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Effectiveness of face masks for the population

A. Santarsiero[1], M. Giustini[1], F. Quadrini[2], D. D'Alessandro[3], G.M. Fara[4]

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Parole chiave: Mascherine non-mediche, Filtrazione, Infezioni, Mascherine mediche, Prevenzione, Virus, Mascherine commerciali di tessuto, Mascherine fatte in casa

Abstract

Background. *Health authorities and organizations consider non-medical face masks as an additional passive means to prevent virus diffusion. Communication strategies disseminate information among the population that such masks are essential for mitigating virus diffusion. However, scientific studies are not conclusive in showing the undisputed filtration efficiency of fabric/cloth facial masks (both commercial and homemade).*
Objectives. *This study examines scientific data about the effectiveness of face masks before and during the COVID-19 emergency. Present trends in the making of commercial and homemade fabric/cloth face masks are also examined.*
Methods*. Statistical data of published studies are analyzed and compared. Main considerations and suggestions are also extracted and discussed. Current approaches are examined for assessing the characteristics and effectiveness of fabric/cloth commercial and homemade face masks intended for the population.*
Results*. Conflicting data exist as to whether non-medical masks have a protective effect from the spread of respiratory viruses. Both medical masks (MDs) and respiratory personal protection equipment (PPE) show a given effectiveness value.*
Conclusion. *Concerning commercial and homemade fabric/cloth masks, giving general indications on the choice of materials and their assemblage is difficult as it is not possible to assess the effectiveness of the filter media with respect to the kind of multiphase fluid that may be emitted upon breathing, sneezing, or coughing under different environmental conditions. This is particularly important because airflow rate, temperature, humidity, and duration of use will affect the performance of filter media. Moreover, while a mask may have excellent filter media, droplets may leak into the face-piece unless there is an adequate facial seal. In the presence of leaks, any type of mask may actually offer less protection independently of its nominal filtering efficiency.*

[1] *Department of Environment and Health, Italian National Institute of Health, Rome, Italy*
[2] *Department of Industrial Engineering, University of Rome "Tor Vergata", Rome, Italy*
[3] *Department of Civil, Building and Environmental Engineering, Sapienza University of Rome, Italy*
[4] *Department of Public Health and Infectious Diseases, Sapienza University of Rome, Italy*

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Introduction

Owing to the SARS-COV-2 pandemic, in addition to the well-regulated facial masks there are also face masks intended for the use by the general population, that can be divided into two categories: commercial and homemade fabric/cloth masks. This almost unique situation is hard to compare with similar scenarios in the past, which entails the difficulty of using scientific data for predictions. These masks are worn in various social environments and settings, and non-predictable living conditions, i.e. in places and occasions quite different from those in which conventional face masks have been always designed for. Moreover, they are worn by the general public, not professionals or experts, and very often by children. Therefore, deriving effectiveness for the population at large from information on the use of masks by physicians, nurses and technicians, may be risky. Briefly, the following types of face masks are currently available on the market or simply used:

- Surgical face masks, also called medical masks, which fall within the category of medical devices (MDs) (1).
- Filtering face piece (FFP1, FFP2 and FFP3) masks, which are respiratory protective devices and fall within the category of personal protection equipment (PPE) (1).
- Commercial fabric/cloth masks, also called filtering face masks (1) or barrier masks, or non-medical masks (non-MDs), intended for use by the general population, are neither MDs in the sense of Regulation EU/2017/745 (2) nor PPE in the sense of Regulation EU/2016/425 (3).

Homemade fabric/cloth masks, i.e., "Do it Yourself" (DIY) masks, "*Confection artisanale*" in French (4), are made out of household materials by any person for personal use.

WHO (5) defines non-medical or "fabric" masks all those masks made from a variety of woven and non-woven fabrics (NWFs), such as polypropylene. WHO reports the following:

- *Non-medical/fabric masks may be made of different combinations of fabrics, layering sequences, and available in diverse shapes; few of such combinations have been systematically evaluated and there is no single design, choice of material, layering or shape among the non-medical masks that are available; the unlimited combination of fabrics and materials results in variable filtration and breathability.* (5).
- *A non-medical mask standard has been developed by the French Standardization Association (AFNOR Group), to define minimum performance in terms of filtration (minimum 70% solid particle filtration or droplet filtration) and breathability (maximum pressure difference of 0.6 mbar/cm^2 or maximum inhalation resistance of 2.4 mbar and maximum exhalation resistance of 3 mbar).*

Moreover, WHO sets a value, even if only as a preliminary guide, for the following three parameters: initial filtration efficiency, pressure drop and Filtering Quality Factor (FQF or simply Q).

The use of face masks in public indoor and outdoor settings, although considered as a passive measure additional to others (e.g. social distancing, hand washing), has been widely recommended by public health authorities during the current COVID-19 pandemic, especially when social distancing is not technically possible, to mitigate the risk of infection via respiratory droplets (1). Available studies and guidelines, however, are rather generic and conflicting when they come to denominating the masks (i.e. commercial fabric/cloth and homemade mask etc.), the parameters that measure their performance (i.e. FQF), the materials they are made of. Common fabrics (natural or synthetic) (1) are alternative materials to NWFs of which MDs and respiratory PPE are usually made. Specifically, NWF mainly consists of polypropylene (PP), rarely of polyethylene terephthalate (PET) or polyamide. The predominant use of PP for MDs and respiratory PPE is due to technological and marketing factors, for PP is one of the cheapest polymers on the market and one of the most easily spinnable to micron size, which is a prerequisite to achieve good filtering properties. Masks made of synthetic NWF mostly consist of three or more layers. The outermost layer of the mask, usually made of spunbond NWF with a hydrophobic treatment, is inexpensive, light, and provides mechanical strength and functional properties to the mask.

Available studies on both commercial and homemade fabric/cloth masks do not sufficiently describe the structure of the masks, so as to be able to characterize them from the point of view of properties and performance.

Aims of the present study are:

- to assess the effectiveness of commercial and homemade fabric/cloth masks by examining the statistical results from relevant scientific literature;
- to assess factors concerning the choice of materials and related layers in the manufacturing of commercial fabric/cloth masks, which may help both manufacturers and health authorities in assessing their efficiency and effectiveness.

Methods

Statistical data on mask effectiveness were gathered as follows.

A search on Medline for studies on face masks was carried out using the following selection criteria:

[(home-made) OR (homemade) OR (home made)] AND [(mask) OR (masks)]

or

[(cloth) AND (mask) OR (masks)]

or

[(face) AND (mask) OR (masks)]

The search was conducted between May 1 and July 15 2020; all studies published in the last 15 years before the search date were included. A further selection criterion was the availability of a free full text.

We found 1,983 papers on Medline of which 1,943 were excluded by title and abstract review.

We read the full texts of the remaining 40 papers and selected 16 for this brief review because we found them more pertinent for assessing the effectiveness of mask use by the general population.

Published in the past 13 years, these studies included Randomized Controlled Trials (RCTs), comparative experimental studies, mathematical modelling, systematic reviews and meta-analysis (regarding both RCTs and observational studies). Efficacy studies were selected, which mainly assessed MDs vs homemade cloth masks, and MDs vs N95/FFP2 (respiratory PPE). The effectiveness of facial masks was assessed against SARS, MERS, Influenza-Like Illness (ILI) and SARS-CoV-2 virus. Statistical results were collected in terms of odds ratio (OR) and relative risk (RR) together with 95% confidence interval (CI).

The analysis was divided into two sections: 1) before and 2) during the SARS-CoV-2 virus outbreak.

WHO guidelines (5) were examined, specifically the FQF, in order to carry out a proper comparison among face masks made of materials with different filtering performances.

State-of-the-art knowledge on commercial and homemade masks

1. Statistical data on mask effectiveness

1.1 Studies made before COVID-19 pandemic

According to a meta-analysis of six case-control studies (6), wearing MDs is effective in preventing the spread of SARS (OR=0.32; 95% CI: 0.25-0.40) as well as wearing N95 masks (OR= 0.09; 95% CI: 0.03-0.30).

The results of an experimental study (7) showed that all types of masks reduced aerosol exposure, regardless of the duration of wear or type of activity, but with a high degree of individual variation. MDs provided about twice as much protection as homemade masks. FFP2 masks provided adults with about 50 times as much protection as homemade masks, and 25 times as much protection as MDs. The increase in protection for children was less marked, about 10 times as much protection by FFP2 versus homemade masks and 6 times as much protection as MDs.

In a household-based RCT in Hong Kong (8), which was later laboratory confirmed, statistically significant reductions of influenza virus infections in household contacts were observed upon mask wearing plus hand hygiene as compared with the control arm (adjusted OR=0.33; 95% CI: 0.13-0.87).

According to a cluster-randomized household study (9), using P2 or MD significantly reduces the risk for ILI infection (hazard ratio=0.26; 95% CI: 0.09-0.77; p= 0.015), but the underpowered study was unable to detect a difference in efficacy between P2 masks and MDs.

Aiello et al (10) described a RCT in which 1,437 university students were randomized in three arms: control, MDs alone, and MDs plus hand hygiene. Compared with the control arm, significant reductions in ILI were observed in the mask and hand hygiene group ranging from 35% (95% CI: 9%–53%) to 51% (95% CI: 13%–73%), after adjusting for other covariates. Neither face mask use plus hand hygiene nor face mask use alone were associated with a significant reduction in the rate of ILI.

An experimental study (11) aimed to assess the filtration performance of common fabric materials showed that cloth masks and other fabric materials tested had penetration levels of both polydisperse and monodisperse aerosols much higher (6 to 8 times greater) than the penetrations for the control N95 respirator filter media.

According to a comparative experimental study (12), common household fabrics (100% cotton T-shirt, scarf, tea towel, pillowcase, antimicrobial pillowcase, vacuum cleaner bag, cotton mix, linen and silk) were tested with high concentrations of Bacteriophage MS2 and viral aerosols (*Bacillus atrophaeus*) to assess their filtration effectiveness. MDs were used as a control. The total bacterial count was measured when the volunteers coughed wearing their homemade mask and a MD. Both masks significantly reduced the number of microorganisms expelled by volunteers, although the MD was 3 times more effectual in blocking transmission than the homemade mask.

1.2 Studies made during the COVID-19 pandemic

A recent wide systematic review (13) of 172 observational studies across 16 countries, and 44 relevant comparative studies in healthcare and non-healthcare settings, including 25,697 patients with SARS-CoV-2, SARS, or MERS, found that respiratory protection face masks (N95) and MDs use overall reduce the risk of infection (OR=0.15; 95% CI: 0.07-0·34) compared with no use. In a subgroup analysis, N95 respiratory PPE showed increased protection (OR=0.04; 95% CI: 0.004-0.30) with respect to disposable MDs or similar (eg, reusable 12–16-layer cotton masks, OR=0.33, 95% CI: 0.17-0.61. The chance of viral infection was 5-6 times lower wearing the face mask than not wearing it.

A systematic review that selected 10 RCTs (14) reported estimates of the effectiveness of facemasks in reducing laboratory-confirmed influenza virus infections in the community. In a pooled analysis, the authors found no significant reduction in influenza transmission with the use of facemasks (RR=0.78; 95% CI: 0.51–1.20).

Another recent systematic review (15) found that, according to three RCTs, a MD might marginally decrease the chance of developing ILI /respiratory symptoms by around 6% (OR=0.94; 95% CI: 0.75-1.19). Greater effectiveness was suggested by observational studies: wearing the facemask the odds of becoming ill may be reduced by around 19% (OR=0.81; 95% CI: 0.48-1.37). The Authors suggest that wearing facemasks can be only slightly protective against primary infection from casual community contact, and modestly protective against household infections.

According to a compartmental mathematical model developed by Eikenberry et al (16) for assessing the community-wide impact of mask use by the general asymptomatic public, masks are found to be useful for preventing both illness in healthy persons and transmission by the asymptomatic. Hypothetical mask adoption scenarios, for Washington and New York States, suggest that immediate near universal (80%) adoption of moderately (50%) effective masks could prevent 17%-45% of deaths over two months in New York. Even very weak masks (20% effective) can still be useful if the underlying transmission rate is relatively low: in Washington, where baseline transmission is much less intense, 80% adoption of such masks could reduce mortality by 24-65%. The obtained results suggest that the use of face masks by the general public is potentially of high value in reducing community transmission.

In a recent systematic review and meta-analysis (17), the authors analysed 15 RCTs investigating the effect of masks in healthcare workers and the general population. Compared to no mask use, there was no reduction of ILI cases (RR=0.93; 95% CI: 0.83-1.05) or influenza (RR=0.84; 95%CI: 0.61-1.17) for masks in the general population. There was no difference between surgical masks and N95 respirators for ILI (RR=0.83; 95% CI: 0.63-1.08) as well as for influenza (RR=1.02; 95% CI: 0.73-1.43).

A systematic review and meta-analysis including 21 studies (18) shows that the use of masks by non-healthcare workers can reduce the risk of respiratory virus infection by 47% (OR=0.5; 95% CI: 0.36-0.79). Masks had a protective effect against influenza viruses (OR=0.55; 95% CI: 0.39-0.76), SARS (OR=0.26; 95% CI: 0.18-0.37), and SARS-CoV-2 (OR=0.04; 95% CI: 0.00-0.6). In the subgroups based on cluster randomized trials and observational studies, significant protective effects of wearing masks were observed (OR=0.65; 95% CI: 0.47-0.91 and OR=0.24; 95% CI: 0.15-0.38, respectively).

Leung et al. (19) found that surgical masks could reduce the emission of influenza virus particles into the environment in respiratory droplets, but not in aerosols. They also demonstrated the effectiveness of surgical masks to reduce coronavirus detection and viral copies in large respiratory droplets and in aerosols. This has important consequences for the control of SARS-CoV-2, suggesting that surgical face masks could be used by ill people to reduce onward transmission.

A recent systematic review and meta-analysis (20) analyzed six RCTs involving 9,171 participants to evaluate the efficacy of N95 respirators versus surgical masks against influenza. The Authors found no statistically significant differences in preventing laboratory-confirmed influenza (RR=1.09; 95% CI: 0.92-1.28), laboratory-confirmed respiratory viral infections (RR=0.89; 95% CI: 0.70-1.11), laboratory-confirmed respiratory infection (RR=0.74; 95% CI: 0.42-1.29) and ILI (RR= 0.61; 95% CI: 0.33-1.14). Meta-analysis showed a protective effect of N95 respirators against laboratory-confirmed bacterial colonization (RR=0.58; 95% CI: 0.43-0.78).

Ma et al. (21) evaluated the effectiveness of three types of masks in blocking Avian

Influenza Virus (AIV) in aerosols used to mimic SARS-CoV-2 because they are both enveloped and pleomorphic spherical viruses with a diameter of around 80 to 120 nm. This study showed that N95 masks blocked almost all the mimic virus, MDs blocked approximately 97% of the virus, and homemade masks blocked approximately 95% of the virus. Therefore, the MDs are not fully protective in hospitals, but are useful for common social occasions. When MDs are in shortage, the homemade masks made of four-layer kitchen paper (each layer contains three thin layers) and one layer of polyester cloth should be helpful, as indicated by this study. Kitchen paper is effective in blocking the virus, possibly because of its multiple layers, non-woven structure, and virus-absorbing property. One advantage of the homemade mask is that the kitchen paper can be frequently changed. Other types of homemade masks, especially those made of cloth alone, may be unable to block the virus and thus don't confer sufficient protection against it.

1.3 Discussion

Our exploration of relevant literature highlighted that mask effectiveness during the pre COVID-19 period was unambiguous and in favour of the generalized use of facial masks by the population (including homemade masks). The onset of SARS-COV-2 virus pandemic brought about a dramatic rise in dedicated studies together with more complex and ambiguous evidence.

The level of protective effectiveness of the masks varies greatly depending on the type of study: according to Brainard et al. (15) the RCTs often suffered from poor compliance and controls. As expected, putting together different observational studies in systematic reviews and meta-analysis approaches makes the evidence in favour of wearing facemasks much stronger.

Conversely, single studies display high variability of the estimates. The selected RCTs and experimental studies enrolled few subjects and often the results, although statistically significant, are associated with wide confidence intervals.

Another great source of variation is due to the different composition of homemade masks: according to Davies et al. (12) the vacuum cleaner bag and the tea towel had the highest filtration efficiency but they are unsuitable for a face mask. Conversely, due to the slightly stretchy quality of the 100% cotton t-shirt, this fabric was found to be the most suitable household material for an improvised face mask. The wide variation in penetration levels obtained for many fabric materials tested in this study agree with the penetration results previously reported (11, 22, 23). Comparing a MD (which complies with a specific standard, i.e. EN 14683 or ASTM F2100) with a homemade one yields widely varying results, depending on the fabric used to make a mask at home. On average, the results of this first block of studies indicate that surgical masks are at least twice as effective as homemade ones.

The results of the most recent studies changed the issue of scientific evidence. Four out of six systematic reviews and meta-analyses (14, 15, 17, 20) found no significant or very slight reduction in virus transmission with the use of face masks. According to these authors, the evidence is not sufficiently strong to support the widespread use of face masks as a protective measure against COVID-19. Conversely, the other two analysed systematic reviews and meta-analyses (13, 18) show that the use of masks can reduce the risk of respiratory virus infection in the general population by 47%-85%.

Another three recent studies (16, 19, 21) confirm, both from a mathematical modelling and an experimental point of view, that using the face masks (even the homemade ones, as long as the multilayer) is potentially of high value in reducing community transmission.

Conflicting data exist as to whether non-MDs have a protective effect on the spread of respiratory viruses among the population. Both MDs and respiratory PPE show a certain effectiveness value but sometimes lower than expected. The discordant data obtained for the various types of masks may be ascribable to the different environmental conditions under which the studies have been carried out.

Furnishing general indications for mask use is difficult because not enough studies assess the effectiveness of filter media withstanding the kind of multi-phase fluid that may be emitted during breathing, sneezing or coughing in different environmental conditions (air flow rate, temperature, humidity etc.) surrounding the mask.

This is a critical factor, because airflow rate, temperature, humidity, and duration of use will have an effect on the performance of filter media. Moreover, whereas a mask may have excellent filter media, droplets may go around the sides of the face-piece unless there is an adequate facial seal. In the presence of leaks, any type of mask may actually offer less protection independently from its nominal filtering efficacy.

Confusion in the comparison between studies arises also from the absence of a shared standard for the definition of mask. According to Scopus database, in the current year (2020), 134 studies have been published with the association of COVID with "face mask", 63 with "surgical mask", 17 with "medical-mask", 10 with "cloth mask", 2 with "homemade mask", and 1 with "filtering mask" or "non-medical mask". In the minds of the authors all these kinds of masks are supposed to work with the same function, and readers will reasonably consider all those terms as synonyms, but manufacturing conditions and design options will definitely play a role in the definition of mask performances. Existing standards could be used to identify mask categories, but at times standards are not comparable, and one typology of mask according to a given standard can fall within none, one or more typologies according to other standards. Neither communication does help on this issue, as the man in the street will consider all the devices they wear as masks. Therefore, making a review of the relevant literature, defining first the type of mask according to the classification reported in the Introduction section would help choose the studies to include in the research, and improve scientific discussion about mask effectiveness against COVID-19.

2. Current trend in the assessment of materials with different filtering effectiveness for mask making

As mentioned above for non-medical masks, WHO (5) sets a value, even if only as a preliminary guide, to the three parameters (initial filtration efficiency, initial pressure drop (Pa) and FQF) (Table 1) that would allow the use of materials with different filtering efficiency to make masks.

In particular, FQF is suggested to be the best parameter for comparison, and optimal values are reported for it.

The FQF of a mask (24) is used to make a comparison among many devices which are different in structure, materials, and manufacturing. By definition, it is the ratio between the logarithm of the reciprocal of the fraction of aerosol penetration (P) during a filtering test, and the applied or measured pressure drop in the same test (Δp) according to (1):

$$Q = \ln\left(\frac{1}{P}\right) / \Delta p \qquad (1)$$

The concept is that the best device is able to reduce P without the need of high Δp. The higher FQF is, the better the mask. If the filter structure is intricate, it will more easily stop droplets but higher pressure drops are necessary for the air flow with negative effects on breathability. The terms P and Δp are directly extracted in a typical filtering

Table 1 - Non-medical mask filtration efficiency, pressure drop and filter quality factor*

Material	Source	Structure	Initial Filtration Efficiency (%)	Initial Pressure drop (Pa)	Filtering quality factor, FQF** (kPa^{-1})
Polypropylene	Interfacing material, purchased as-is	Spunbond (Nonwoven)	6	1.6	16.9
Cotton 1	Clothing (T-shirt)	Woven	5	4.5	5.4
Cotton 2	Clothing (T-shirt)	Knit	21	14.5	7.4
Cotton 3	Clothing (Sweater)	Knit	26	17	7.6
Polyester	Clothing (Toddler wrap)	Knit	17	12.3	6.8
Cellulose	Tissue paper	Bonded	20	19	5.1
Cellulose	Paper towel	Bonded	10	11	4.3
Silk	Napkin	Woven	4	7.3	2.8
Cotton, gauze	N/A	Woven	0.7	6.5	0.47
Cotton, handkerchief	N/A	Woven	1.1	9.8	0.48
Nylon	Clothing (Exercise pants)	Woven	23	244	0.4

* "This table refers only to materials reported in experimental peer-reviewed studies. The filtration efficiency, pressure drop and FQF factor are dependent on flow rate" (verbatim cited text).
** "According to expert consensus, 3 is the minimum recommended value for the FQF (verbatim cited text).

test, apart from the applied standard, and they can be immediately used to calculate FQF. The logarithm is necessary only to have numerical results within a selected range. However, the value of FQF depends on the adopted criterion for P evaluation, as it can be calculated in terms of mass percentage, number of particles or other.

2.1 Discussion

There is no straightforward physical interpretation of FQF. Probably, the best way is considering FQF as a sort of efficiency term, being the ratio between the expected performance (low penetration) and the applied effort (the pressure drop). From a scientific point of view, it is difficult to assess that the functional behavior of complex systems may be represented by just one number. It is evident that this kind of simplification is useful in a rough comparison or for regulatory needs. In fact, the scientific literature rarely mentions this approach. Using the scientific database Scopus as a reference, 64 contributions were found by searching "filtering quality factor" or FQF in the abstract, 24 of which in the last 5 years. In order to make a comparison, 203 contributions in the last 5 years were found when searching "surgical masks". It is reasonable that FQF be accepted by the scientific community but it is not recognized as an undisputed term of comparison. From a technical point of view, the advantage of choosing materials, architectures and design strategies just on the basis of a single numerical value is evident, but this advantage entails several risks. Above all, masks with very different values of P and Δp may have the same FQF. In the practice, an increase in P may be compensated by a reduction of Δp. For example, reducing the number of filtering sheets from a mask would increase P and reduce Δp, and the overall FQF may remain unchanged. The same FQF value could also be achieved by adding sheets in a mask. Nevertheless, reducing P means losing the mask function, whereas increasing Δp means making the mask difficult to wear. From this point of view, FQF should be at least associated with a threshold or preferred values for P and Δp. Using FQF in a scientific study is not problematic as this parameter is one of the elements under discussion. Whereas in a technical context, some manufacturing and design solutions could be forced to reach some FQF values instead of a good overall mask performance. In order to avoid bad practice, FQF could be used only for the definition of big performance classes. In this sense, only changes of 1 or 2 orders of magnitude should be discussed, and differences of a few percentage points should not be considered.

Another issue related to FQF is the absence of any material parameter in its definition. Pressure drop is not normalized by filtering material density or thickness. On the other side, the test for FQF evaluation is a laboratory test, and does not take into account any possible interaction of the device with users. Nevertheless, masks have to be flexible and wearable. In practice, FQF has to be applied after a technical evaluation of mask wearability and easiness of use. If the device is difficult to wear or if it does not fit correctly the user's face, the FQF value measured in laboratory would not lead to a real filtering action during use. Therefore, a mask may not be designed or chosen only on the basis of FQF. A solution could be normalizing FQF by the device thickness or weight. By increasing the number of mask layers, P decreases, Δp increases but normalized FQF decreases as well because of the increase in thickness. This normalization forces designing toward light solutions, and prefers devices with high P and low Δp over devices with low P and high Δp. At least mask wearability is ensured as low thickness leads to flexible and easy-to-wear devices.

In view of the above, adopting FQF for comparing masks made of different materials is not straightforward. When using common fabrics, values of FQF are often too close to make an evaluation. On the other side, it is difficult to identify materials on the basis of their use (paper towel, tissue paper) as very different values of P and Δp will be found.

Conclusions

Homemade masks are broadly used to protect from droplet and aerosol exposure, although their effectiveness is not being studied as a source control for the community. On the other hand, there is even limited knowledge on the performance of commercial fabric/cloth masks in natural fabrics. In spite of existing standards and experimental procedures, the enormous availability of common materials that can be used as filters in homemade masks, makes it impossible to have valid comparisons between different solutions. Moreover, the effect of the fabrication procedure cannot be kept under control as everyone uses their own tools and competences to produce the masks. Indications and suggestions from WHO and AFNOR SPEC S76-001 (4) exhibit the same uncertainty.

The results of the studies on the efficacy of the cloth masks vary greatly depending on study design, sample size, target of the study (community-wide or health care setting), type of fabric and number of layers in the mask.

In the hierarchy of evidence the scientific community considers RCTs more reliable because they reduce spurious causality and bias (25-27). While there are consistent RCTs, evidence in healthcare workers that wearing MDs and N95 respirators can reduce the risks of respiratory illnesses by at least 50% (28-31), there is limited evidence from RCTs that homemade masks show some degree of protection. RCTs evidence in the general population is more limited because it is challenging to carry out in practice and there is high risk of non-compliance and cross-contamination (15, 32).

To our knowledge, MacIntyre et al. (33) performed the first RCT on cloth masks. The results show that the rates of all infection outcomes were higher in the cloth mask arm (two cotton layer) compared to the surgical mask arm, with a RR=13.00 (95% CI: 1.69-100.07). Despite the statistical significance, which leads us to believe that fabric masks are much less effective than surgical masks, the range of the confidence interval associated with RR forces caution in interpreting the results.

Recently MacIntyre et al. published a systematic review (34) aimed to assess the efficacy of face masks against respiratory transmissible viruses for the community, healthcare workers and sick patients. The Authors found eight clinical trials on the use of masks in the community. The evidence seems to be conflicting: according to some studies, masks seem to be effective (9, 10, 35-38) however, other RCTs did not measure the effect of masks use (8, 39).

One of the sources of variability in the results is due to the different composition of homemade masks. Comparing a surgical mask (which complies to specific international standards such as EN 14,683 and ASTM F2,100) with a homemade mask leads to different results depending on the fabric and the number of layers in the homemade one, taking into account that the gap between most cloth fibres depends on weave thickness and can be 1,000 times bigger compared with the N95/FFP2 respiratory PPE. For example, according to a recent wide systematic review (13) a multi-layer cotton mask (12–16-layer) might result in a large reduction in risk of infection (Odds Ratio 0.15; 95% CI: 0.07-0·34).

Numerous experimental studies show a wide variation in penetration levels obtained for many fabric materials (7, 11, 12, 22, 23). According to these studies the surgical mask was 2-3 times more effective in blocking transmission than the homemade mask, and N95/FFP2 masks provided adults with about 6-50 times more protection than home-made masks.

According to two recent experimental studies (21, 40), if properly implemented (fourΔlayer kitchen paper or multilayer cotton) a homemade mask could have about the same performance as a surgical mask, and could be a potential substitute for MDs to prevent respiratory infection in healthy people.

Evidence from a recent laboratory study (41) suggests that droplets can travel distances as great as 7-8 m and ultrafine aerosol droplets, smaller than 5 μm, may also carry SARS-CoV-2, remaining airborne for very much longer. Cloth masks could be only marginally beneficial in protecting individuals from particles <2.5μm.

Finally, Eikenberry et al. (16) showed with a mathematical model that a hypothetical near universal (80%) use of moderately (50%) effective masks could prevent 17%-45% deaths over two months in New York State. Even very weak masks (20% effective) can still be useful if the underlying transmission rate is relatively low: in Washington State, where baseline transmission is much less intense, 80% adoption of such masks could reduce mortality by 24-65%.

Although the suggestion seems to confirm a minimal effectiveness of the cloth masks as a prevention device for the general population, bearing in mind the proliferation of homemade cloth mask designs (many of which are single-layered), further laboratory studies are needed on a wide sample of fabrics, shapes and layers to establish a minimum standard of effectiveness.

While there have been prior studies on the performance of MDs and PPE, there are insufficient data on commercial fabric/cloth masks and only a few data on the homemade masks that are being used by the vast majority of the general population.

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Riassunto

Efficacia delle mascherine facciali per la popolazione

Stato dell'arte. Le maschere facciali non-mediche sono considerate da Autorità e Organizzazioni Sanitarie come mezzi passivi, in aggiunta ad altri, di prevenzione della diffusione del virus. A livello di comunicazione, si insiste per diffondere nella popolazione l'informazione che l'uso di queste maschere è necessario per mitigare la diffusione del virus. Tuttavia, gli studi scientifici non sono incisivi nel mostrare un'indiscussa efficacia filtrante di tali maschere facciali (sia quelle commerciali in tessuto che quelle fatte in casa).

Obiettivi. Lo studio vuole esaminare dati scientifici riguardanti l'efficienza delle mascherine per la popolazione prima e durante l'emergenza del COVID-19. Sulla base di tali dati si discutono anche le attuali tendenze per la realizzazione di queste mascherine.

Metodi. I dati statistici di diversi studi pubblicati sono analizzati in maniera tale da estrarre considerazioni di sintesi e possibili suggerimenti. Allo stesso modo si analizza quello che è l'attuale approccio per stabilire le caratteristiche strutturali e di performance delle mascherine da destinare all'uso civile.

Risultati. Esistono dati conflittuali sull'efficienza protettiva delle mascherine per uso civile nel limitare la diffusione delle infezioni respiratorie. Le mascherine chirurgiche e i dispositivi di protezione individuali delle vie respiratorie mostrano invece una certa efficacia.

Conclusioni. Fornire indicazioni generali sulla scelta dei materiali e realizzazione delle mascherine per la popolazione è molto difficile a causa dell'indeterminatezza della loro efficienza nel catturare micro-particelle nei diversi contesti in cui potrebbero essere usate, soprattutto in relazione alla tipologia di fluido multifasico che si produce nei vari ambienti da parte della respirazione, di uno starnuto o di un colpo di tosse. Questo aspetto è forse il più vincolante, vista la scarsa conoscenza dell'effetto sulle prestazioni filtranti di parametri importanti come il flusso di aria, la temperatura, l'umidità o il tempo di uso. Inoltre, benché le mascherine siano costituite da idonei materiali filtranti, non è detto che questo si traduca automaticamente in alta efficienza del dispositivo durante l'uso, nel caso, ad esempio, di scarsa adesione al viso. Nel caso di piccole alterazioni della struttura filtrante, si potrebbero osservare prestazioni molto al di sotto di quelle nominali.

References

1. Santarsiero A, Ciambelli P, Donsì G, et al. Face masks. Technical, technological and functional characteristics and hygienic-sanitary aspects related to the use of filtering mask in the community. Ann Ig 2020; **32**(5): 472-520. doi:10.7416/ai.2020.2371.
2. Europa. Regolamento 2017/745 del Parlamento Europeo e del Consiglio del 5 aprile 2017 relativo ai dispositivi medici, che modifica la direttiva 2001/83/CE, il Regolamento CE n. 178/2002 e il regolamento CE n. 1223/2009 e che abroga le direttive 90/385/CEE e 93/42/CEE del Consiglio. Gazzetta Ufficiale dell'Unione Europea del 5 maggio 2017, n. L 117/1.
3. Europa. Regolamento UE 2016/425 del Parlamento Europeo e del Consiglio del 9 marzo 2016 sui dispositivi di protezione individuale e che abroga la direttiva 89/686/CEE del Consiglio. Gazzetta Ufficiale dell'Unione Europea del 31 marzo 2016, n. L 81/51.
4. AFNOR. 2020. SPEC S76-001: Masque barrière. Guide d'exigence minimales, de méthode d'essais, de confection et d'usage". Available on: https://www.snof.org/sites/default/files/AFNORSpec-S76-001-MasquesBarrieres [Last accessed: 2020, Sep 11].
5. World Health Organization (WHO). Advice on the use of masks in the context of COVID-19. Interim guidance. 5 June 2020. Available on: https://apps.who.int/iris/handle/10665/332293 [Last accessed: 2020, Sep 11].
6. Jefferson T, Foxlee R, Del Mar C, et al. Physical Interventions to Interrupt or Reduce the Spread of Respiratory Viruses: Systematic Review. BMJ 2008; **336**: 77-80. doi: 10.1136/bmj.39393.510347.BE.
7. van der Sande M, Teunis P, Sabel R. Professional and Home-Made Face Masks Reduce Exposure to Respiratory Infections Among the General Population. PLoS One 2008; **3**(7): e2618. doi: 10.1371/journal.pone.0002618.
8. Cowling BJ, Chan KH, Fang VJ, et al. Facemasks and Hand Hygiene to Prevent Influenza Transmission in Households: A Cluster Randomized Trial. Ann Intern Med 2009; **151**(7): 437-46. doi: 10.7326/0003-4819-151-7-200910060-00142.

9. MacIntyre CR, Cauchemez S, Dwyer DE, et al. Face mask use and control of respiratory virus transmission in households. Emerg Infect Dis 2009; **15**(2): 233-41. doi: 10.3201/eid1502.081167 PMID: 19193267.
10. Aiello AE, Murray GF, Perez P, et al. Mask Use, Hand Hygiene, and Seasonal Influenza-Like Illness Among Young Adults: A Randomized Intervention Trial. J Infect Dis 2010 15; **201**(4): 491-8. doi: 10.1086/650396.
11. Rengasamy S, Eimer B, Shaffer RE. Simple Respiratory Protection--Evaluation of the Filtration Performance of Cloth Masks and Common Fabric Materials Against 20-1000 Nm Size Particles. Ann Occup Hyg 2010; **54**(7): 789-98. doi: 10.1093/annhyg/meq044.
12. Davies A, Thompson KA, Giri K, Kafatos G, Walker J, Bennett A. Testing the Efficacy of Homemade Masks: Would They Protect in an Influenza Pandemic? Disaster Med Public Health Prep 2013; **7**(4): 413-8. doi: 10.1017/dmp.2013.43.
13. Chu DK, Akl EA, Duda S, Solo K, Yaacoub S, Schünemann HJ on behalf of the COVID-19 Systematic Urgent Review Group Effort (SURGE) study authors. Physical Distancing, Face Masks, and Eye Protection to Prevent Person-To-Person Transmission of SARS-CoV-2 and COVID-19: a systematic review and meta-analysis. Lancet 2020; **395**(10242): 1973-87. https://doi.org/10.1016/S0140-6736(20)31142-9. [Last accessed: 2020, Sep 10].
14. Xiao J, Shiu E, Gao H, et al. Nonpharmaceutical Measures for Pandemic Influenza in Nonhealthcare Settings—Personal Protective and Environmental Measures. Emerg Infect Dis 2020; **26**(5): 967-75. doi: 10.3201/eid2605.190994.
15. Brainard J, Jones N, Lake I, Hooper L, Hunter PR. Facemasks and similar barriers to prevent respiratory illness such as COVID-19: A rapid systematic review. Preprint, 2020. Available on: https://www.medrxiv.org/content/10.1101/2020.04.01.20049528v1. https://doi.org/10.1101/2020.04.01.20049528.
16. Eikenberry SE, Mancuso M, Iboi E, et al. To mask or not to mask: Modeling the potential for face mask use by the general public to curtail the COVID-19 pandemic. Infect Dis Model 2020; **5**: 293-308. https://doi.org/10.1016/j.idm.2020.04.001
17. Jefferson T, Jones MA, Al-Ansary L, et al. Physical interventions to interrupt or reduce the spread of respiratory viruses. Part 1 - Face masks, eye protection and person distancing: systematic review and meta-analysis. medRxiv 2020.03.30.20047217. doi: https://doi.org/10.1101/2020.03.30.20047217.
18. Liang M, Gao L, Cheng C, et al. Efficacy of face mask in preventing respiratory virus transmission: a systematic review and meta-analysis. Travel Med Infect Dis 2020; 36: 101751. https://doi.org/10.1016/j.tmaid.2020.101751. Epub 2020 May 28.
19. Leung NHL, Chu DKW, Shiu EYC, et al. Respiratory virus shedding in exhaled breath and efficacy of face masks. Nat Med 2020; **26**(5): 676-80. doi: 10.1038/s41591-020-0843-2. Epub 2020 Apr 3.
20. Long Y, Hu T, Liu L, et al. Effectiveness of N95 respirators versus surgical masks against influenza: a systematic review and meta-analysis. J Evid Based Med 2020; **13**(2): 93-101. doi: 10.1111/jebm.12381. Epub 2020 Mar 13.
21. Ma Q-X, Shan H, Zhang H-L, Li G-M, Yang R-M, Chen J-M. Potential utilities of mask wearing and instant hand hygiene for fighting SARS-CoV-2. J Med Virol 2020 Mar 31; 0.1002/jmv.25805. https://doi.org/10.1002/jmv.25805.
22. Guyton HG, Decker HM, Anton GT. Emergency respiratory protection against radiological and biological aerosols. AMA Arch Ind Health 1959; **20**(2): 91-5.
23. Cooper DW, Hinds WC, Price JM. Emergency respiratory protection with common materials. Am Ind Hyg Assoc J 1983; **44**(1): 1-6.
24. Huang SH, Chen CW, Kuo Y-M, Lai C-Y, McKay R, Chen CC. Factors Affecting Filter Penetration and Quality Factor of Particulate Respirators. Aerosol Air Qual Res 2013; **13**(1): 162-171. https://doi.org/10.4209/aaqr.2012.07.0179.
25. Benson K, Hartz AJ. A comparison of observational studies and randomized, controlled trials. N Engl J Med 2000; 342: 1878-86. doi: 10.1056/NEJM200006223422506.
26. Concato J, Shah N, Horwitz RI. Randomized, controlled trials, observational studies, and the hierarchy of research designs. N Engl J Med 2000; **342**(25): 1887-92. doi: 10.1056/NEJM200006223422507.
27. Vandenbroucke JP. Observational research, randomised trials, and two views of medical science. Version 2. PLoS Med 2008; **5**(3): e67. doi: 10.1371/journal.pmed.0050067.

28. Da Zhou C, Sivathondan P, Handa A. Unmasking the surgeons: the evidence base behind the use of facemasks in surgery. J R Soc Med 2015; **108**(6): 223-8. doi: 10.1177/0141076815583167.
29. Radonovich LJ Jr, Simberkoff MS, Bessesen MT, et al. N95 Respirators vs Medical Masks for Preventing Influenza Among Health Care Personnel: A Randomized Clinical Trial. JAMA 2019; **322**(9): 824-33. doi: 10.1001/jama.2019.11645.
30. Offeddu V, Yung CF, Low MSF, Tam CC. Effectiveness of Masks and Respirators Against Respiratory Infections in Healthcare Workers: A Systematic Review and Meta-Analysis. Clin Infect Dis 2017; **65**(11): 1934-42. doi: 10.1093/cid/cix681.
31. Lee SA, Hwang DC, Li HY, Tsai CF, Chen CW, Chen JK. Particle Size-Selective Assessment of Protection of European Standard FFP Respirators and Surgical Masks against Particles-Tested with Human Subjects. J Healthc Eng Open 2016. ID 8572493. doi: 10.1155/2016/8572493.
32. Chan KH, Yuen KY. COVID-19 epidemic: disentangling the re-emerging controversy about medical facemasks from an epidemiological perspective. Int J Epidemiol 2020; 1-4. doi: 10.1093/ije/dyaa044.
33. MacIntyre CR, Seale H, Dung TC, et al. A cluster randomised trial of cloth masks compared with medical masks in healthcare workers. BMJ Open 2015; 22; **5**: e006577. doi:10.1136/bmjopen-2014-006577
34. MacIntyre CR, Chughtai AA. A rapid systematic review of the efficacy of face masks and respirators against coronaviruses and other respiratory transmissible viruses for the community, healthcare workers and sick patients. Int J Nurs Stud 2020; **108**: 103629. doi.org/10.1016/j.ijnurstu.2020.103629.
35. Aiello AE, Perez V, Coulborn RM, Davis BM, Uddin M, Monto AS. Facemasks, hand hygiene, and influenza among young adults: a randomized intervention trial. PLoS One 2012; **7**(1): e29744. doi: 10.1371/journal.pone.0029744.
36. Larson EL, Ferng YH, Wong-McLoughlin J, Wang S, Haber M, Morse SS. Impact of non-pharmaceutical interventions on URIs and influenza in crowded, urban households. Public Health Rep 2010; **125**(2): 178-91. doi: 10.1177/003335491012500206.
37. Cowling BJ, Fung RO, Cheng CK, et al. Preliminary findings of a randomized trial of non-pharmaceutical interventions to prevent influenza transmission in households. PLoS One 2008; **3**(5): e2101. doi: 10.1371/journal.pone.0002101.
38. Suess T, Remschmidt C, Schink SB, et al. The role of facemasks and hand hygiene in the prevention of influenza transmission in households: results from a cluster randomised trial; Berlin, Germany, 2009-2011. BMC Infectious Diseases 2012; **12**: 26. doi: 10.1186/1471-2334-12-26.
39. Simmerman JM, Suntarattiwong P, Levy J, et al. Findings from a household randomized controlled trial of hand washing and face masks to reduce influenza transmission in Bangkok, Thailand. Influenza Other Respir Viruses 2011; **5**(4): 256-67. doi: 10.1111/j.1750-2659.2011.00205.x.
40. Ho KF, Lin LY, Weng SP, Chuang KJ. Medical mask versus cotton mask for preventing respiratory droplet transmission in micro environments. Sci Total Environ 2020; **735**: 139510. doi: 10.1016/j.scitotenv.2020.139510.
41. Bourouiba L. Turbulent Gas Clouds and Respiratory Pathogen Emissions: Potential Implications for Reducing Transmission of COVID-19. Epub 2020 March 26. doi:10.1001/jama.2020.4756.

Corresponding Author: Dr. Ing. Anna Santarsiero, Dipartimento Ambiente e Salute, Istituto Superiore di Sanità, Viale Regina Elena 299, 00161 Rome, Italy
e-mail: anna.santarsiero@iss.it