(47)</sup>. The problem with DIY is that the physical properties of the fabrics are very different from each other and so is the number of used layers. Too few layers or with very porous fabrics do not generate enough protection, and too many layers or using too dense fabrics can cause hypercapnia, fatigue, etc. Usually, DIY masks with three or four fabric layers are recommended, with half gauze<sup>(2)</sup>.

Assuming that they have some advantageous element, their incorrect removal for destruction or washing incurs in significant contagion risks during its handling.

Very few solutions are under research of structural new paths for masks<sup>(17)</sup>. The more diversified the solutions, the greater the response capacity in supply and the less the risk of stock rupture. Much thought and research should be done to expand the mask

options in terms of materials, supply chain sources, technological sources, to reduce the massive concentration of supply that results in the appalling lack of critical PPE.

#### **6.4. Mask misuse by the population**

The indication regarding the use of masks by the population who have access to this resource does not provide any guarantee that it is correctly used<sup>(59)</sup>.

No studies were found comparing incorrect mask use between professionals and general citizens, or only misuse by the population alone.

However, it must be noted that even among healthcare workers, it is common to observe the mask being misused or ill-fitted<sup>(60)</sup>. In a study from 2000, that assessed the correct use of respirators in the context of tuberculosis-patient isolation settings, the number of healthcare workers that did not comply with the correct use of these PPE materials was of 65%<sup>(61)</sup>. Therefore, the claimed performance by producers for each medical device and is very different from the real efficacy in the field.

To compare the efficacy of the masks, one should use data from professionals in the field and its use by the population. No data were found regarding this matter.

#### **6.5. Masks as a vehicle for stigmatization**

Considering that the use of masks is not a common behavior in Western countries, its adoption may lead to stigmatization of the wearer<sup>(63)</sup>. The initial recommendations<sup>(40)</sup> that only patients and health workers should wear masks (in work settings), later revised<sup>(43)</sup> by including risk groups (e.g. immunocompromised patients, etc.), was a stigmatizing measure itself and may even lead people who do not want to expose their pathology to have to do it on the street. Furthermore, as people who are healthy do not need to wear a mask, it may be considered as a threat by people who do not follow this measure, and being a stigmatization factor related to a person being ill, it is within the scope of public health obligations to fight stigmatization in Health<sup>(64)</sup>. The generalization of mask use to all the community eliminates the stigmatization issue to patients.

#### **6.6. Mask ergonomics**

One of the biggest problems with masks is their ergonomics, being generally uncomfortable. In all health services dealing with COVID-19 patients, countless health



professionals are left with creases on the face and other skin damage, which, although not serious in the sense of future injury, disturbs adequate work capacity and increases tiredness.

Moreover, some people live with diseases in which the use of masks might cause discomfort or pain, such as people with dermatological conditions, maxillofacial trauma, among others.

If the use of social masks by the community is recommended, the ergonomic choice will have to be considered. Otherwise, it may lead to the weariness of the user and frequent removals with all the associated risks. There is also scarce scientific literature related to mask ergonomics, and almost all the solutions found are based on instructions out from the field and are mostly based on the Asian experience (where faces have different formats from the ones in western countries)<sup>(2)</sup>, or from designers who strive to present solutions<sup>(53,54)</sup>, which however, have not been tested.

An essential issue must be considered when discussing and designing social masks: the balance between comfort and adequate fit to prevent peripheral air circulation. The lack of research must be considered on subjects related to fabrics usually available in western households, the geometric shape of the mask and its layers, methods of sewing/collage and studies of water-tightness.

## **7. Advantages of mass use of masks by the population**

### **7.1. Droplets, in sprays or aerosols? The size makes the difference**

A very popular argument is that both the surgical and social masks have a much higher degree of porosity than that of viral particles, including the SARS-CoV-2. It is only possible to retain the virus (size 50 to 200 nanometers with FFP2/FFP3 (N95) masks.

The question that must be raised is whether we should look for a first contagion barrier<sup>(66)</sup>, a defense that can only be reached by masks that defend the pulmonary alveoli (reached by aerosols)<sup>3</sup> or, above all, the upper nasal region (reached by sprays)<sup>4</sup>.

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<sup>3</sup> The aerosol is defined by particles smaller than 10 microns

<sup>4</sup> The spray is defined by particles larger than 10 microns

Given that the viral load necessary to trigger COVID-19 is unknown, one can look for part of this answer in the input protein used by SARS-Cov2 (the ACE2), which is rarer in the cells of the pulmonary alveoli and very present in the upper area of the nose<sup>(47)</sup>.

The probability that sprays represent a real risk of contagion is not out of context and is possibly even greater than aerosols, particularly in sprays from sneezing or coughing, visible to the naked eye when reaching dimensions close to the millimeter<sup>(67)</sup>. Masks that can be used will be insufficient for 100% protection; however, since 2008 different studies, relative efficiency rates for larger particles were already pointed out including DIY masks efficiency, presumably those where contagion is more likely. Results show an efficiency level regarding median interquartile range (IQR) protection factors of 66-113 for FFP2 masks (depending on the activity performed); 4.1 to 5.3 for surgical masks; 2.2 to 3.2 for DIY masks in adults<sup>(21)</sup>. For children these values correspond to 13-35, 3.2-4.9, 1.9-2.2, respectively<sup>(21)</sup>.

For all the aforementioned masks, the efficiency is related to adequate compliance with its use and was found to decrease with the duration of continuous mask use<sup>(68,69)</sup>. Also, extended use beyond the recommended for each facemask and/or respirator and its reuse are both risk practices that should be avoided by the wearer due to increased risk of contamination<sup>(70)</sup>.

Surgical masks or even DIY masks made under technical instructions can play a valuable role in defending populations and in containing epidemics, as presented below.

## **7.2. Protection from asymptomatic patients**

An important consideration is the capacity for viral containment of those who are already transmitting the virus but are not yet identified as COVID-19 patients. People who are infected with SARS-CoV-2 have an unknown degree of transmission of infection<sup>(43,65)</sup>. It has been estimated by the CDC that there is a 25% probability of individuals who are infected with COVID-19 are asymptomatic cases<sup>(71)</sup>. There is therefore a potential to protect uninfected members of the public from asymptomatic people carrying the virus. The use of masks would be an additional barrier to reduce overall droplet transmission<sup>(7,72,73)</sup>, thus having the potential to reduce infection rates by preventing contamination of the environment<sup>(43)</sup>. As a consequence, considering the multiplicative nature of the cycles, avoiding contagion in an initial cycle can lead to major future consequences<sup>(65,74,75)</sup>. Although it is not the most appropriate vision, if a person in the community (who is not aware of being infected) is assumed as an initial patient (in the absence of a better value, the 25% proposed by the CDC may be

considered), and in this case is wearing a mask, the probability of transmission will be reduced substantially, thus lowering what would conceptually be  $R_0$ .

### **7.3. The positive contribution from masks requires adequate use compliance**

The implementation of widespread mask use (mandatory or non-mandatory) measures must always be accompanied by education formation programmes on how to use these PPE pieces to reduce the potential of misuse or ill-fitting situations. The training should focus the instructions on its production, use and disposal/washing, among other aspects<sup>(43)</sup>. Considering the recommendations of WHO, it is stated that if one is to wear a mask it is necessary that its handling and disposal are adequate.

Raising awareness and citizenship is the only safe way towards responsible societies. In favor of the rapid adoption of care with the use and handling of masks by the population, it is known that everyone is primarily concerned with the health and safety of those they care for. If it is communicated that the first to potentially suffer from mishandling masks are the household members, due to being the closest relationships, it is a strong persuasive argument. To this end, written instructions, posters and videos were developed<sup>(40)</sup>.

If training programmes do not follow the implementation of the widespread mask use, new contagion risks for the infection by SARS-CoV-2 are originated. Considering that the efficiency of the masks for children and young people, as presented above, is substantially lower, the educational apparatus in each country can be mobilized so that this weakness can be partially compensated by providing better and insightful training. It is also possible to discuss specific training needs in population groups that, due to their nature, age, education, diseases, among others, require specific training.

### **7.4. Masks as a tool for raising physical distance awareness**

Most countries have adopted the recommendation of maintaining a physical distance of 1 to 2 meters in communication between people. Considering that saliva particles that are expelled when speaking have a usual range of up to 1.2-1.4m, this physical distance seems to be enough. The question that must be raised is that people who are sick in the contagion phase, sneeze (airflow of 50 m/sec) and cough (airflow of 10/sec)<sup>(47)</sup>, with these symptoms being present in most COVID-19 cases.

The airflow may project particles up to 6m away from the emitter, making the recommended physical distance little or not useful at all. It is defended that along with physical distance measures and mask use it is possible to significantly diminish possible airborne transmission by droplets if the projection of respiratory particles to the air is lessened<sup>(76)</sup>.

## **7.5. Masks as a psychological support mechanism**

As mentioned in point 3.1.3., the use of the mask has undeniable advantages of psychological response<sup>(62)</sup>. It turns risk into something tangible with an object that embodies the threat and its defense against it, thus reducing the feeling of lack of protection. When most people feel the need to use something to protect themselves, it is due to danger being more present than many want to admit. This physical sense of danger allows people to think better, better manage negative feelings and their relationship with others.

In various pathologies (and particularly in pediatrics), for example in oncology, a psychotherapy technique is used in which dolls that represent the disease are used to have something that makes the threat something tangible.

In the pandemic context, there is the idea that the use of masks, including social masks, contributes to the awareness of physical distance in social contexts and more conscious health behavior<sup>(62)</sup>. It can also be an element of inner peacemaking while providing a feeling of parity with people that seemed to be dominating the epidemic so far and that steps are being taken in the right direction, aiming at the end of this difficult period.

However, it is important to note that the use of masks can generate a feeling of protection that leads to relaxing essential safety measures (e.g. hand hygiene, social distancing, etc.) But evidence for this has yet to be shown.<sup>(62)</sup>

## **7.6. The mask as a tool to deal with the end of the confinement period**

It is also important to consider that, with the prolongation of the social confinement time, the desire to resume social contacts will increase.

When the lifting of the quarantine measures is decided by many countries to a greater or lesser extent, there is a risk associated with the people's longing to resuming contact with their loved ones (especially in southern European countries where this intergenerational contact is double that of Northern Europe), considering that many

may be infected and unaware of their condition. It must be noted that the concept of social confinement has not required the isolation of 100% of the population. Therefore, people who continued to work (25% to 50% of the active population) were reducing contact with family members to a minimum. The end of the confinement will determine, for those who became infected during this period but who are still asymptomatic, the probability of spreading the disease.

This period might lead to a reset of pandemic dissemination among older people and at-risk groups since on a first stage people will tend to visit the elderly and sick family members. The mask may have a role in reducing the likelihood of the epidemic expanding in a new wave. Again, even if the mask efficacy was only around 30-40%<sup>(47)</sup> (worst scenario of protection into different activities) it would still be very significant, especially after a series of cycles.

It should be remembered that this kind of measure only results with strong campaigns of awareness, instruction and many more. The sole recommendation of masks use is almost a no effect measure. The pros will be almost equivalent to the cons.

## **7.7. Mask usefulness in the next autumn**

A similar area of interest in discussing the use of masks is the previous adequate instruction of the population regarding the possibility of a second pandemic wave by next autumn. No one knows whether it will occur, but many mathematical models predict it as the one of the American Medical Association<sup>(77)</sup>, among many others<sup>(78-80)</sup>.

The sole presence of this threat in the near horizon, whether it materializes or not, will generate anxiety in society: The political class is already very worn out by the first wave (or first and second if the pandemic resumes after the confinement period), along with the wear and tear caused in health systems (personnel, material, delay in all other clinical cases that are now being postponed, etc.) will compel to take preventive measures that show the population the effective concern and action of the political class. The widespread use of masks may be part of that answer.

Also, there is time to instruct people on how to use masks, to order millions of the PPE from the industry, and any other necessary procedures.

Therefore, the use of masks by the community can be a political response by itself, with many people need to be led in times of crisis due to the decrease in their capacity for initiative. The Key Opinion Leaders who have been most efficient in communicating have focused on involving people in the processes of fighting the pandemic. This way

they attributed meaning to what people had to do (in everything different from usual) and a feeling of belonging to a larger group that struggles with completing a common task.

As a result, the widespread use of masks has the potential to become a tool for social mobilization in the fight against the pandemic.

## **Synthetic Conclusion**

The synthetic conclusion of the literature review is that the use of social masks is a very complex issue, with diverse interconnected dimensions, and not a binary decision-making issue as usually considered. Therefore, the decision for implementing the widespread use of masks must be conducted under a strategic vision with a management plan, implementation phases over time, each with different characteristics, objectives and supply chain specificities, among other aspects.

It is advantageous and the generalized use of masks by the community should be implemented, as long as it is always inserted in a set of NPMs and never as an isolated form of protection. Use of masks by the public should be considered primarily as a way of mitigating the spread of COVID-19, in the asymptomatic period of the disease and post illness. To implement the generalized use of masks there is the need to assume that, by many reasons, the supply-chain of professional masks are not enough to fulfill the necessities. Therefore, it is necessary to assume that a strategy of generalized use of masks must incorporate social masks. The use of the latter is also a means of being able to prioritize professional masks for the groups that need them most, namely professionals, patients, and other high priority professional groups; finally, it is indicated that the massive use of masks by the entire population can support the containment of the epidemic expansion in the transitional period that mediates between social confinement and the resumption of economic activity, thus assuming great economic importance.

## **Part B – Possible Recommendations for Field Application**

# **1. Proposal of hierarchical priorities for access to masks: A Protocol of Use, Management and Risk Mitigation**

## **1.1. Use of masks by the entire population**

### **1.1.1. Everyone should use a mask in public places.**

From a public health perspective, it is assumed that if all the population is included in a measure of widespread mask use there are more gains than cons.

### **1.1.2. Mandatory/non-mandatory use.**

The discussion around the options of either using masks as a mandatory measure (a concept that has the consequence that the violation of the mandatory use can determine a sanction), or either recommended, must be based on the laws and culture of each country. Various elements external to the public health system, can increase the weight of arguments against mandatory use. However, the option of not being mandatory must carefully weigh the arguments, knowing that the non-adoption of masks by all citizens will increase the spread of the disease COVID-19 and, consequently, increase the number of deaths, the number of people in need of hospital care and social and economic losses.

## **1.2. Conceptual principles that instruct the Guideline**

- Principle of priority access to masks.
- Principle of complementarity of NPM.
- Principle of masks Supply-Chain Management under Just in Time (JIT) philosophy.
- Principle of differential effectiveness of masks.

## **1.3. Definition of the basic principles of the Protocol.**



### 1.3.1. Principle of Priority of Access to masks

The first principle of this protocol is based on a hierarchy of accesses to masks. It declares that each person, depending on the job done during the pandemic, has a different level of access to the masks. The objective of this principle is to contribute to the sustainability of the system for the fight against the pandemic, through the optimization of management and the use of respiratory protection devices (masks). The aim is to guarantee the best availability of masks for critical human resources.

The population is organized into four groups, in a hierarchy of access and availability of masks:

1st: Health and care workers as well as other workers with critical roles in crisis management.

2nd: Patients in a hospital or COVID-19 out-patients environment receiving home care.

3rd: Risk groups and other workers in key sectors exposed to increased risk during the performance of their tasks.

4th: General population.

In detail:

- a. Health Workers.** Guaranteeing facemasks to health workers is essential in the fight against the COVID-19 pandemic, as only by ensuring their safety, will it be possible to guarantee the sustainability of health services and to provide the best medical care services<sup>(81)</sup>. Available data shows that one of the main problems of the health systems is that a significant rate of professionals that deal with COVID-19 patients become sick or in quarantine. Those professionals are lacking in the most critical moment. In other situations, professionals reach high levels of tiredness and emotional exhaustion that recommend HR reserves for professionals' rotation. Only by preserving them in good health is it possible to apply this rotation strategy.

Regarding respiratory PPE for healthcare workers, the ideal materials would be the FFP2/3 (N95) masks due to their higher efficiency when compared to facemasks<sup>(68)</sup>.

However, in many countries, these masks are of short supply to meet the technical needs of this group. Therefore, not only disposable facemasks are also used by healthcare workers<sup>(70)</sup> but also reusable cloth masks are under use in many countries. However, it should be noted that, in previous studies, cloth

masks are not recommended to be used by healthcare workers as it is associated with higher rates of infection when compared with medical masks<sup>(23,82)</sup>.

Other mask alternatives have been studied and presented as an emergency resource<sup>(2,17)</sup>. However, it is noted that all the materials used in Health must be subject to the classification of Medical Device, certification processes (currently the Standards in force are “EN 149:2001 + A1:2009 Respiratory protective devices” and “EN 14683:2019 + AC:2019 Medical face masks” certifications)<sup>5</sup> and traceability. As none of these new masks fulfill these conditions, its use is only considered for outside health facilities.

- b. *Other critical non-health personnel for fighting the pandemic.*** During a huge crisis as a pandemic, countries need to have other critical workers beyond the health field, namely the various levels of country commands (civilians, military, civil protection and police) among other irreplaceable critical work positions.
- c. *Maintain an updated list of all professional positions provided in the points a. and b.*** There must an identification of who is the critical personnel (Health + command levels + others considered as having critical roles during the pandemic) so that at every moment people who are performing tasks with high contagion risk or maintenance of the national structure can receive the best masks available.

### 1.3.2. Principle of NPMs complementarity

This principle defines that no isolated NPM can succeed in creating barriers to the transmission of COVID-19 solely by its action.

Communication with the population about the use of masks should always be

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<sup>5</sup> European Committee for Standardization (CEN), European Norms:

- EN 149:2001 + A1:2009 Respiratory protective devices – Filtering half masks to protect against particles - Requirements, testing, marking (commonly referred to as ‘FFP masks’).
- EN 14683:2019+AC:2019 Medical face masks - Requirements and test methods.

In addition, ASTM presents a list of standards for masks, namely:

- ASTM F2299/F2299M-03(2017) Standard Test Method for Determining the Initial Efficiency of Materials Used in - Medical Face Masks to Penetration by Particulates Using Latex Spheres
- ASTM F2101-19 Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of *Staphylococcus aureus* (EN 14683)
- ASTM F2100-19 Standard Specification for Performance of Materials Used in Medical Face Masks
- ASTM F1862/F1862M-17 Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)
- ASTM F1494-14 Standard Terminology Relating to Protective Clothing

considered as an articulated set of: masks, frequent hand washing, physical distance, population confinement at the most critical moments of the pandemic curve and others that may be determined by the Health Authorities.

The citizen must be able to understand that he can obtain different degrees of effectiveness (measured by the non-transmission of the disease) and efficiency (measured by the optimization of the use of resources) depending on whether he adopts all or only part of the NPMs.

Different social groups also have different needs in the creation of NPMs protective barriers depending on the tasks they are developing concerning the degree of risk of contagion to which they are exposed. This should be distinguished in two levels:

- a. **Health facilities that receive COVID-19 positive patients.** Hospital settings have their own guidelines for NPMs directed for infection prevention and control precautions for COVID-19 (disinfection, hand/respiratory hygiene, PPE use, resource management, etc.)<sup>(83)</sup>. Despite being a broader NPM set than anywhere else, the philosophy is the same: the mask is only one piece among several constituents of the PPE.
- b. **Other places and social groups.** The presentation of masks to the population can never be made as a panacea for the risk of contagion, but always inserted in a broader context of NPMs in which the use of the mask has a partial contribution to the defense of its wearer.

This approach must be carried with specific means and greater intensity among the audiences where the masks tend, for reasons of use, to be less effective, for example: children and young people, individuals with mental illness, people with dementia and others in specific situations that should also be advised.

### **1.3.3. Principle of masks Supply Chain Management under JIT philosophy**

This principle states that the stock of masks of a country is at each moment the result of the existing previous stock, minus the present consumption, plus the present capacity of new supplies by the masks supply-chain. All of this regarding the forecast of pandemic evolution and the performance at a short-medium range supply-chain capacity. The following consequences were identified:

- a. The stock mask management should be conducted with basis on the forecast of needs, in strong relation to the pandemic expected curve, aiming to avoid a situation of mask stock collapse. Those situations already occurred and have shown aggravated consequences that never must be repeated.

- b. As stated in Principle one, the best masks available must be reserved for those exposed to higher risk. Only after guaranteeing the full supply and full stock reserves, in line with what is expected of needs for a short-medium term, could the next hierarchy level be supplied. Under this principle, this means that a legal framework must be produced that establishes priorities to access masks over the free market. The objective is to avoid the use of FFP2/FFP3 masks, for example, by regular citizens while high-risk professionals are working with low levels of mask capacity. If needed, the supply-chain of masks must be under Health or Economical Authority domain to rule its distribution.
- c. Due to the high unpredictability levels associate with a pandemic in each specific place, the masks supply chain should be ruled by a JIT (just in time) system for national distribution in a high capillarity level. This point aimed to solve many issues reported at a worldwide level, which despite having adequate masks supply at a national level, the distribution system did not match the necessities, especially for those facilities located far from the big centers or with small dimensions. The JIT system could manage, on a daily basis and, if needed, more than twice a day at all the healthcare network.

#### **1.3.4. Principle of differential effectiveness of masks**

Masks are considered as having an order of use associated with their effectiveness:

1. The classification of this access is assumed in order of decreasing effectiveness: FFP3 - FFP2 - Surgical - Social.
2. The latter can be split into industrialized and DIY masks. It is assumed that if produced by the industry, despite not being a medical device, it will at least have the same care as any cloth piece (the indication of fabric, instruction of washing and other technical specifications demonstrating that appropriate fabrics were used). As a result, it should present better performance than a home-made mask.

#### **1.4. Articulating the Principles in a functional system**

- 1.4.1.** The distribution of masks must be carried through a JIT supply system starting with the best masks being directed to the 1st group of workers in most need. Only after a hierarchical level of higher risk is fully satisfied does the next level

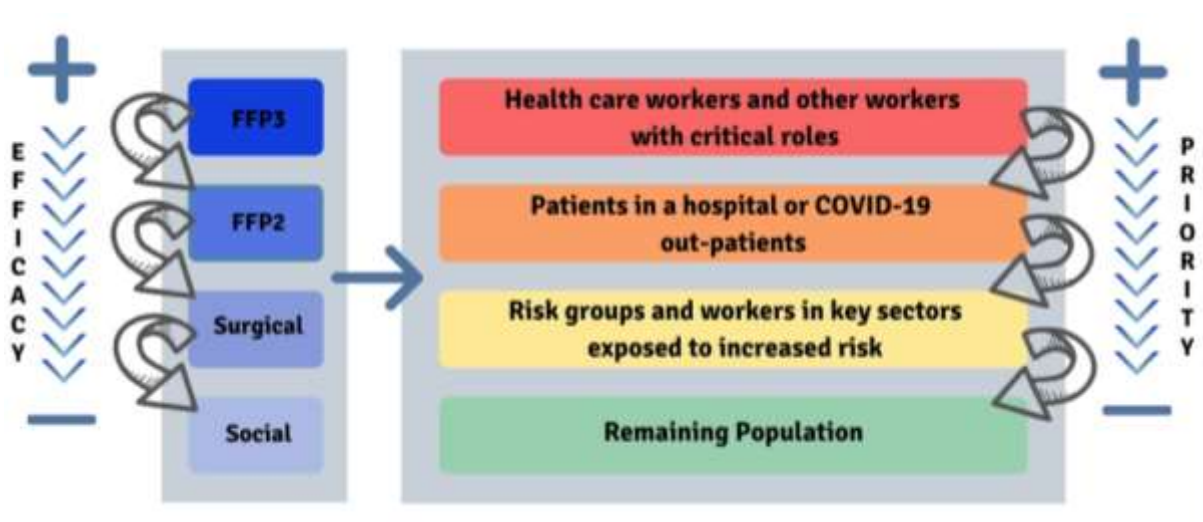
of need arises in the attribution of a given type of masks. When the desirable qualifying masks are not adequate to fully supply a given risk group (e.g. FFP2/FFP3 are not sufficient for health workers dealing with COVID-19), it must be supplied with the next qualified level of masks.

**1.4.2.** It should be considered that the total population is covered, from professional masks to DIY masks. The different mask types available for distribution should be thought on a daily base, aiming to establish an equilibrium between objective needs and objective availability of the supply chain, not only at the present but considering future needs, as explained above.

**1.4.3.** Any campaign directed to the mandatory or recommended use of masks must be accompanied by strong training action on the use and disposal of masks. It is essential that what is gained by not spreading the epidemic by aerial pathways is not lost through mishandling or incorrect disposal. Once again, children, young people and other groups mentioned above should be the object of specific actions.

**1.4.4.** In the case of the use of reusable masks, there must be training on the recognition of disposal points, shapes and storage care when left unused and in washing.

**Figure 2: Hierarchical priority distribution regarding the technical availability of masks and technical needs of specific groups**



## **1.5. The application of the Protocol in the context of specific positions on the pandemic curve**

The specific time in which the pandemic moment occurs has an impact on the strategy regarding the widespread use of masks. One of the consequences is that the population should not be obliged to wear masks all the time.

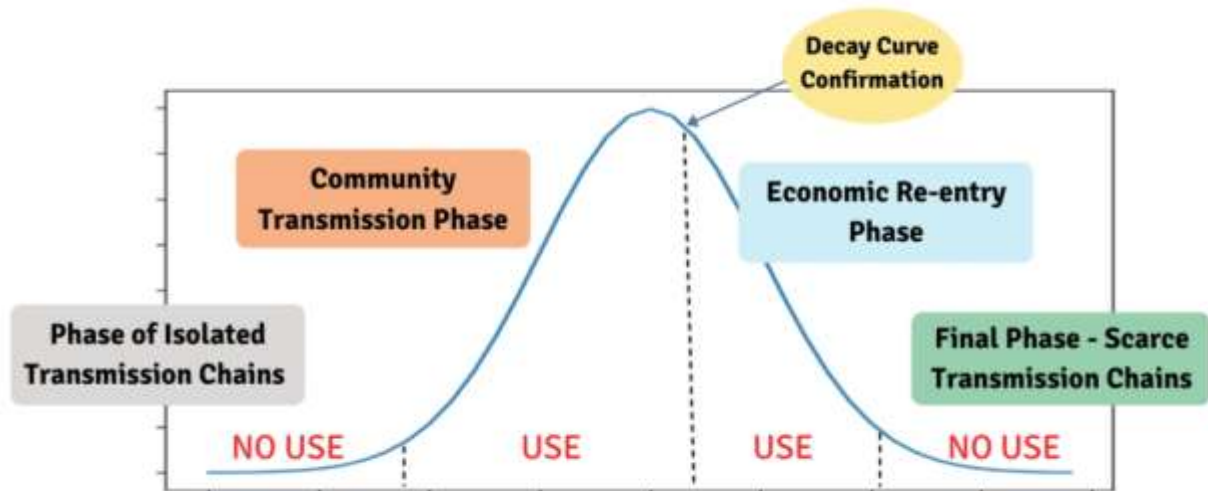
**1.5.1.** When a country is still at an early stage of the epidemic, with only imported or isolated transmission-chains, it only makes sense that masks are used by restricted groups of the population such as professionals, people who are ill and few other groups that could be considered. However, if the strategy to fight the epidemic is to be the widespread use of masks, that is the period in which the country should prepare the formation and training of populations, planning the JIT system for the distribution and management of masks, stocking the most complex materials, among other actions.

**1.5.2.** During the exponential growth phase of the epidemic, the use of the mask in public places is applied as reinforcement of confinement, since there is always a significant percentage of active people so that the society continues to function. The person wearing a mask is thus protecting other individuals almost as if he or she was also at home.

**1.5.3.** In the re-entry phase of the functioning economy and progressive end of the confinement period, the use of masks by the entire population has huge importance but a slightly different function: being impossible to avoid the compulsion to revisit loved ones and the resumption of intensified social contacts, asymptomatic infected people are much more likely to spread to more people. The mask is thus assumed as a tool to achieve an earlier economic recovery in addition to the role described above.

**1.5.4.** In the final phase of the epidemic, the widespread use of masks ceases to make sense and returns to a system of use, as in the first phase, alongside the evaluation of the indicators used in the management process. This last aspect is very important to be carried at this point to preserve operational memories and through them extracting knowledge for the future.

**Figure 3: Protocol application regarding the epidemic curve**



## 2. Proposal for Guideline of instructions for masks use

The second recommendation aims to fill the lack of knowledge concerning the population in Western countries in technical aspects of social masks regarding its use if produced by the clothing industry or by DIY.

People do not know how to choose the shape and characteristics that such a mask should have; the number of masks each person should have; rules on materials and production procedures, if self-produced; other technical aspects about the social mask that is considered to be of the utmost importance for the population.

Almost every country proposes different specifications for social masks: different number of layers, different shapes, different materials, among other aspects.

This recommendation could support the introduction of science and technique on the matter to establish a common base.

### **3. Proposal for Guideline programmes on training for the use of masks**

The third recommendation focuses on how to use social masks, the articulation with the remnant NPMs and care for the use, washing/recycling and safe disposal of these materials.

The main part of the risk in using a strategy of mask generalization is due to errors of use: handle contamination, erroneous elimination of masks, to leave the nose or mouth uncovered by the mask.

This guideline focuses on the topics that those programs should cover.



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