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Efficacy of face masks as source control and respiratory protection against transmission of SARS-CoV-2

Marius Dybwad
Else Marie Fykse
Thor Gjesdal
Agnieszka Anna Gorzkowska-Sobas
Anders Helgeland
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Summary

During the COVID-19 pandemic, medical and community face masks have been used extensively by health care workers and the general public to reduce transmission of the SARS-CoV-2 virus.

This report reviews the available literature on the efficacy of medical and community face masks, both as a means for source control and respiratory protection. The literature spans a multitude of scientific disciplines. The review has, however, mainly focused on aerosol physics, aerobiology, microbiology and occupational health and safety.

The literature shows that medical and community face masks remove almost all large and medium-sized respiratory droplets from the exhaled air. To some extent, they also reduce the number of emitted small droplets. All respiratory activities generate turbulent jet plumes in the direction of exhalation. These directed jet plumes are able to augment the travel distance of droplets of all sizes and lead to localized regions with elevated droplet concentrations. An important function of face coverings, such as medical and community face masks, is their ability to obstruct these jets, and thereby diffuse the droplet concentration. Due to the combined effect of the above factors, medical and community face masks appear to be highly efficient when used as a means for source control.

On the other hand, medical and community face masks do not typically fulfill the performance requirements that apply to respiratory protection devices. The reason for this is twofold. First, medical and community face masks are loose-fit devices prone to gap leakages around the perimeter. Therefore, a substantial fraction of the respiratory droplets may bypass the filtering layer of the mask. Second, the filtration efficiency for very small droplets is highly variable for medical and community face masks.

This finding is not surprising, since the intended use for medical face masks as a personal protective device is limited to direct transmission via splashes and sprays. The performance requirements and test methods applied to such devices, according to the relevant harmonized standards, do therefore not consider their function as a respiratory protection device. The role of very small droplets in the transmission of SARS-COV-2 is currently not well understood. Therefore, it is difficult to ascertain whether the strict performance requirements for respiratory protection devices are necessary to achieve a sufficient protection level. Some studies show that the use of medical face masks may offer some degree of respiratory protection to the wearer, in particular if additional measures such as double masking or knotting and tucking are used to improve the fit and reduce gap leakages.

Sammendrag

Under Covid-19-pandemien har medisinske og ikke-medisinske munnbind blitt brukt av helsearbeidere og i den øvrige befolkningen for å redusere spredning av SARS-CoV-2.

Denne rapporten presenterer en litteraturstudie av effekten av medisinske og ikke-medisinske munnbind brukt både som kildekontroll og åndedrettsvern. Litteraturen kommer fra et bredt spekter av fagområder. Gjennomgangen har, imidlertid, i hovedsak fokusert på aerosolfysikk, aerosolbiologi, mikrobiologi og arbeidsmiljø.

Litteraturen viser at medisinske og ikke-medisinske munnbind fjerner nesten alle store og mellomstore respiratoriske dråper fra utåndingen. Til en viss grad reduserer de også utslippet av små dråper. Alle former for åndedrett ¬slik som pusting, hosting, nysing og snakking ¬genererer rettede jetstrømmer i forkant av ansiktet. Disse jetstrømmene kan øke rekkevidden til respiratoriske dråper i alle størrelser og føre til områder med økt dråpekonsentrasjon. En viktig funksjon for ansiktsmasker, som medisinske og ikke-medisinske munnbind, er at de kan bremse disse jetstrømmene og redusere dråpekonsentrasjonen. Disse to faktorene kombinert fører til at medisinske og ikke-medisinske munnbind ser ut til å være svært effektive med tanke på kildekontroll.

Medisinske og ikke-medisinske munnbind oppfyller imidlertid generelt ikke ytelseskravene til åndedrettsvern. Årsaken til dette er todelt. For det første har medisinske og ikke-medisinske munnbind en løs passform som gjør dem utsatt for lekkasjer. Derfor kan en betydelig andel av dråpene slippe fordi munnbindets filtermateriale. For det andre har medisinske og ikke-medisinske munnbind stor variasjon i filtreringseffektiviteten for veldig små dråper.

Disse funnene er ikke overraskende. Dette fordi medisinske munnbind, brukt som personlig beskyttelsesutstyr, ifølge spesifikasjonen er begrenset til sprutbeskyttelse. Ytelseskravene og testmetodene som brukes på slike produkter, i henhold til relevante harmoniserte standarder, anser ikke at de kan brukes som åndedrettsvern. Det er foreløpig begrenset kunnskap om rollen til veldig små dråper i overføringen av SARS-CoV-2. Derfor er det vanskelig å fastslå om de strenge ytelseskravene til åndedrettsvern er nødvendig for å oppnå et tilstrekkelig beskyttelsesnivå ved bruk av medisinske og ikke-medisinske munnbind. Noen studier viser at bruk av medisinske ansiktsmasker kan gi brukeren en viss grad av beskyttelse, særlig dersom ytterligere tiltak som dobbel maske eller manuelle justeringer gjøres for å forbedre passformen og redusere lekkasjer.

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1 Introduction

Coronavirus disease (COVID-19) is an infectious disease caused by a newly discovered coronavirus, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), previously not found in humans. The World Health Organization (WHO) declared COVID-19 a public health emergency of international concern (PHEIC) on January 30 2020 and a global pandemic on March 11 2020 [1]. As of June 2021 more than 179 million people have been infected and as many as 3.8 million people have died [2]. As a result, the health care systems in most countries have been under severe and persisting strain, including periods of shortage of critical human resources as well as medical and protective equipment. In order to reduce or avoid SARS-CoV-2 transmission, human disease and deaths, and collapse of organized health care services, governments across the world have instituted general mandatory use of face coverings for the general public in situations where close contact is unavoidable. Public masking is also recommended by organizations and institutions responsible for infectious disease control and prevention, among others the European Centre for Disease Prevention and Control (ECDC) [3], the U.S. Centers for Disease Control and Prevention (CDC) [4] and the WHO [5].

Health care workers (HCWs) have used various face coverings, including medical face masks (MFMs), filtering facepiece respirators (FFRs), powered air-purifying respirators (PAPRs) and face shields, to reduce SARS-CoV-2 transmission in the hospital environment by protecting HCWs and patients against virus-laden respiratory droplets and aerosols. The utter need to protect HCWs from infection have caused an increased demand for personal protective equipment, in particular respiratory protection devices (RPDs) such as FFRs and PAPRs. MFMs are classified as medical devices and not RPDs. According to the relevant standards their primary intended use is source control, i.e. to control and prevent emission of respiratory droplets from the wearer in order to protect others. MFMs are typically used by HCWs in the hospital environment to protect patients from respiratory tract-associated microorganisms emitted by HCWs during surgery and other medical procedures. As a personal protection device, the intended use for medical face masks is limited to direct transmission via splashes and sprays including large respiratory droplets. In the specific context of small and medium-sized respiratory droplets, the intended use for MFMs is limited to source control. The performance requirements and test methods applied to such devices according to the relevant standards do therefore not consider their function as a RPD.

During the COVID-19 pandemic, the use of MFMs has become widespread also among the general public. As a result, the use of these devices have surged, which at times have resulted in poor availability and a skyrocketing market prices [6, 7]. Both for RPDs and MFMs, which are typically single-use devices, there have also been concerns regarding the amount of plastics produced and utilized, and the resulting environmental impact [8-11]. Re-usable (washable) cloth masks, both commercial and home-made versions, have therefore gained popularity among the general public [5, 12]. To clearly separate such face coverings from MFMs, non-medical cloth masks for community use are therefore categorized and referred to as community face masks (CFMs) throughout the rest of this report.

MFMs and CFMs are loose-fitting devices with relatively low breathing resistance, which does not contribute significantly to a physical and psychological burden for the wearer. MFMs and CFMs are also more readily available than RPDs and have a simpler design and form that does not require fit testing. MFMs and CFMs can therefore be used by a much larger group of individuals, with different facial anthropomorphic dimensions, facial hair, etc., and better compliance can be expected given their easier donning and lower price. However, many questions have been and are still being asked regarding the widespread use of MFMs and CFMs during the COVID-19 pandemic and the actual benefit/efficacy that can be expected in terms of preventing and controlling SARS-CoV-2 transmission both inside the health care service and in the community. Several of these questions have so far been difficult to answer because of a lack of knowledge regarding COVID-19, and to some extent also viral respiratory diseases in general, concerning the benefit/efficacy of MFMs and CFMs in preventing and controlling SARS-CoV-2 transmission when used as a mean for source control and respiratory protection. Another challenge is the fact that expertise from a variety of different scientific disciplines, including infectious disease medicine, epidemiology, occupational health and safety, infection prevention and control, microbiology, aerobiology and aerosol physics, is needed, and which is seldom accessible within any single organization. This in turn demands a cross-disciplinary approach and coordination, which is of vital importance to fully grasp, reconcile and answer many of these questions and truly understand and communicate their implications. Although a massive global research effort has been launched since the start of the COVID-19 pandemic, much of the emerging scientific knowledge is still captured only in pre-print publications that have not yet been peer reviewed. Even the sheer amount of new information, which due to the inherent nature of scientific process consists of a complex blend of consistent and conflicting findings, makes it difficult even for the experts to navigate this landscape in search of tangible information and answers.

In this report, we address and critically discuss, and whenever possible also attempt to answer, some of the questions asked about face coverings based on a cross-disciplinary review of the available scientific literature. Our review is focused on aerosol physics, aerobiology, microbiology, and occupational health and safety, and we attempt to describe the current state-of-knowledge and scientific evidence concerning the benefit/efficacy of MFMs and CFMs in the specific context of; a) source control and b) personal respiratory protection, from different perspectives, including filtration efficiency of filter materials, mask fit and outward/inward leakage, and handling and (re-)use issues.

Briefly, Chapter 2 covers transmission of SARS-CoV-2 via respiratory droplets. Chapter 3 covers different types of face coverings, particularly MFMs and CFMs, and introduces important terms and definitions used to describe their properties, performance and test methodology. Chapter 4 covers the filtration efficiency of MFMs and CFMs. Chapters 5 and 6 cover the efficacy of MFMs and CFMs as source control and respiratory protection, respectively, against transmission of SARS-CoV-2. Chapter 7 covers topics related to long-term use, humidity, washing and reuse of CFMs. Finally, Chapter 8 rounds of the report with a discussion and conclusions.

2 Transmission routes for SARS-CoV-2

The transmission routes for SARS-CoV-2 has been a subject to much debate since the beginning of the pandemic [13-18]. Historically, three different transmission modes of viral respiratory infections have been distinguished: (i) contact transmission, (ii) droplet transmission, and (iii) airborne transmission. CDC has recently attempted to clarify the transmission routes relevant for SARS-CoV-2 [14], which are now referred to as (i) inhalation of virus, (ii) deposition of virus on exposed mucous membranes, and (iii) touching mucous membranes with soiled hands contaminated with virus. Note that there is not a strict one-to-one correspondence between the two sets of transmission route definitions. In particular, the inhalation route will comprise transmission both by small droplets and droplet nuclei, commonly referred to as aerosols, as well as inhalable medium-sized droplets.

The size distribution of respiratory droplets spans a continuous range of diameters from sub-micron to about 1 mm. After exhalation, evaporation will tend to shrink the droplets, but this will not significantly affect the span of the droplet size distribution. An operational classification into small, medium and large droplets can be obtained by considering their mechanical properties. In particular, the interplay of gravitational settling, inertia, and aerodynamic drag determines how they move in an airflow. Small droplets evaporate rapidly into droplet nuclei that have negligible settling velocity and inertia. As a consequence, they respond quickly to the aerodynamic drag imposed by the airflow and follow the air passively. In terms of indoor ventilation flows and respiratory flows, this may apply to droplets smaller than approximately 15 μm. In terms of pathogen transmission, droplets smaller than 5 μm have traditionally been termed aerosols, although this usage of the term aerosol is not consistent with the use in other disciplines [19]. Probably, the 5 μm definition was linked to the so-called respirable fraction [20, 21], i.e. droplets small enough to penetrate the lower airways. Large droplets have substantial settling velocities, i.e tens of centimeter per second, slower evaporation rates, and their inertia is so large that they respond slowly to changes in the airflow, thus displaying ballistic behaviour. For indoor ventilation and respiratory flows, this may refer to droplets larger than approximately 100 μm. In between these cases, we find medium-sized droplets with a mixed behavior. These droplets may readily follow the airflow despite a non-negligble settling velocity. According to ISO 7708:1995(E) [20], droplets smaller than 100 μm constitute the inhalable fraction. Throughout the rest of the report, and in accordance with Stadnytskyi et al. [22], we will use the above operational definition of small, medium and large droplets despite the fuzzy boundaries between the different classes.

There is evidence that the risk of infection is greatest within 2 m distance of an infected source [14]. Within such distances, it is difficult to distinguish between the different modes of transmission [23]. Recent evidence suggests that contact with contaminated surfaces (fomites) plays a less important role than previously assumed in transmission of SARS-CoV-2 [15-18]. WHO has also acknowledged that in addition to large droplets, transmission of SARS-CoV-2 via small droplets and droplet nuclei (aerosols) cannot be ruled out, especially in enclosed indoor settings [5, 24]. In particular, small droplets are frequently produced in hospital environments during aerosol generating procedures [5].

Transmission routes of COVID-19:

According to the U.S. Centers for Disease Control and Prevention (CDC) "the principal mode by which people are infected with SARS-CoV-2 (the virus that causes COVID-19) is through exposure to respiratory fluids carrying infectious virus. Exposure occurs in three principal ways [14]:

(1) **inhalation** of very fine respiratory droplets and aerosol particles

(2) **deposition** of respiratory droplets and particles on exposed mucous membranes in the mouth, nose, or eye by direct splashes and sprays

(3) **touching** mucous membranes with hands that have been soiled either directly by virus-containing respiratory fluids or indirectly by touching surfaces with virus on them (fomites)"

Some of the evidence for aerosol transmission of SARS-CoV-2 come from epidemiological studies, and the outbreaks most often cited as indirect evidence of aerosol transmission are the Guangzhou restaurant [25], the Eastern Chinese bus riders [26] and the Diamond Princess cruise ship [27]. A superspreading event at a fitness center in Hong Kong (102 cases) highlights the risk for virus transmission in confined spaces with poor ventilation [28]. The study was unable to identify the predominant transmission mode accounting for the event, but a recent study indicates that physical activities in a fitness center can create high levels of saliva aerosols [29]. These studies are, however, epidemiological case studies and not direct evidence.

Azimi et al. [30] performed a modeling study of SARS-CoV-2 transmission modes on the Diamond Princess cruise ship, utilizing the recently proposed terminology of short-range and long-range airborne transmission routes introduced by Liu et al. [23]. They estimated that the contributions of short-range, long-range, and fomite transmission modes to infected cases were 35%, 35%, and 30%, respectively. Estimates of the contributions of larger respiratory droplets and smaller respiratory aerosols were 41 and 59%, respectively. A conservative assumption of high ventilation rates and no air recirculation conditions for the cruise ship was used in the modeling. In this modeling, the cutoff to distinguish between aerosols and larger droplets was 10 μm.

Li et al. [31] performed a thorough reconstruction of the Guangzhou incident using both CCTV recordings, *in situ* measurements and numerical simulation to recreate the ventilation flow pattern in the restaurant. All affected guests were seated at three tables in a crowded area that constitutes a separate ventilation zone, in which the airflow was virtually disconnected from the rest of the room. CCTV footage did not record any interactions between the guest at the threes tables, and the distance between the affected persons was sufficiently large to limit the possibility of classical

large droplet transmission. Based on the available evidence, Li et al. [31] concludes that classical airborne transmission of the SARS-CoV-2 virus is possible in crowded spaces that are poorly ventilated.

Other experimental indirect evidence of classical airborne transmission is the identification of SARS-CoV-2 nucleic acids (RNA) in airborne particles smaller than 4 μm collected in clinical settings [32, 33]. Nevertheless, an obvious prerequisite for aerosol transmission of SARS-CoV-2 is that sufficient amounts of virus-containing aerosols are emitted from the respiratory tract of infected individuals and that, in addition to the viral nucleic acids, the virus remains infective in the airborne state for a sufficiently long period to be inhaled by and establish an infection in others [34, 35]. Controlled animal studies on ferrets showed that transmission of SARS-CoV-2 via both direct contact and air is possible [36, 37]. However, these studies could not discriminate between transmission via small and large droplets.

The exact role and importance of classical airborne transmission of SARS-CoV-2 is still largely unknown, much debated, and a subject to ongoing investigations. Similarly, the role of small droplets for the transmission of influenza virus is also debated. Infectious influenza virus has been detected in small droplets in exhaled breath and coughs and in the air, whereas other studies only recover RNA from air samples and not infectious virus (reviewed in Leung 2021) [38]. Respiratory droplets are further detailed and discussed in Chapter 2.2.

2.1 SARS-CoV-2

Coronaviruses are a group of related RNA viruses that cause diseases in mammals and birds. Most of the viruses cause mild illness such as common cold symptoms [39]. COVID-19 is caused by SARS-CoV-2, a virus first identified in Wuhan, China, in December 2019 [40]. The virus is an enveloped, positive-sense single-stranded RNA *Betacoronavirus* related to SARS-CoV (causing SARS) and MERS-CoV (causing Middle East Respiratory Syndrome) [25]. SARS-CoV was first identified in China in 2002 and had a case-fatality rate of 7%, whereas MERS-CoV emerged in Saudi Arabia in 2012, and had a case-fatality rate of more than 30% [41]. The individual unit size of a SARS-CoV-2 virion is 60-140 nm [42]. A meta-analysis based on 99 studies estimated that the mean incubation period for SARS-CoV-2 was 6.38 days ranging from 2.33 to 17.60 days [43]. Angiotensin I converting enzyme 2 (ACE2) is a cellular host receptor for SARS-CoV-2 and SARS-CoV in humans. The surface spike glycoprotein (S protein) interact with extracellular domains of the human ACE2 to enter the cells [44]. A study by Ortiz et al. [45] shows that ACE2 receptor is highest within regions of the sinonasal cavity (nose) and in the pulmonary alveoli (lungs), which correlates with sites for virus transmission and severe disease development in the lungs, respectively. The S protein of SARS-CoV-2 is different from the S protein of SARS-CoV and it is assumed to bind more strongly to human ACE2 [46, 47]. The high binding affinity of the S protein surface to the host receptor ACE2 is important for SARS-CoV-2 infectivity [46]. Variants of the SARS-CoV-2 with S protein mutations have emerged [48]. The B.1.1.7 variant, named “Alpha” by WHO [49] (first identified in the United Kingdom), has since spread across the world [50]. Other recently emerged SARS-CoV-2 variants of concern with S protein mutations are the B.1.351 named Beta (first identified in South Africa) and B.1.1.28 named

Gamma (first identified in Brazil). Mutations in the receptor binding domain of the S protein contribute to enhanced binding with the ACE2 receptor, and a specific mutation found in these variants is believed to enhance the transmissibility of SARS-CoV-2 [48]. It is hypothesized that the increased transmission of the B 1.1.7 variant is partly due to the increased binding affinity of the S protein with the ACE2 receptor [51]. Another variants of concern is the B.1.617.2, named Delta (first identified in India).

Current diagnostic testing of SARS-CoV-2 includes detection of virus RNA by PCR assays. Detection of virus RNA by PCR does not provide direct evidence about the presence of infectious virus. Direct evidence for the presence of infectious SARS-CoV-2 can only be provided by the use of cell culture (*in vitro*) assays or an appropriate animal model (*in vivo*) [52]. However, cell culture assays are typically less sensitive and much slower than PCR assays.

2.1.1 Environmental stability

The environmental stability (persistence) of SARS-CoV-2 in respiratory droplets on surfaces and in air can affect transmission of COVID-19. At the beginning of the pandemic, contact transmission via contaminated surfaces (fomites) was particularly feared, and efforts were made to disinfection of surfaces [53]. A publication from Van Doremalen et al. [54] showed that SARS-CoV-2 persisted on surfaces such as plastic, stainless steel, copper and cardboard for various times. The longest persistence was observed on stainless steel and plastic with an estimated median half-life of up to 24 hours. The persistence of SARS-CoV-2 was measured as titer of recovered active (infectious) viruses in cell culture experiments [54], and a high concentrations of virus, 10^4 infectious virions, was deposited on surfaces. In general, higher temperatures and/or higher relative humidity have a detrimental effect on SARS-CoV and SARS-CoV-2 stability [55, 56], and the decay rate per minutes of viral infectivity was increased from 2% to approximately 4-6% per minute at higher relative humidity or temperatures [56]. At typical air-conditioned environmental conditions (22-25°C and relative humidity of 40-50%) SARS-CoV persisted on smooth surfaces for more than five days. It has been argued that infections through fomites are unlikely in real-life situations. In recent reviews published by Kampf [57] and Goldman [15], it is concluded that the chance of SARS-CoV-2 transmission through surfaces are small. The methodology of many studies on fomites was critically reviewed, stating that the concentrations used were very high in comparison to real-life situations [58]. This conclusion is further supported by studies performed by Mondelli et al. [16-18] whose attempts on using cell culture to propagate virus from swipe-samples collected in hospital settings, where COVID-19 patients were treated, were mostly unsuccessful. Nevertheless, at the same time the authors emphasize the importance of cleaning and disinfection procedures, and the use of proper respiratory protection in the health care setting.

The transmission potential of SARS-CoV-2 via respiratory droplets in air is influenced by the period of time during which SARS-CoV-2 can remain infectious in the airborne state. Laboratory studies suggest that the persistency of SARS-CoV-2 in airborne droplets will be influenced by environmental conditions such as temperature, humidity and sunlight [54, 56, 59, 60]. Under conditions similar to those expected for air-conditioned indoor environments, the decay rates of SARS-CoV-2 were reported to be less than 3% per minute and the time needed for 90% loss of

infectious virus was more than 75 minutes [54, 59]. Smither et al. [59] studied the decay rate of aerosolised SARS-CoV-2 in cell culture media or in artificial saliva at medium (40-60%), and high relative humidity (68-88%). In cell culture medium, SARS-CoV-2 was more stable at medium relative humidity (decay rate of 0.91% per minute) compared to higher relative humidity (decay rate 1.59% per minute). In artificial saliva, however, the decay rate was 2.27% and 0.4% per minute, at medium and high relative humidity, respectively. Dabisch et al. [56] demonstrated that under conditions representative of those expected indoors, or outdoors during nighttime, the decay rate of airborne SARS-CoV-2 was low and the time needed for 90% loss of infectious virus was more than two hours. By contrast, the time needed for 90% loss of infectious virus at high intensity simulated sunlight (40°C, 20% relative humidity) was approximately 5 minutes [56]. Similarly, Schuit et al. [60] also observed that simulated sunlight rapidly inactivated SARS-CoV-2 in aerosols with half-lives of less than 6 minutes, and 90% of the virus was inactivated in less than 20 minutes. An earlier study [61] showed that the half-life for inactivation of human coronavirus 229E decreased from approximately 67 hours at 50% relative humidity to 3 hours at 80% relative humidity. In a more recent study by Schuit et al. [62], it was shown that the aerosol stability of SARS-CoV-2 has not varied greatly among the currently circulating virus lineages, including the B.1.1.7 Alpha mutant.

It is challenging to estimate the impact of environmental conditions on risk associated with surfaces as well as classical airborne transmission of SARS-CoV-2 based on laboratory studies only, since neither the artificially generated virus-laden droplets nor the environmental conditions will be perfect representations of real-world environments or situations.

2.1.2 Infectious dose and viral load

The transmission characteristics of SARS-CoV-2 make it difficult to control the disease. The SARS-CoV-2 appears to be shedded both by asymptomatic and pre-symptomatic infected individuals, and superspreading events are frequently observed [63]. In Hong Kong, several clusters of superspreading events were identified and characterized, and it was estimated that 10-20% of the patients accounted for 80% of all SARS-CoV-2 transmission [64]. Superspreading has also been observed for transmission of SARS and MERS [65]. The number of SARS-CoV-2 virions needed to start an infection, also known as the infectious dose, is still unknown [65]. The diversity (age, underlying health condition etc.) of COVID-19 patients also makes it challenging to converge on the infectious dose that will apply to everyone from observational epidemiological data only [66]. The effect of the new variants, such as the Alpha, Beta, Gamma and Delta on the infectious dose of SARS-CoV-2 is still unclear.

While infectious dose and persistence of SARS-CoV-2 is highly relevant for the back-end of any potential transmission route, another relevant parameter at the front-end is the virus concentration found in the bodily fluids of the host, such as respiratory tract secretions, at different stages of the infection. A meta-analysis by Cevic et al. [67] showed that SARS-CoV-2 viral load appeared to peak in the upper respiratory tract within the first week after symptom onset, and later in the lower respiratory tract. In contrast, the viral load of SARS-CoV peaked at days 10–14 of illness and that of MERS-CoV peaked at 7–10 days of illness. Viral RNA was detected in the upper airways, in the lower airways, in stools and in serum for weeks after infection, however, the infectious virus

was not detected nine days after onset of symptoms in the patients, despite persistently high virus-RNA loads. Note that the diagnostic PCR test detecting virus-RNA does not reflect the presence of infectious virus in a patient, as the presence of RNA can remain long after the disappearance of infectious virus [68]. Recently, Kim et al. [69] isolated in tissue culture the SARS-CoV-2 10 days after onset of symptoms, and in an observation study of a patient, the viral culture remained positive through day 15 and was negative on day 22 from symptom onset [70].

High viral load of SARS-CoV-2 was also reported among asymptomatic and presymptomatic individuals [71]. Notably, asymptomatic individuals with high viral load could potentially be super-emitters of SARS-CoV-2, however, their role in superspreading events is not clear. Oran and Topol [72] reviewed 16 infectious cluster events and concluded that asymptomatic persons probably account for approximately 40% to 45% of SARS-CoV-2 infections. Recent studies show that asymptomatic patients are responsible for fewer secondary infections than estimated early in the pandemic [71]. In an Argentine cruise ship, a febrile passenger emerged, and after testing of all 217 passengers and crew members it turned out that 59% (128) tested positive for COVID-19, of whom 81.3% (104) were asymptomatic [72]. Pan et al. [73] studied respiratory samples from 80 individuals in different stages of the infection, and overall viral load early after onset of the infection was high (more than 10^6 copies/mL). The viral load peaked around 5-6 days after onset of symptoms. In patients with SARS (SARS-CoV), the viral load normally peaked at around 10 days after onset of symptoms [74]. Avadhanula et al. [75] identified a small group of individuals with mild symptoms and with high viral load (up to 10^{10} copies/mL) of SARS-CoV-2. The viral load varied between 10^4 and 10^{10} copies/mL [75]. Wölfel et al. [76] also observed viral concentrations in this range in patient samples.

It is surprising that despite the high viral load in the airways during COVID-19, few published experimental studies have so far succeeded in recovering infectious virus from air samples. The majority of the studies have detected viral RNA in air samples and on no-touch surfaces in health care facilities [34]. Wölfel et al. [76] were unsuccessful in obtaining a viral culture from samples with a viral load below 10^6 copies/mL. In other studies, no positive culture was obtained in samples with quantitative RT-PCR cycle threshold (Ct) values higher than 24-34 (approximately 10^4-10^6 copies/mL) with the fraction of culture positive samples declining with increasing Ct values [67]. For comparison, Milton et al. [77] only detected infectious influenza virus in exhaled breath samples with high (approximately 10^4-10^5) copy numbers by quantitative RT-PCR. Technical limitations associated with air sampling and viral tissue culture may partly explain the low success rate of such experimental studies. In particular, it is difficult to preserve the biological state of the collected virus particle. The relatively high limit of detection of cell culture assays may present an additional challenge. As a result of these factors, the potential for transmission of SARS-CoV-2 by inhalation, and particularly aerosol transmission, may be underestimated. Nevertheless, it has recently been possible to detect infectious SARS-CoV-2 from air samples collected close to COVID-19 patients in a hospital environment [78].

2.2 Transmission of SARS-CoV-2 by respiratory droplets

Transmission of viral respiratory diseases is caused by the transport of virus-laden respiratory droplets expelled by an infected individual during respiratory activities such as breathing, talking, singing, coughing, and sneezing. These respiratory droplets consist of liquid fluid, dissolved salt and solid residues, as well as infectious virus particles and viral residues [79]. Droplets of all sizes is subject to evaporation and thus reduction in size. The rate of evaporation depends on droplet size, temperature and the relative humidity of the air [80]. Specifically, the rate of evaporation increases with increasing temperature and with decreasing humidity [80]. The presence of salt and solid residue prevents a complete evaporation. Consequently, the final size of the resulting droplet nuclei is in the range 20-50% of the original diameter [79, 81-84]. The droplets or droplet nuclei may stay suspended in the air or fall to the ground depending on their size and the ambient conditions [80, 85]. In the remaining text, we will refer to small droplets, small particles, small droplet nuclei, and aerosols interhangeably.

2.2.1 Droplet generation

Respiratory droplets are believed to be generated by means of a liquid sheet breakup from the mucosal layers coating the respiratory tract during breathing, talking, and coughing (see Mittal et al. [86] and references therein). Different activities yield different instantaneous concentrations. Duguid [81] reported that a sneeze releases about one million droplets, about 200 times more than for a single cough. Because of the short duration of coughing events, more droplets can be released during speech than during coughing. For example, counting aloud from 1 to 100 is reported to release three times as many droplets as a single cough [87-89].

In the literature, there are large discrepancies in the characterization of droplet sizes between different sources. According to Nicas et al. [82] and Johnson et al. [83], early works such as Duguid [81], Loudon and Roberts [90], and Papineni and Rosenthal [91] suffer from methodological weaknesses. Johnson et al. [83] found that the size distribution of the droplets produced during speaking and coughing has three distinct peaks. For speech, the peak droplet diameters, *before evaporation*, were found to be 1.6 μm, 2.5 μm, and 145 μm. For coughing, the corresponding peaks were found at 1.6 μm, 1.7 μm, and 123 μm. The first peak relates to the so-called *Bronchiolar film burst*, a mode also found in regular breathing. The second, referred to as the *Laryngeal mode*, is most active during speaking and coughing. Finally, the third so-called *Oral cavity mode* is also active during speaking and coughing. We show the combined tri-modal droplet size distribution function in Figure 2.1. Contrary to the decrease in droplet count in the sub-micrometer range observed by [83], several recent studies (Fabian et al. [92], Lindsley et al. [93], and Asadi et al. [94]) find the highest droplet counts in the smallest size classes (below 0.7 μm). None of these results appear to be corrected for evaporation, which renders comparison of the droplet size distribution from different sources difficult. Neverheless, all these studies find the highest droplet count in the smallest size range measured. This is an important finding, since the review from Fennelly [95] indicates that pathogens predominate in small droplets. Several of the reviewed studies appear to have sampled droplets at a distance, which may make the results susceptile to bias because of fallout of the larger droplets.

Asadi et al. [88] found that the particle count correlates positively with loudness, regardless of language, but that the droplet size distribution is relatively unaffected. Whispering the vocal /a/ resulted in an instantaneous particle concentration of approximately 500 particles per litre whereas shouting gave just over 3000 particles per litre. Between these two extremes, an approximate linear relation with amplitude was seen. Reading an English passage resulted in an average concentration of 200 particles per litre, but there was a large variability between different subjects. They also found that a small fraction of individuals expel a significantly larger number of droplets than the rest, and thus behave as speech superemitters. We refer to Chapter 2.1.2 for a discussion of this topic and for further references.

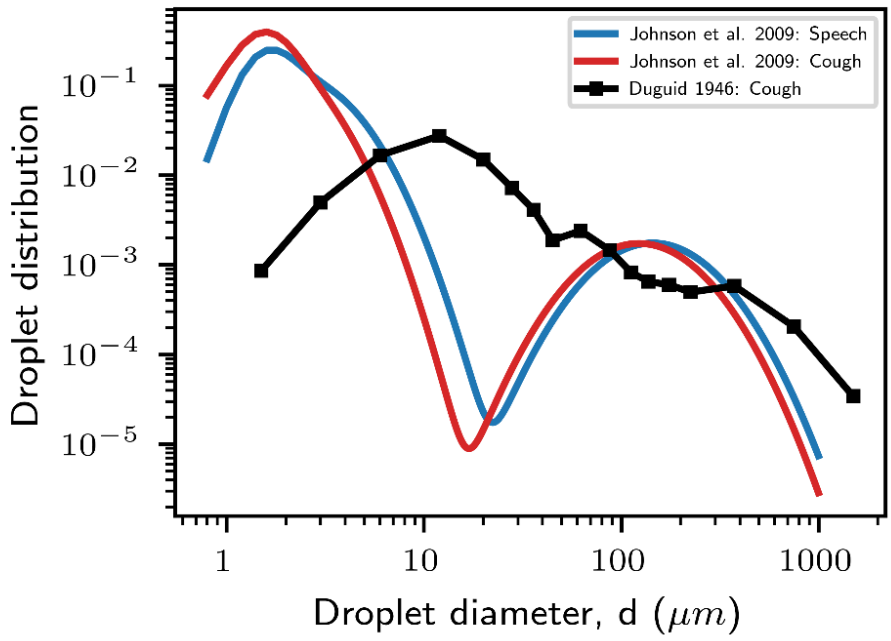


Figure 2.1 Tri-modal droplet size distribution function according to Johnson et al. [83].

There is clear support in the literature that more than half of the expelled droplets are smaller than 10 µm [81, 83], and this has a at least two important implications. First, droplets in this size range may hover in the air for very long periods of time and may thus contribute to a background concentration in the surrounding air. Second, droplets smaller than 4 µm comprise the so-called respirable fraction able to deposit in the bronchiole and alveoli [20].

Lee [96] discussed the minimum droplet size able to contain SARS-CoV-2. He assumed spherical droplets and spherical virions, and used established size data of the virus (70–90 nm [97, 98]) and concentration data from patients (7×10^6 – 2.3×10^9 copies per mL [76]. Assuming a uniform concentration of virus, for the highest viral load the author estimates the minimum droplet size that may contain one SARS-CoV-2 virion would have a diameter of 4.7 µm. Lee's calculation contains an error by a factor of two[1], meaning that the correct estimate based on these assumptions

[1] This has been confirmed by the author (personal communication).

should be 9.3 μm. There are indications that this estimate is too large since viral material has been detected in much smaller droplets. For example, Liu et al. [33] detected viral RNA in a large fraction of droplets smaller than 0.5 μm in air samples taken from a Wuhan hospital. Lee [96] discusses these results and speculates that they can either be explained by evaporation of the droplets or that the model estimates are based on a too low viral concentration. It is unlikely that evaporation can reduce the size of respiratory droplets by an order of magnitude, since the accepted final droplet size after evaporation is in the range of 20–50% [79, 84]. Using a final size of 20%, the model in [96] would require a hundred-fold increase in the viral concentration, which is not supported in the literature [75, 76]. Lee's analysis does not take into account that the small droplets dominate the respiratory droplet size distribution, and that virions may be enclosed in any droplet that is larger than the virion size, i.e. approximately 100 nm. The minimum size obtained must therefore be interpreted as a statistical measure, and Lee's estimate should therefore be interpreted such that, statistically, we expect to find one virion in each droplet of 9.3 μm diameter. Likewise, if we consider a smaller droplet of size 2 μm, we expect to find one virion in every hundred droplets. Combining these data with the size distribution of respiratory droplets in Figure 2.1, which shows that there are approximately 2000 times more droplets of size 2 μm than of size 9.3 μm, we estimate that it is twenty times more likely to find a virion in droplets of size 2 μm than in droplets of size 9.3 μm.

2.2.2 Droplet transport

In his seminal work on droplet evaporation and settling, Wells [85] reported that droplets with diameters larger than 100 μm would settle to the ground in liquid form within seconds. Droplets with diameters smaller than 100 μm would evaporate into droplet nuclei and stay suspended in air. According to Bourouiba [99], this led to a physics based dichotomy that classified respiratory transmission into a large- versus small-droplet route. In this isolated droplet view, it is easy to realize that larger droplets (larger than 150 μm) can reach 1-2 m before they impact the ground, whereas smaller droplets (smaller than 100 μm) encounter significant aerodynamic drag that limits their initial travel distance distance to a few decimeters[2]. This view has led to the conjecture that most droplets are unable to travel further than two meters as a result of respiratory activity.

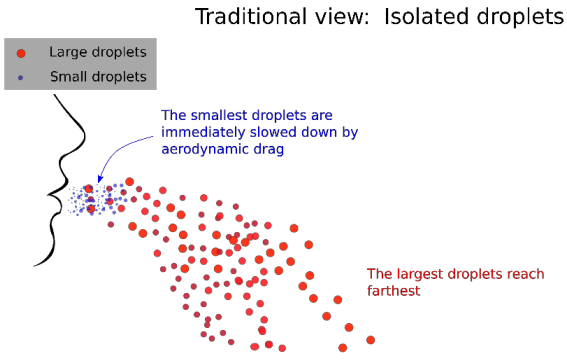
Recent experiments [99-101] and simulations [102], however, contradict this conjecture. Bourouiba [103] claims that for violent sneezes, the flight path of droplets of all sizes may extend up to 7-8 m, even in the absence of background airflow. Likewise, the droplets expelled by coughing may reach 2-3 m [104, 105]. The reason for this discrepancy is related to the presence of the respiratory jet; the expelled droplets are suspended in a fully turbulent humid and warm puff cloud [99]. This cloud initially has the form of a turbulent jet that will be of different strengths depending on the type of respiratory activity (from breathing to sneezing). As the jet slows down, buoyancy effects will at some point become dominant. This cloud is able to augment the travel distance for droplets of all sizes. Furthermore, the cloud is warm and humid thus delaying the evaporation process. As the jet disperses downstream, the turbulence levels decrease resulting in a continuous fallout of droplets. The smallest droplets may, however, become trapped in the

[2] These small droplets will however be suspended in air for long times and may be transported considerable distances by the background flow.

buoyant cloud and stay suspended for a long time. We depict the differences of the traditional isolated droplet view and the modern multiphase view in Figure 2.2.

Abkarian et al. [106] showed that also speech can generate turbulent jets able to reach up to 1-2 m from the host. Although they did not study droplet transport directly, they postulated that small droplets can be transported a distance of 2 m by speech jet puffs during a conversation. This seems reasonable given that droplets in this size range have little inertia. To the best of our knowledge, data are lacking to be able to quantify the maximum droplet size that this type of jet can entrain. Building on the findings in [106], Yang et al. [107] discuss improvements to the standard "well-mixed"[3] model for infection probability. In their proposed model, they account for the higher concentration of virions present for people in zones affected by the speech jet. The authors applied their exposure model to a poorly ventilated space for typical droplet production rates and viral saliva loads reported in literature. The exposure model showed that due to the speech jet it takes only 8 min at 1 m distance from an infected subject to reach a high risk of infection. Similarly, the time needed to reach a high risk at a separation distance of 2 m was 16 min. It is not straightforward to compare these results to the risk experienced in well mixed background concentration conditions, but a rough estimate can be found by using the same framework and basic assumptions as Bazant and Bush [108]. For two persons occupying a poorly ventilated room (0.3 ACH) with dimensions 9 m^2 × 2.4 m, we find that the time needed for high risk of infection in such well mixed conditions is just short of two hours. Hence, at distances shorter than two meters, the time needed to experience a high risk of infection is at least a factor of ten times shorter when directly exposed to the speech jet than for well mixed, poorly ventilated, conditions. From these results, it is straightforward to conclude that the risk of infection is greatly enlarged when exposed directly to any kind of resperatory jet.

The processes of inhalation and exhalation are fundamentally different. Whereas exhalation produces a strong directed jet, inhalation draws in air almost uniformly from a hemispherical region in front of the head [101], as illustrated in Figure 2.3.



[3] In this context, well mixed means that the concentration of virions is uniformly distributed throughout a room.

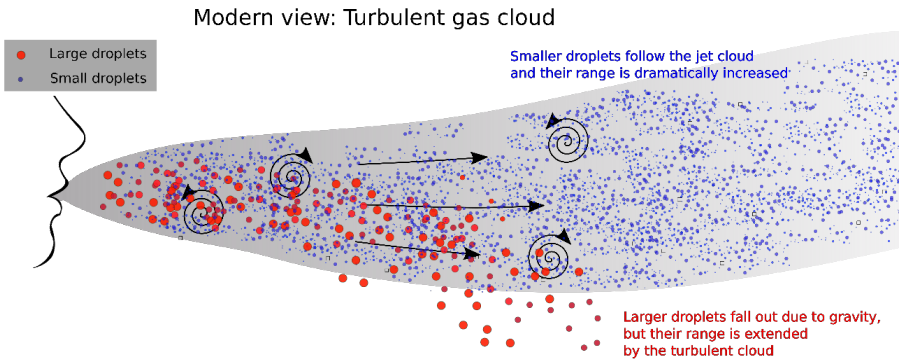


Figure 2.2 Schematic depiction of the two models of exhaled droplet transport for all respiratory modes. The top frame shows the classical isolated droplet model after Wells [85], whereas the bottom frame shows the more realistic turbulent multiphase model after Bourouiba [99]. Note that different respiratory activities differ in velocities as well as droplet distribution.

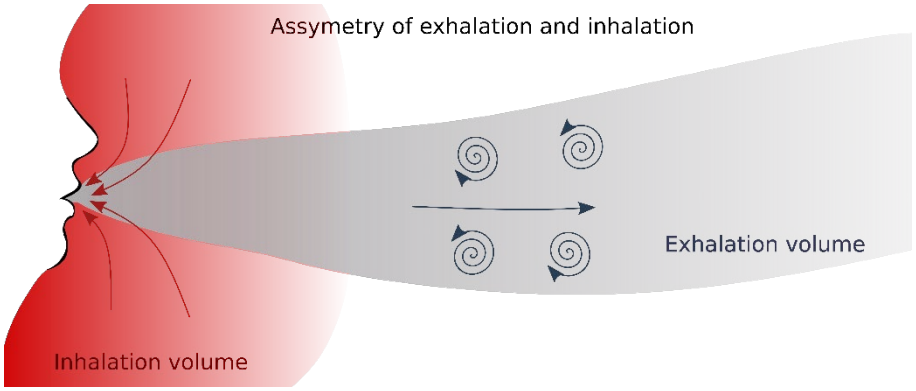


Figure 2.3 Conceptual view on the difference between exhalation and inhalation. Exhalation results in the formation of a turbulent respiratory jet with high velocities, whereas inhalation draws air from a hemispherical region in front of the face with lower velocities. Figure is based on Abkarian et al. [101].

2.3 Source control versus respiratory protection

When discussing the benefit and efficacy of different types of face coverings in terms of controlling and preventing transmission of respiratory droplets containing SARS-CoV-2, it is important to distinguish between the two main contexts of their use, namely *source control* and *respiratory protection*.

A COVID-19-infected individual will, depending on the stage of the infection, emit respiratory droplets containing SARS-CoV-2, which upon inhalation by a non-infected individual may pose a transmission risk. In particular, infected individuals who remain asymptomatic or develop only mild symptoms can unwarily infect others [109]. In order to reduce transmission of respiratory

diseases, a common approach involves efforts to stop the emission of these respiratory droplets at its origin – namely the infected host – by using a face covering such as a MFM or CFM to provide *source control.* According to the relevant standards the intended use for MFMs and CFMs is first and foremost to control and prevent the outward emission of respiratory droplets by introducing a physical barrier that provides a filtration mechanism and also dampens the propagation of the respiratory jet.

At the same time, the respiratory tract is a gateway for many air-transmitted factors such as bioaerosols, dust particles, or toxic fumes and gases, which may pose an inhalation hazard and a threat to human life, health and wellbeing. For this reason it is often necessary, especially in an occupational setting, to provide *respiratory protection* for individuals that may be exposed to such inhalation hazards. This is typically achieved using personal protection equipment such as respiratory protective devices (RPDs). Several kinds of RPDs, including filtering facepiece respirators (FFRs), are used to provide respiratory protection by filtering contaminated air, thus stopping e.g. potentially virus-laden respiratory droplets from being inhaled by a wearer. The intended use of RPDs is reflected in their performance requirements and test procedures. At the same time, even though MFMs and CFMs are made of materials with filtering properties, it is neither clearly defined nor understood if, or to what degree, MFMs and CFMs offer any respiratory protection to the wearer. These devices are not classified as RPDs and the performance requirements and test methods applied to these devices according to the relevant standards do therefore not consider this function.

Source control and respiratory protection

According to the U.S. Centers for Disease Control and Prevention (CDC), two conceptual approaches can be distinguished with respect to the use of face coverings as a mean for control and prevention of COVID-19 transmission [110]:

Source control protects others. Source control refers to the use of face coverings (medical face masks, MFMs, community face masks, CFMs) to cover a person's mouth and nose and to help reduce the spread of respiratory droplets to others when the person talks, sneezes, or coughs. This can help reduce the spread of SARS-CoV-2, the virus that causes COVID-19, especially by someone who is infected but does not know it.

Respiratory protection protects the wearer. Respiratory protection refers to respirators (respiratory protection devices, RPDs), which are protective devices that cover a person's nose and mouth or the entire face or head to help reduce the wearer's exposure from breathing in air that contains contaminants, such as respiratory droplets from a person who has COVID-19. This type of protection can include filtering facepiece respirators (FFRs), like N95 respirators.

3 Face coverings against biological contaminants in air

In this chapter, a brief description of different types of face coverings (masks), including their intended use, performance requirements, and testing methodology, is presented with reference to applicable European directives, regulations and harmonized test standards. It should be mentioned that some of the terminology is often used inconsistently in the literature and may even differ between countries and regions. The most consistent terminology can be found in documents issued by relevant national and international standardization bodies. Conformity assessments of commercially available face coverings are generally carried out on the basis of tests performed according to harmonized performance requirements and test procedures defined in standards issued by e.g. the European Committee for Standardization (CEN), the International Organization for Standardization (ISO), and the American Society for Testing and Materials (ASTM). In Norway and in the European Union (EU), RPDs such as FFRs require certification, including an EU Type Examination Certificate by a Notified Body, since FFRs are products falling under the European Regulation for Personal Protection Equipment (EU Regulation 2016/425). MFMs are medical devices that fall under the European Medical Device Directive (EU Directive

93/42/EEC), and therefore do not require third-party certification. Nevertheless, both for FFRs and MFMs, it is ultimately a sole responsibility of the manufacturer to ensure that the product conforms to all the applicable regulatory requirements, and to formally accept responsibility for this by issuing the mandatory EU Declaration of Conformity document.

3.1 Basic terms and definitions

Several parameters and terms are used to describe the properties and protective performance of face coverings such as MFMs, CFMs and FFRs. For this reason, it is useful to introduce some key terminology covering their classification, protective performance and standard testing procedures. A short introduction to FFRs, a specific class of RPDs, is also included, since they are frequently used as a benchmark when considering the performance of MFMs and CFMs. In addition, standard testing procedures for FFRs are often employed to evaluate the protective performance of MFMs and CFMs in the context of respiratory protection.

3.1.1 Filtration efficiency (FE)

Protective performance of face coverings or filter materials is often given in terms of *Filtration Efficiency (FE)* for solid or liquid aerosol particles of a certain size. In general, during FE testing a stream of aerosol-containing air is flowing at a certain speed through the filter material or face covering (mounted in a holder or donned on an artificial head-form) while the upstream and downstream particle concentrations are measured. For RPDs such as FFRs the test aerosol typically consists of sub-micron droplets/particles of sodium chloride (NaCl) or oil (paraffin oil, corn oil) with defined size distributions, whereas for MFM the test aerosol consists of approximately 3 μm droplets/particles containing living *Staphylococcus aureus* bacteria. The FE is calculated based on the amount of particles that are retained by the filter material or face covering (downstream concentration) relative to the amount of particles in the air stream (upstream concentration). Depending on the test aerosol used, the FE can be expressed as particle filtration efficiency (PFE), bacterial filtration efficiency (BFE) or viral filtration efficiency (VFE). The FE depends on several parameters such as particle size distribution, airflow and the type of filter material [111-114]. The airflow used for testing is given as the amount of air per unit time (e.g. L/min) or as a face velocity (e.g. cm/s). It should be mentioned that for FFRs the FE is measured for the entire device, whereas for MFMs and CFMs only a selected area is tested.

3.1.2 Fit factor (FF)

FE values alone cannot be used to predict the protection level of face coverings, since the openings (gaps) along the perimeter of the mask may be a source of leakage (i.e. contaminated air may penetrate through these gaps during inhalation and/or exhalation, and thus bypass the filter material). In particular, tight-fitting RPDs, such as FFRs, must form a seal between the mask perimeter and the wearer's face to function as intended. With a sufficient seal, a negative pressure is created inside the mask during inhalation, and the air stream must pass through the filtrating layers before reaching the respiratory tract of the wearer. Therefore, the protection level provided by FFRs depend also on several user-related factors, including shape and size of the FFR relative

to the anthropomorphic facial proportions of the wearer. Proper training and stringent donning and doffing procedures are also crucial. To ensure the mask is properly fitted, a quantitative or qualitative evaluation of *Fit Factor (FF)* is performed, during which the leakage around a faceseal is assessed. For qualitative FF measurements, an aerosol of a substance with a pronounced smell (e.g. isoamyl acetate – "banana oil") or taste (e.g. Bitrex) is introduced and the fit is assessed based on whether the wearer can taste or smell the test substance. For quantitative FF measurements, aerosolized droplets/particles are used (e.g. NaCl or corn oil, see also Appendix-A.2 for further details regarding testing). The test person dons the FFR and enters an enclosure filled with the test aerosol, while the test particle concentration is measured inside and outside of the FFR.

3.1.3 Total Inward Leakage (TIL)

A more accurate estimation of the protective performance of FFRs in terms of leakage is the measurement of *Total Inward Leakage (TIL)*. According to EN149, TIL "consists of three components: faceseal leakage, exhalation valve leakage (if exhalation valve fitted) and filter penetration" [115]. During TIL measurements a trained RPD user dons the FFR, enters an enclosure filled with air containing a test aerosol or gas, and performs a series of movements (exercises), which simulate usual activities performed while wearing RPDs [115, 116]. The test aerosol typically consists of sub-micron droplet nuclei of NaCl with defined size distributions. The test aerosol concentration is measured inside and outside of the FFR during each exercise, and the TIL is calculated as the ratio between these two concentrations (for details see Appendix-A.2). It should be mentioned that since MFMs and CFMs are loose-fitting devices that are not used for respiratory protection purposes, no TIL requirements exist for these types of face coverings.

3.1.4 Protection factor (PF)

The protective performance of RPDs can be also expressed as *Protection Factor (PF),* which in a simple approach is the inverse of TIL. The practical implication of PF is easy to understand since if the PF is e.g. 100, then the concentration of a harmful substance in the surrounding air is reduced 100 times while wearing the RPD. However, if the PF is measured under laboratory conditions, it does not necessarily reflect the level of respiratory protection achieved in the working environment. For this purpose, the *Assigned Protection Factor (APF)* is used [117, 118]. Measured under simulated working conditions, the APF is the realistic level of respiratory protection that can be achieved by 95% of the trained wearers, provided that their RPD is properly fitted and well-functioning.

3.1.5 Pressure resistance

Another important property of face coverings is the *pressure resistance*. Various other terms are also used such as differential pressure, pressure drop and breathability, although the latter is somewhat ambiguous since breathability also may refer to the ability of a fabric to allow for moisture transport. For testing purposes, e.g. for FFRs, the device can be donned and sealed on

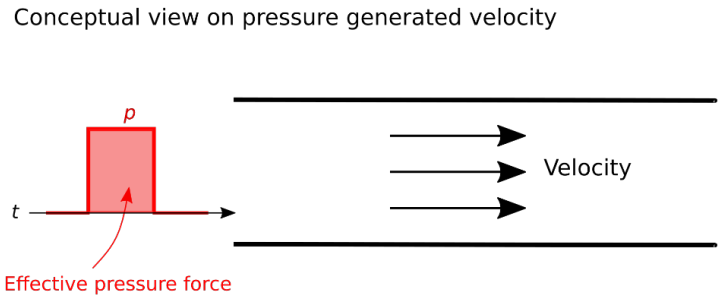
an artificial head connected to a breathing simulator, and the pressure difference is measured in the vicinity of the mouth opening [115]. A relatively high airflow is used to ensure a labored breathing will not be significantly obstructed by the FFR. For MFMs a part of the device is spread flat on the holder and a defined area is exposed to the airflow while the pressure drop is measured.

3.2 Alternative methods for filtration efficiency testing

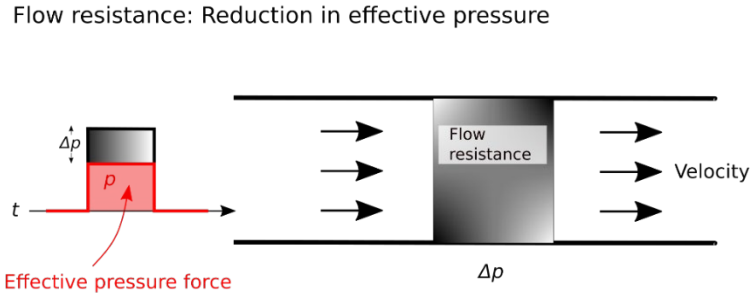
The standard FE testing procedures for RPDs are sometimes used for testing MFMs and CFMs, especially for the sub-micron particle size range. However, these procedures exclusively involve droplets/particles of salt, oil or other chemical substances. For this reason, suitability of FFR-related standards for assessing FE against an aerosol containing microorganisms (bioaerosol) has sometimes been questioned [119]. To determine whether the aerosol type (chemical vs. biological) would introduce any significant change in the performance evaluation of MFMs, several authors have evaluated the FE of MFMs and FFRs using viral (VFE) or bacterial (BFE) aerosols, and compared the results with those obtained using salt particles or oil droplets (PFE). In a study by Rengasamy et al. [120], six N95 FFRs, three surgical N95 FFRs and three models of FDA-cleared MFMs were tested against bacterial, viral and particulate aerosols. The authors discussed VFE, BFE and PFE test methods and concluded that tests for BFE (*S. aureus*) and VFE (bacteriophage phiX174) performed according to a modified ASTM F2101 are much less demanding than the NIOSH standard testing procedures for N95 FFRs, in terms of airflow velocity and particle size range. For FFRs the NIOSH test conditions are believed to already represent the worst case scenario, with high airflow and charge-neutralized particles of a size close to the most penetrating particle size, and for this reason an additional VFE or BFE evaluation is not necessary. When MFMs were measured using the same NIOSH N95 [121] method with salt particles, their PFE was in the range of 54.74 – 88.4%, while for comparison their VFE and BFE measured according to ASTM tests were over 99% [122]. By contrast, the PFE values obtained during salt particle tests for all N95 FFRs were higher than 98%, and for VFE and BFE higher than 99%. Similar results were obtained by Wen et al. [119] who developed a method for testing VFE using NIOSH-certified N99 FFRs and found that FFRs are equally efficient against 1.2 µm f2 phage aerosols as it is against solid salt particles in a standard NIOSH FFR test. Likewise, Balazy et al. [123] tested two different models of N95 FFRs from two different manufacturers against a 30 nm bacteriophage MS2 aerosol and concluded that testing with solid salt particles can be used to evaluate the FE also against viral aerosol particles of the same size. These results indicate that the use of a "living" bioaerosol is not necessary for assessment of FE and that testing with charge neutral salt particles give a good indication of the FE against other kinds of aerosols, including bacterial and viral ones. If the conservative methods using neutral salt aerosols are indeed sufficient for reliable prediction of the FE of MFMs against bioaerosols, a direct implication could be that the VFE and BFE of MFMs and CFMs can be evaluated using much less resource- and time-consuming PFE tests, and which may allow for a wider or more targeted particle size range to be covered. In order to establish such equivalent procedures it first has to be clearly defined which testing parameters should be used for evaluation of MFM and CFM performance in terms of particle size distribution, airflow velocity, and most importantly, the pass-fail criteria [124].

3.3 The mechanics of face coverings

Wearing any type of face covering will influence the respiratory flow. The main reason for this is that the porous face coverings offer flow resistance that changes the flow pattern close to the face. In particular, the respiratory jet generated by exhalation is obstructed whereas the changes in the flow pattern during inhalation will be smaller but nevertheless important. We show a simplified sketch of the effects of flow resistance in Figure 3.1. The actual porous flow mechanism is quite complicated to fully describe, but on a macroscopic scale it is often modelled as a pressure drop that depends on the internal geometry of the porous elements (see for instance Tamayol et al. [125]). For exhalation, the flow resistance results in an overpressure in the region between the face and the face covering. Likewise, for inhalation, the flow resistance results in a negative pressure between the face and the covering, but numerical simulations by Xi et al. [126] show that, in the absence of leaks, the additional pressure drop moderately alters the flow pattern during inhalation. Therefore, face coverings appear to have a greater impact on exhalation flows.



a) A pressure pulse leads to an exhalation flow



b) Flow resistance reduces the effective pressure available to generate flow, resulting in a lower velocity. Due to mass conservation, the velocity is the same before and after the region of flow resistance.

Figure 3.1 Schematic of the effects of flow resistance. The pressure-driven respiration flow is affected by the extra resistance provided by the face covering.

Another important aspect for the mechanical description is the principle of mass conservation. An immediate effect of this is that there is a direct relationship between flow velocities and the area available for the flow. Additionally, we must take into account leakage caused by gaps between the face covering and the face, which will change the flow resistance distribution, thus also affecting the local flow field. Gaps will typically have less flow resistance than the filter material that leads to escape of air and small droplets. We show sketches depicting these effects in Figure 3.2 and Figure 3.3.

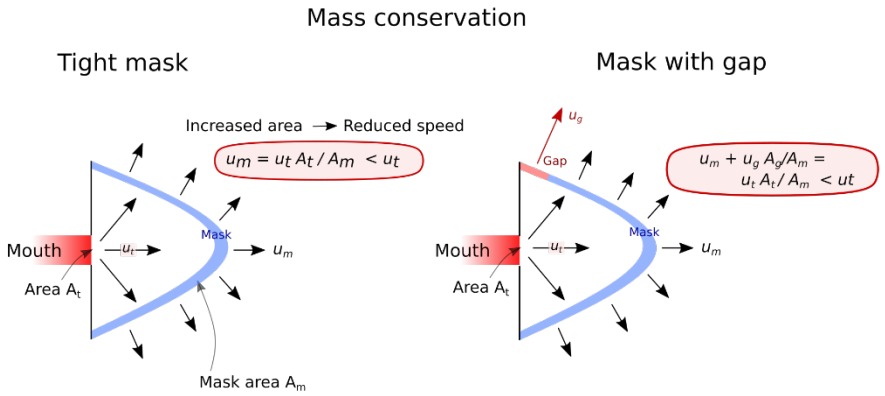


Figure 3.2 Schematic description of the principle of mass conservation, as applied to an example of exhalation. The magnitude of the mask and gap velocities (u_m and u_g) depends on the properties of the gap area compared to the rest of the mask and the exit velocity (u_t).

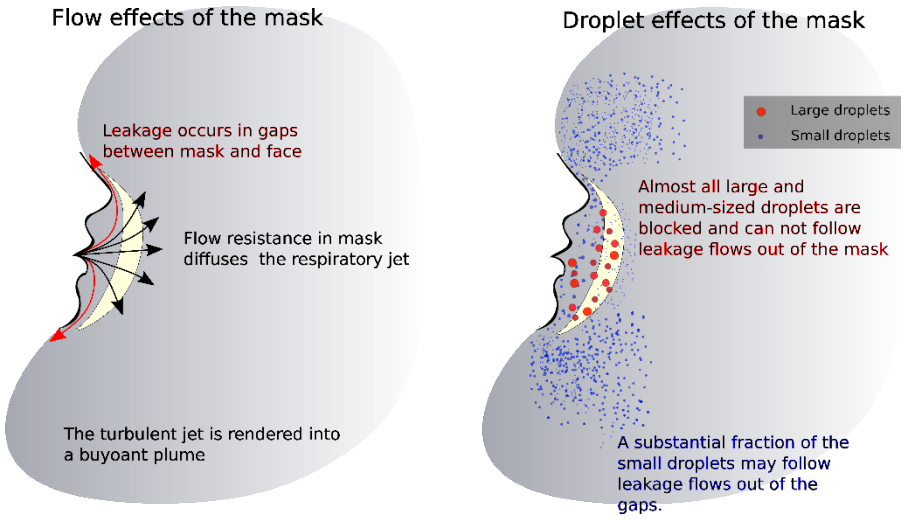


Figure 3.3 Effect on exhalation flow and droplets from face covering. Similar effects will be seen during inhalation.

The distribution of flow through the filter and gaps is complicated to describe accurately, but Perić and Perić [127] employed the basic principles discussed above to develop a simple model that describes the velocities through the mask and gaps. Assuming that there is leakage through gaps spanning one third of the mask perimeter, the model predicts that gaps as small as 0.15 mm may result in approximately 2% leakage, and that a uniform gap of 1 mm cause more than half the airflow to pass through the gaps. It is important to note that these results stem from a highly simplified model, and in later chapters we will present experimental data that give a better quantification of mask performance.

3.4 Filtering facepiece respirators (FFRs)

FFRs are a class of RPDs and therefore fall under the European Regulation on Personal Protection Equipment (EU Regulation 2016/425). RPDs can filter the contaminated air (e.g. FFRs, powered air-purifying respirators, PAPRs) or supply clean air to the wearer from an external source, e.g. self-contained breathing apparatus (SCBA). RPDs can have numerous designs and technical solutions (e.g. full mask, half mask, hood or helmet; loose or tight fit; with or without powered air supply etc., see Figure 3.4).

In occupational settings, a respiratory protection program is implemented to ensure the workers are sufficiently protected and legal regulations concerning the proper use and intended function of RPDs are followed [118, 128]. During the COVID-19 pandemic, WHO recommends the use of FFRs with the highest protection levels (FFP3, N99 or N100) by HCWs during aerosol generating procedures, otherwise the use of FFR may be affected by their availability and costs [5].

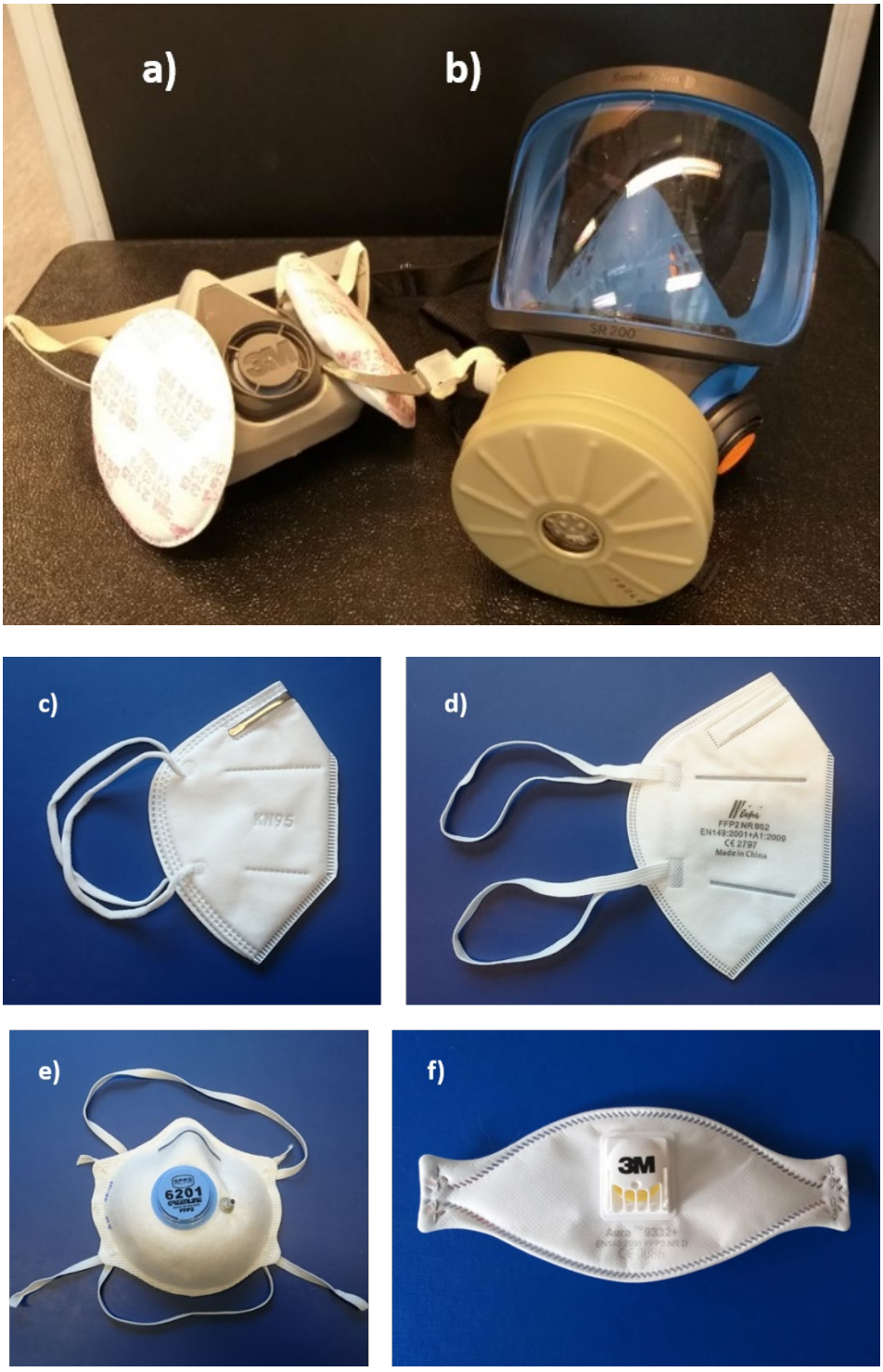


Figure 3.4 Different types of RPDs: elastomeric a) half-mask and b) full-mask, c) FFR folded with earloops and d) head bands; e) mold extruded with exhalation valve, f) horizontally folded with exhalation valve (Photo:FFI).

3.4.1 Product categories

FFRs consist “entirely or substantially of filtering material” and covers mouth and nose of the wearer, creating a seal between the mask’s material and the skin [115]. Different models of FFRs are available with or without a valve to reduce the breathing resistance during exhalation (Figure 3.4 e-f). Most FFRs are disposable (single use), although decontamination methods have been applied to allow for emergency reuse of FFRs in times of critical shortage [129]. In general, FFRs consist of several layers of plastic fiber material, such as polypropylene [10]. The in-between layer(s) made of melt-blown or spun-bonded (non-woven) plastic fibers have filtering properties due to their net charge, which allows them to efficiently capture charged particles [10, 113]. This allows for constructing relatively thin filtering materials with low pressure drop and high FE. Studies show that the electrostatic mechanism can be gradually weakened during the mask use by e.g. contact with water, water vapor or solvents [129], or build up of particulates, which are screening the fiber charge and the mechanical filtration mechanisms (Brownian diffusion for smaller particles, and interception and inertial impaction for larger ones) [111-113]. It is acknowledged that for the mechanical filtration media the most penetrating particle size is approximately 0.2-0.3 μm [112], whereas for the electrostatically charged ones (electret), such as those used in FFRs, this size is smaller than 100 nm [111-113, 130, 131] for the airflow velocities usually used in testing. The most penetrating particle size represents a minimum on the penetration curve, with lower penetration of particles with sizes above and below this size.

3.4.2 Performance requirements and test methodology

FFRs should provide protection against different kinds of aerosols, solid and liquid, and it has been shown that FFRs also are highly effective against viral and bacterial bioaerosols, including SARS-CoV-2 [10, 123, 132, 133]. For certification purposes several FFR specifications are tested, the two most relevant for respiratory protection being FE and TIL [114]. Other requirements, such as flammability, compatibility with the skin, pressure drop across the mask, CO_2 accumulation during breathing etc., and their testing procedures are beyond the scope of this report, and can be found elsewhere [115, 118]. Here, we will shortly discuss the standard testing procedures for PFE and TIL found in the European, US and Chinese test standards.

A summary of standard testing procedures and experimental conditions for FE of FFRs is given in Appendix, Table A.1. Briefly, PFE is established by testing against one or more aerosols, usually solid (NaCl) and liquid (paraffin oil, emery oil). The standard testing procedures for PFE are meant to represent the “worst case scenario”, with high airflows of 85-95 L/min (EN, GB, NIOSH) and polydispersed aerosols where the particle size distribution is chosen to represent the MPPS for the filter material [120]. The airflow is similar to a wearer’s minute volume under strenuous activity [123]. In most European countries, FFR performance is evaluated according to the standard testing procedures described in “EN149: Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking” [115]. According to EN149 FFRs are divided into three classes depending on their performance: FFP1, 2 and 3. All classes are tested against both solid particle (NaCl) and liquid droplet (oil) aerosols (PFE of FFP1, 2 and 3 should be 80%, 94% and 99%, respectively). In the US, FFRs are divided into several classes, depending on their performance towards solid particles (NaCl) - N95, N99 and N100

(PFE of 95%, 99% and 99.97%, respectively), and liquid droplets oil) (P- and R-series respirators).

For proper assessment of FFR protective performance knowing the leakage is essential (e.g. TIL, FF, PF, APF). Different standard protocols for measurement of TIL for FFRs are given in Appendix, Table A.2. More about the different methods of measurements, and factors and parameters affecting the leakage and fit testing can be found in e.g. [132, 134-139]. A comparison of TIL, PF and APF for EN149-certified FFRs is given in Table 3.1. In the US, according to Occupational Safety and Health Administration (OSHA), FFRs are expected to have APF of at least 10, regardless of their class [117].

Table 3.1 Total Inward Leakage, Filtration Efficiency, Protection Factor, and Assigned Protection Factors requirements for different FFR classes according to EN149 [115, 118].

Class	TIL (maximum)	FE (minimum)	PF	APF
FFP1	22%	80%	4.5	4
FFP2	8%	94%	12.5	10
FFP3	2%	99%	50	20

To summarize, all the standards set high requirements towards the FE of the FFRs, with FFP2, and N95 having similar PFE against solid aerosols. Nevertheless, the PFE is one of many elements affecting the protective performance, and should be considered in conjunction with the parameters referring to leakage of contaminated air into the FFR, such as TIL, PF and APF. The real-life assessment of FFRs must be done by measuring leakage experienced by an individual RPD user.

3.5 Medical face masks (MFMs)

MFMs, often referred to as surgical masks especially in the US, are classified as medical devices and therefore fall under the European Medical Device Directive (EU Directive 93/42/EEC), which is scheduled to be replaced by the European Medical Device Regulation (EU Regulation 2017/745) as of 26 May 2021. MFMs are therefore not RPDs. In Europe, the manufacturer is responsible for issuing the EU Declaration of Conformity document and ensuring that sufficient technical documentation has been established [140, 141]. In the US, the US Food and Drug Administration (FDA) is responsible for clearing MFMs for the US market based on tests performed according to ASTM F-2100 standard [122, 142-144].

The main purpose of MFMs is to to provide source control by controlling and preventing the emission of respiratory droplets from the wearer to the surrounding environment, e.g. protect the patient from respiratory droplets emitted from the respiratory tract of medical personnel, or *vice versa*, if the patient is wearing the MFMs [145]. Certain MFM classes are splash resistant and can provide protection to the wearer from splashes that could occur during surgical and other medical procedures.

3.5.1 Product categories

MFMs consists of several fabric layers usually made of non-woven polyester fibers, where the outer layer (cover web) protects the inner filter layer supported by a shell layer [146]. It may have different forms, as seen in Figure 3.5. The most common types are pleated surgical masks with elastic ear-loops or straps tied at the back of the head.

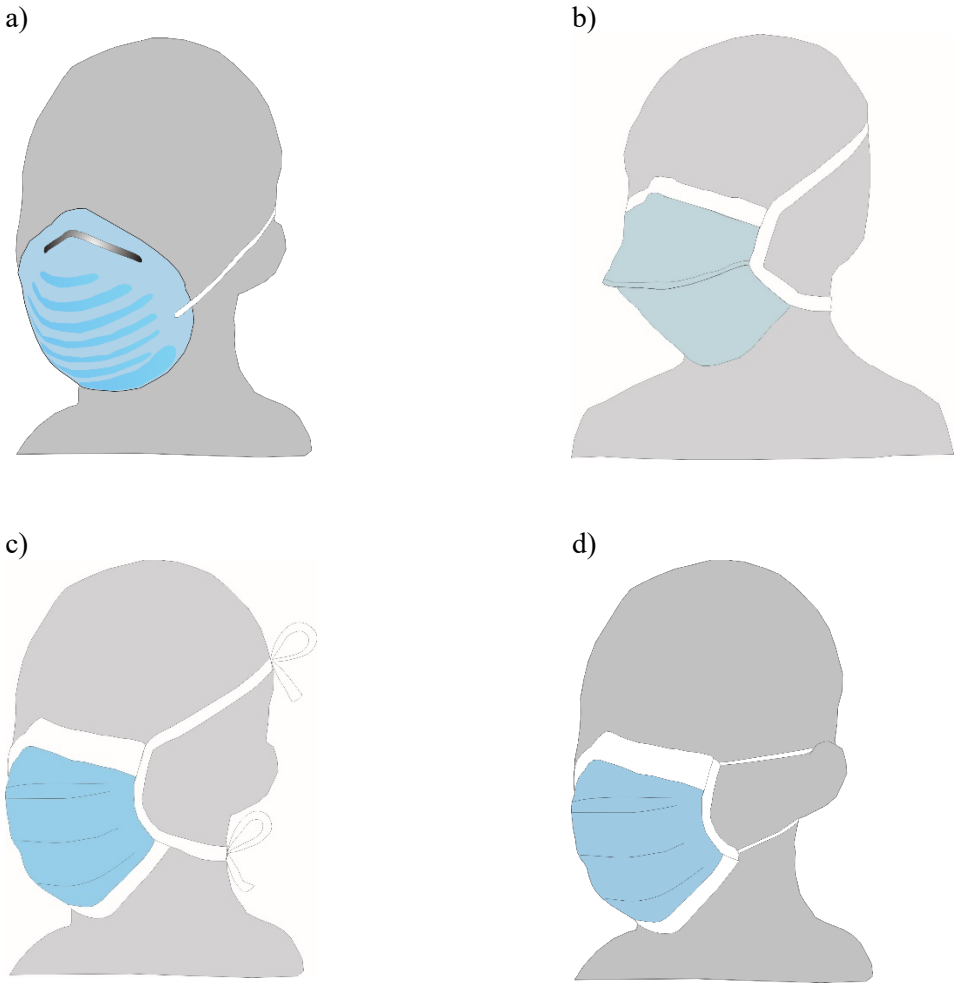


Figure 3.5 Examples of different models of MFMs: a) molded cone-shaped, b) duck bill, c) pleated with ties and d) ear-loops (drawing by FFI).

3.5.2 Performance requirements and test methodology

Several properties of MFMs are typically tested including their BFE, pressure resistance and splash resistance. Performance testing of MFMs for the European market are done according to harmonized standard EN 14683:2019+AC:2019 issued by CEN [145]. In the US, MFM tests are performed according to ASTM standards. The method for BFE testing of MFMs is similar for all standards. A summary of different European and international standards used for testing of MFMs can be found in Appendix, Table A.3.

According to the CEN standard [145], during BFE testing, air mixed with a bacterial aerosol should flow through the mask material to a 6-stage cascade impactor. The aerosol consists of droplets/particles with mean particle size (MPS) of 3.0 ± 0.3 μm containing living *S. aureus* bacteria, and the airflow is 28.3L/min (close to minute volume under rest or light activity). The BFE is evaluated based on the number of colony forming units observed on the agar plates after at least 20 hours of incubation compared to positive control experiments (performed without the mask material). A splash resistance to blood and a pressure drop across the mask are also tested according to ISO 22609:2004. Depending on the BFE and other test results (differential pressure, blood splash resistance, microbial cleanliness), the masks are divided into different classes/cathegories, as shown in Table 3.2. For comparison, MFM classes according to the US standards are given in Table 3.3.

Table 3.2 Performance requirements for medical face masks (MFMs) according to European standard EN14683:2019+AC:2019.

Test	Type I*	Type II	Type IIR
Bacterial filtration efficiency (BFE), [%]	≥95	≥98	≥98
Differential pressure [Pa/m^2]	<40	<40	<40
Splash resistance pressure [kPa]	Not required	Not required	≥ 16,0
Microbial cleanliness [cfu/g]	≤30	≤30	≤30

*According to EN 14683:2019+AC:2019 Type I MFMs "*should only be used for patients and other persons to reduce the risk of spread of infections particularly in epidemic or pandemic situations. Type I masks are not intended for use by healthcare professionals in an operating room or in other medical settings with similar requirements*".

Table 3.3 Performance requirements for medical face masks (MFMs) according to US standards ASTM F-2100.

Characteristic	Level 1 Barrier	Level 2 Barrier	Level 3 Barrier
Bacterial Filtration Efficiency (BFE) [%]	≥95	≥98	98
Differential pressure [mm H2O/cm2]	<5.0	<6.0	<6.0
Sub-micron particulate filtration efficiency (PFE) at 0.1 μm [%]	≥95	≥98	≥98
Resistance to penetration by synthetic blood [mm Hg]	≥80	≥120	≥160
Flame spread	Class 1	Class 2	Class 3

It is worth mentioning that MFMs cleared by the FDA for the US market must have PFE tested according to ASTM F2100 with monodispersed aerosol of 0.1 μm latex particles [147]. It is unclear why exactly this particle size was chosen, and the airflow is somehow arbitrary, since according to the standard, air velocity can be in the range of 1-25 m/s. Thus, PFE values may differ depending on which velocity was chosen by the manufacturer, which makes a direct comparison of the PFE performance between different MFMs difficult. Nevertheless, the results from this test may still provide additional information regarding the FE of MFMs against particles in the sub-micron size range, which is not a mandatory test requirement for MFMs approved for the European market.

3.6 Community face masks (CFMs)

CFMs are also frequently referred to as cloth masks, non-medical face masks, and re-usable/washable face masks. CFM are neither medical devices nor personal protective equipment, and they vary widely in their design and performance including material and construction (Figure 3.6). Governments across the world have recommended general mandatory use of face coverings for the general public in situations where a sufficient distance cannot be maintained. In order to avoid shortages of MFMs needed by HCWs, the WHO [5] recommends that the general public should wear a non-medical community face mask (CFM). This type of face covering is also common in some parts of the world as a way to protect against air pollution. However, many questions concerning the use and effectiveness of CFMs in controlling and preventing transmission of SARS-CoV-2 have surfaced, especially whether CFMs can be used instead of MFMs. As a result, different guidelines and scientific publications aiming to prove or disprove the efficacy of CFMs have been published [148, 149]. The two most important documents specifying the expected performance of these masks are developed by the WHO [5], and CEN [150]. Further, national standards have also been developed by some European countries including the French Standardization Association (AFNOR) [151] and the Royal Netherlands Standardization Institute (NEN) [152] .

Figure 3.6 Examples of different CFM models. (Photo: FFI).

3.6.1 Product categories

The WHO recommends that cloth masks have a three-layer structure where each layer provides a function. It is recommended that the innermost layer is made of a hydrophilic material, and the outermost and middle layers of a hydrophobic material to enhance filtration and/or retain droplets. Factory-made cloth masks should meet the minimum thresholds related to three performance and design parameters: FE, pressure resistance/breathability and shape. For technical specifications WHO refers to a standard by the AFNOR group [151]. The standard reconmmends that the materials used in CFMs must withstand at least five cleaning and drying cycles. The standard defines minimum performance in terms of FE (≥70%) and breathability (maximum inhalation resistance of 2.4 mbar and maximum exhalation resistance of 3 mbar). In Europe, a non-binding standard (guidelines) for CFMs was issued by CEN in June 2020 (CWA 17553:2020 Workshop Agreement - Community face coverings - Guide to minimum requirements, methods of testing and use) [150]. The standard is rather careful when describing the protective potential of these masks, stating that their role is to "*minimizes the projection of user's respiratory droplets saliva, sputum or respiratory secretions when talking, coughing or sneezing. This community face covering may also limit penetration in the user's area of nose and mouth of the respiratory droplets from external origin without claiming the user protection. It also prevents this user's area from any contact with the hands.*"

In this respect, it seems that the role of CFMs is mainly source control rather than providing respiratory protection to the wearer, although it may also prevent infection via contact with fomites by hindering the subsequent transfer to the face and nose area by touch. This is even more pronounced in the following statement from the standard: "*The community face covering specified in this document do not fall under as a medical device (MD) within the meaning of Directive 93/42/CEE or Regulation EU/2017/745, nor as a personal protective equipment (PPE) with the meaning of Regulation EU/2016/425*."

CWA 17553:2020 states that CFMs should cover mouth, nose and chin. Interestingly, unlike for MFMs, the dimensions of the mask are also defined with respect to the anthropometric measurements of the face. There are no recommendations regarding user seal check or fit measurements for these devices, as they are loose-fitting by design.

3.6.2 Performance requirements and test methodology

Testing of CFMs can be performed according to the methods described in CWA 17553:2020, although the standard refers to several other standardization documents issued by CEN, including those for MFMs and FFRs, as alternative methods for CFM testing. This offers more leeway to the manufacturers if they have test methods already established, but at the same time makes comparison of CFM performance more complicated. According to CWA 17553:2020 the PFE of a CFM could as an example be measured for mono- or polydispersed aerosol droplets/particles, and the upstream concentration should then be at least 40 particles/droplets per cm^3. More details regarding test conditions for CFMs are given in Table 3.4.

Table 3.4 CFM testing conditions according to CWA 17553:2020.

CFM Class	Minimum FE	Aerosol type	Aerosol size	Breathing resistance	Face velocity
level 90%:	≥ 90%	solid (sodium chloride NaCl, Talcum powder, Holi powder, dolomite, PSL) or liquid (DEHS paraffin)	3 (± 0,5) µm	Inhalation 2,4 mbar Exhalation 3 mbar	6 (± 1) cm/s
level 70%:	≥ 70%				

3.7 Face shields

Another type of face covering, face shields (visors), have also been used by HCWs and the general public to control and prevent the transmission of COVID-19. Especially at the beginning of pandemic, the stand-alone use of face shields was at least to some extent considered as an effective strategy, but this notion has since been abandoned [153, 154]. Face shields may reduce the risk of transocular transmission i.e. inoculation via contact with conjunctival tissue, and the transmission via mucous membranes of the lips and nose [155-158]. Face shields are also relatively easy to use even by unexperienced PPE users, can be readily produced in large quantities, are reusable and can be easily cleaned and disinfected, hence their use is encouraged and commonplace, especially by the general public in some countries [159, 160]. In terms of source control, Verma et al. [160] showed that face shields slow down the stream of exhaled air, during coughing or sneezing. Whereas large droplets may impact on the face shield, smaller droplets are deflected around the edges of the visor. Similarly, in terms of respiratory protection, Lindsley et al. [161] conclude that face shields can substantially reduce exposure to infectious respiratory droplets, while smaller particles flow around the face shield more easily. Face shields are therefore not an adequate substitute for face coverings based on filtration (filter materials) that are capable of stopping the emission (source control) and/or inhalation (respiratory protection) of both large and small infectious droplets/particles, and should therefore be supplemented by other devices such as a MFM or FFR [162].

3.7.1 Product categories

Face shields are classified as PPE (EU Regulation 2016/425). Their intended use is to protect the eyes of the wearer against splashes and ballistic liquid and solid particles. As such, they fall under category of eye protectors [163, 164]. Face shields are typically mounted on a device such as headband, browguard, helmet or hood.

3.7.2 Performance requirements and test methodology

Face shields must cover a rectangular area in the eye-region and provide a certain viewing area. Depending on their specific use, different optical and non-optical properties of face shields are

tested, such as optical radiation filtration, protection against solid particles of different speed, and droplets and splashes of liquid [163-165]. Face shields primarily protect the eyes and the surrounding face area from mechanical (projectiles) or radiation damages. Thus, no requirements are defined regarding their properties in terms of source control or respiratory protection against inhalable respiratory droplets/particles.

4 Filtration efficiency of face masks

Filtration efficiency (FE) is one of the key properties that governs the performance of MFMs and CFMs. It is therefore crucial to describe and systematically discuss the FE of MFMs, CFMs, and different materials used to manufacture face coverings. The amount of respiratory droplets that penetrates through a face covering is determined by the FE. The FE of MFMs and CFMs will be further discussed in the context of source control and respiratory protection. For further evaluation of the efficacy of MFMs and CFMs it is important to answer the following key question:

- How effective are different materials used to manufacture MFMs and CFMs in filtering (removing/retaining) the respiratory droplets and droplet nuclei from the air stream penetrating the face covering?

The FE of a certain material depends on several factors, including the air velocity and particle size distribution. As discussed in Chapter 2, respiratory droplets and droplet nuclei can occur in a wide size range, including sub-micron particles [88, 93]. There is, however, limited information available concerning the exact particle size range that is the most important, relevant and representative for SARS-CoV-2 transmission. For this reason, the contribution of sub-micron droplets cannot be overlooked, and studies where the FE is quantified over the entire respiratory droplet size range for MFMs and CFMs are of special interest. Notably, some authors focus on nanometer particles that correspond to the size of SARS-CoV-2 virions (approximately 100 nm) [114, 119, 123], even though the virions in reality are contained in respiratory droplets of much larger size.

The ability of MFMs and common materials/fabrics used for CFM manufacturing to filter different particle sizes have been investigated in several studies using test methodology based on existing FFR standards as well as custom author-developed test procedures [114, 119, 120, 123, 132, 133, 147, 149, 166-168]. Based on these findings, we will describe and discuss the current state-of-knowledge regarding the FE of MFMs and CFMs.

4.1 Filtration efficiency of medical face masks

The standard test and evaluation methods used to determine the FE of MFMs are derived from and associated with their intended use, i.e. as a mean for source control. The FE of MFMs is therefore evaluated against living *S. aureus* bacteria (BFE) delivered as a test aerosol containing approximately 3 μm droplets/particles, for which a high FE of at least 95% is required [145]. Little is known about the FE for other particle sizes. The requirements and test methods for MFMs are described in more detail in Chapter 3.5.2.

As mentioned before, FFR standard testing procedures are sometimes used to evaluate the FE of MFMs against sub-micron particles/droplets (PFE). These procedures are quite stringent since high airflows and high concentrations of sub-micron particles are applied. Consequently, when MFMs are tested according to these procedures, their FE for sub-micron particles is usually only 50-90% [114, 120, 147, 169].

In an early study by Tuomi [170], two MFMs from the same manufacturer were taped to an artificial head to eliminate the influence of faceseal leakage, and their FE were measured against polydispersed 0.3 – 10 μm corn oil droplets. Both MFMs reached 50% FE for 2 μm particles and 95% for particles larger than 5 μm. However, their performance was significantly different for the sub-micron particles - one of the MFM had 30-50% FE for the particles between 0.3 and 2 μm size, whereas FE for the other was almost zero in this size range. Furthermore, the MFM with poor FE for sub-micron efficiency used in the study did not reach the required minimum FE for 3 μm particles, and had a sharp drop in FE at around 2 μm. Weber et al. [171] examined eight MFMs from four different manufacturers and found large discrepancies in their performance, with FE between 1-40% for 0.2 μm and more than 98% for 4 μm corn oil droplets. They also noticed an increase in FE at around 2.3 μm droplets for some of the MFMs tested. Similar variations were observed by Chen and Willeke [146], when testing two MFM models with corn oil droplets ranging from 70 nm to 5 μm. Both MFMs had an FE exceeding 90% for droplets larger than 3 μm, whereas in the sub-micron range the FE was 20% for one mask and 40-80% for the other, depending on the airflow. A plausible explanation could be that for the lower airflows, a higher FE was archieved due to a more efficient capturing of these particles by electrostatic filtration mechanism.

In more recent studies, Oberg and Brosseau [147] tested the FE of six different MFM models, all FDA-cleared with a reported BFE of at least 95% and PFE higher than 97% when measured against approximately 3 μm *S. aureus*-containing particles and 0.1 μm latex particles, respectively. They found that the performance of the MFMs was rather variable, with PFE higher than 95% measured with 0.895, 2.0, and 3.1 μm monodispersed latex particles, and PFE of 60-90% measured with 0.3 μm salt particles according to the standard NIOSH N-series FFR testing procedure. Similarly, Drewnick et al. [169] tested three MFM models and found their PFE to exceed 80% for 1 μm salt particles. In the sub-micron range, a large variation was observed in the FE (30-95%), with the poorest performing mask having an FE as low as 30-40% for the 0.3 μm particles (depending on the air velocity), indicating that the most penetrating particle size was in this range.

A standard NIOSH method with 75 nm NaCl particles was also used by Rengasamy et al. [120, 132] where FEs of 55–90% [120], approximately 98% and under 10% [132] were measured depending on the MFM model. He et al. [114] tested the FE of MFMs exclusively against approximately 20-500 nm particles and found that the FE was 80-90% for airflows ranging between 15-85 L/min.

These results confirm that for MFMs the FE is relatively high (95% or higher) for particles that are 3 μm or larger, but tends to be lower in the sub-micron range [114, 120, 132, 146, 147, 170, 171]. The observed variation may be caused by the specific filter material used for mask production. In addition, for some MFMs the most penetrating particle size was 45 nm, while for others it was approximately 350 nm, which corrensponds well with electrostatic and mechanical filtration mechanisms, respectively [120, 132]. Hence, it seems that different masks operate under different filtration mechanisms. There is a lack of knowledge about the FE of MFMs against smaller particles and the factors potentially affecting their filtering performance in the sub-micrometer particle size range.

4.2 Filtration efficiency of community face masks

During the COVID-19 pandemic new guidelines for CFM testing and classification have been published (see Chapter 3.6 for further details). It should, however, be pointed out that these guidelines are a recommendation, and not binding requirements. CFMs are often home-made and many of them have been sold with limited information regarding their FE. It is unclear to what degree and how large a share of the CFMs produced and sold on the global market actually conform to the recommendations provided by e.g. CEN or the WHO.

The FE of CFMs depends on the fabrics (fiber characteristics, including diameter, charge, and packing density) in the face coverings. The experimental studies addressing these questions have often not included sufficiently detailed information about the fabrics characteristics (e.g. thread count, type of weave, and thickness), and their relation to the observed FE, which makes direct comparisons of test results challenging. The FE of different fabrics commonly used in CFMs have been reviewed by Clase et al. [172] and Jain et al.[173].

Several studies have evaluated the FE of fabrics commonly used for CFMs manufacturing with particles ranging from 10 nm to 5 μm [169, 174-178]. The results varied between less than 5% to more than 95% when evaluated across a wide range of particle sizes. The use of multilayer fabrics increased the FE. Drewnick et al. [169] tested the FE of 48 different fabrics, and showed a large variation in FE, from less than 10% to almost 100% for particle sizes ranging from 30 nm to 5 μm. More than 30 of the fabrics tested had a FE larger than 80% for 5 μm particles, while only six fabrics had a FE larger than 80% for 30 nm particles. A study by Konda et al. [174] showed that the FE improved when multiple layers of fabrics were used. For specific combinations of different fabrics (hybrid multilayer), such as cotton−silk, cotton−chiffon, cotton−flannel, the FE was larger than 80% for 20–300 nm particles, and 90% for 300 nm–6 μm particles.

Rengasamy et al. [175] tested different fabrics used in CFMs to establish their FE using 75 nm NaCl aerosols and found that single layers of scarfs, sweatshirts, T-shirts, and towels were associated with a FE of 10-40%.

Wang et al. [179] tested both PFE (75 nm NaCl aerosol) and BFE (approximately 3 µm *S. aureus* aerosol) of different fabrics. PFE of single layer fabrics varied between zero and 23%. When using several layers, the PFE varied between 11 and 56%, depending on the fabrics and their combinations. The BFE varied varied between 16 and 93%, depending on the combinations of fabrics. BFE of single layer fabrics were not tested.

Furuhashi [178] tested the BFE for CFMs consisting of single layers of different types of cottons against an aerosol containing two different bacteria (*S. aureus* and *Serratia marcescens*). The BFE of CFMs ranged from 43-94%, while MFMs that were subjected to the same test had a BFE above 98%.

For CFMs it may be particularly difficult to assess their FE using FFR tests with sub-micron salt particles or oil droplets, because some fabrics can be a source of small particles and fibers, complicating the interpretation of results based on non-specific particle counting and sizing measurements [176].

Filtration efficiency of face masks
Take-aways 1. Medical face masks are more than 95% effective in filtering particles larger than 3 μm, and usually have a filtration efficiency for sub-micron particles between 50% and 90%. 2. Community face masks span a wider range of filtration efficiencies, and have been shown to have a filtration efficiency between 15% and 95% for particles larger than 3 μm, and a filtration efficiency for sub-micron particles between 5% and 90%. 3. The filtration efficiency of community face masks depends strongly on the fabrics. The use of multiple fabric layers and combination of different fabrics increase the filtration efficiency for the entire range of particle sizes.
Knowledge gaps 1. The filtration efficiency of medical and community face masks for particles in the size range between 1–3 μm is not covered by the standard tests. As a result, there is limited information available on the filtration efficiency in this size range, even though the number of generated respiratory droplets is relatively high in this size range. 2. For community face masks, more experimental data are needed to better understand the association between filtration efficiency and different particle sizes, fabric characteristics, and fabric types/combinations.

4.3 Answers to key question in Chapter 4

- How effective are different materials used to manufacture MFMs and CFMs in filtering out the respiratory droplets and droplet nuclei from the air stream penetrating the face covering?

Taken together, the available experimental data show that the filter material in MFMs effectively captures particles that are 3 μm and larger. This is also to be expected since it is in agreement with the harmonized European test methodology and performance requirements that apply to MFMs (EN 14683).

The FE of MFMs in the sub-micron range is often evaluated using standard FFR test methods. In the sub-micron particle range, there are large discrepancies observed and the reported FE values range from less than 5% to more than 95%. It appears, however, that a majority of MFMs display a sub-micron FE from 50-90%. If we assume a constant FE of 95% for 3 μm and larger particles and a linear decrease in efficiency towards 50% at 0.01 μm, we can estimate a total filtration efficiency of approximately 80%.

The FE of fabrics commonly used in CFMs varies greatly depending on both the material properties and the test methods, in particular the particle size used. The FE has been shown to range from less than 5% to more than 90%. The use of multiple layers and/or a combination of different fabrics (hybrid multilayer approach) in CFMs has been shown to increase the FE. CFMs also tend to perform better against particles larger than 3 μm.

5 Efficacy of face masks as source control against transmission of SARS-CoV-2

To initiate a systematic discussion on how effective MFMs and CFMs are in controlling and preventing the transmission of respiratory droplets containing SARS-CoV-2 when used as a mean for source control, i.e. control/prevent the emission of virus-laden respiratory droplets, it may be useful to break the problem into sub-topics and formulate these as a set of key questions:

- What is the spatial distribution of expelled respiratory droplets with and without face covering?
- What is the size distribution of expelled respiratory droplets with and without face covering for different respiratory activities?
- How much of the exhaled air passes through the filtering material and how much passes through the gaps between the face and the face covering?
- How is the respiratory jet affected by the presence of different face coverings and for different respiratory activities?

In this chapter, we will address these questions in light of the available scientific literature, and describe and discuss the current state-of-knowledge and highlight some knowledge gaps.

5.1 Obstructing the respiratory jet

As discussed in Chapter 2.2.2, the respiratory jet is able to transport droplets relatively far from the host in a short time. For instance, violent sneezes, coughs and speech generate respiratory jets that may extend up to eight meters [103], three meters [104, 105], and two meters [101], respectively. In Chapter 3.3, we also discussed how face coverings are able to block the respiratory jet. Figure 2.2 and Figure 3.3 illustrate these effects. In this chapter, we review experiments and simulations aimed at quantifying this effect.

Verma [180] performed experiments in which they used a manekin head and a manual pump to emulate coughs and sneezes, and a laser sheet illuminated tracer particles seeded at the mouth. Their study provides no quantitative data on velocities or on droplet sizes. However, they show that the penetration length of the cough jet may be reduced from more than 3 m for an uncovered face to less than 25 cm by using any face covering. By seeding tracer particles at the source it is difficult to separate the filtering and the fluid dynamical effects of the face covering. To overcome this weakness, Kähler and Hain [181] instead seeded particles in the test chamber. They show that single un-filtered cough can produce air velocities of about 1 m/s at a distance of 1 m from the source. The use of a face covering reduces the velocities to such an extent that the maximum velocity becomes approximately 0.3 m/s very close to the cougher, and less than 0.1 m/s at distances larger than 0.3 m. They conclude that as long as a face covering has a sufficient flow resistance, it will be efficient in diminishing the respiratory jet.

Tang et al. [182] employed an optical Schlieren method to gain quantitative knowledge of the human cough with and without masks. The advantage of the Schlieren method is that it only relies on thermal gradients, in the air, to capture the flow, bypassing the problem of tracer particles and masks altogether. Their results show that both MFMs and N95 FFRs can efficiently reduce the penetration length of the human cough jet, although the effect of an MFM was redirection and diffusion of the flow as opposed to the blocking effect of the N95 FFR. In both cases, the expelled air rapidly mixed with the rising thermal plume generated by the temperature difference between the surrounding air and the human subject. Using the same type of experimental set up, Viola et al. [105] found that the jet distance from a cough was reduced by about 60–80% for all face coverings without exhalation valves. In yet another Schlieren study, Prasanna Simha and Mohan Rao [104] tracked the front of the cough plume from five volunteers. Although there is large variability between different test persons, both with and without face covering, they showed that there is a universal trend in the jet characteristics. In their experiments, the cough plume could reach up to 3 m from the source and the maximum velocities close to the face was approx. 6 m/s. When the test subjects wore MFMs, the plume distance was reduced to 1.5 meters and the maximum velocities were reduced to approximately 2 m/s. The impact of using N95 FFRs was even larger. In this case, the maximum distance was reduced to less than 25 cm and the corresponding velocity was less than 1 m/s.

Computational fluid dynamics (CFD) simulations is a methodology that has the potential to provide detailed qualitative and quantitative data on the respiratory flow and its interactions with the face covering, as well as for the transport and size distribution of droplets. A major challenge

with CFD modeling, in general, is to make sensible simplifying assumptions to establish a useful computational model, and this is especially true for applications with a high degree of complexity. For example, the porous materials that comprise the mask have a geometric micro-complexity that is difficult to represent accurately with current computational resources and methodology. Current studies [127, 183-186] use empirically determined parametrizations that may have reduced validity for materials with high porosity [125]. Another challenging aspect is that both the face and the face mask are deformable. To the best of our knowledge, methodologies for fluid-structure interactions [187] have not been employed to this problem, and current computational modeling efforts have considered static geometries. At present, it is however not clear what improvements can be achieved by the application of more advanced methodologies.

In the simulations reported by Dbouk and Drikakis [183], the rigid mask has a variable gap along the perimeter and the porosity is modelled as a pressure-loss region with added physics to account for filtering of droplets. They show that the cough jet is effectively redirected by the face mask and that the velocities were reduced to less than one tenth of the unmasked cough velocity. Khosronejad et al. [185] performed simulation of coughing through a face mask. Face masks were modeled as a momentum sink with different pressure losses depending on the mask type. The results indicate that the respiratory jet extends up to approximately 0.5 m, 0.75 m, and 2.5 m for the cases with a MFM, a CFM, and without a face mask, respectively. These results are comparable to some of the experimental results discussed above.

Obstructing the respiratory jet
Take-aways 1. Any face covering that provides sufficient flow resistance, i.e. most or all medical and community face masks reduce the forward momentum and redirect part of the flow such that the penetration length of the respiratory jet is reduced by at least 50%. 2. The redirection created by medical and community face masks deflect the flow laterally, vertically, and even backwards, causing the exhaled droplets to mix with the ambient air and contribute to the background concentration. 3. The combination of fit (faceseal) and flow resistance for a filtering facepiece respirator effectively blocks the respiratory jet and thus reduces the penetration length of the jet by as much as 90%.
Knowledge gaps 1. More detailed information, on both the flow field and droplet size distribution, is needed to better understand the role of flow resistance and leakage. This should be possible, even within the framework of current experimental and simulation methodologies, but such data appear to be under-reported. 2. Simulation studies could benefit from adopting methodology that take into account the effect of deformability/suppleness of both the face and face mask geometry to assess the uncertainties of simplifying assumptions.

5.2 Mask fit and outward leakage

Since MFMs and CFMs are loose-fitted devices, they are prone to gap leakages. As a consequence, some of the exhaled air and droplets are able to exit through openings around the mask perimeter and thus bypass the filtering layer of the mask. The removal of exhaled droplets are therefore only partly governed by the FE of the mask material that was discussed in the previous chapter.

For a properly fitted FFR without exhalation valve, most of the exhaled air will pass through the filtering layer, removing most of the respiratory droplets. Note, however, that even for a tight-

fitting FFR, violent coughs and sneezes may result in an overpressure that leads to intermittent breaches of the faceseal and release of non-filtrated air. On the contrary, for loose-fitting face coverings, which do not require fitting or fit testing, gap leakages will normally be present, at least in some form, and the size and number of openings will depend on both the face mask and the facial geometries of the wearer. In terms of the flow distribution, the relative importance of the gap leakage increases with increasing pressure resistance of the mask material [127].

Most studies address the source control aspect by measuring the number of emitted droplets that are able to reach the surroundings without distinguishing between FE and gap leakage. There are, however, some studies that have sought to quantify the flow distribution.

Lei et al. used numerical simulations to address the mask fit problem [186] for an FFR, and the fluid flow through the resulting gap leaks [188]. The computational results show that the ratio of mass flow through the filter and through the gaps heavily depend on the breathing velocity as well as the filter resistance. For a pressure drop representative of a N95 FFR, on average 6% of the mass flow passed through the tiny gaps during the exhalation phase of a breathing cycle during normal respiration. Note that this is a substantially higher leakage ratio than the fit requirements of N95 FFRs for inward protection [147]. The authors report that most of the leaks occurred at the nose and at the cheeks. We have not found similar studies that can be used to characterize MFMs and CFMs. Because of the loose-fit design of MFMs and CFMs, higher leakage ratios must be expected.

Similar leakage jets, as in Lei et al. [188], can be seen in the computational cough results from Dbouk and Drikakis [183]. In the same study, they also consider the effect of the face covering on droplet transport. They used the droplet size distribution of Xie et al. [189], with a peak count at about 70 μm, which means that they have limited support in the small droplet size range. In terms of droplet distance, they find that when wearing a mask, the bulk of the droplets travelled approximately half of the distance compared to not wearing a mask. They do not present results on the distribution of flow and particle flux through the filter and through the gap leaks. Using a similar droplet distribution and mathematical model for the filter, Pendar and Páscoa [184] performed simulations of sneezing in a closed room with two “persons” present. They demonstrated that droplets escaped through any opening in the mask, in particular the larger gaps above the nose. Whereas an unmasked sneeze resulted in droplet transport up to approximately 4 m from the source, the presence of the mask resulted in a spherical contamination region with a radius of approximately 60 cm. However, a major concern about these numerical studies is the lack of validation against experimental data.

Viola et al. [105] used optical Schlieren visualization to experimentally describe the exhaled flow during breathing and coughing for different types of face coverings. They find that MFMs and CFMs generate significant leakage jets. Specifically, their results showed that loose-fitting face coverings could generate intense backward airflow for heavy breathing and coughing conditions.

Bandiera et al. [190] counted ballistic droplets able to hit the ground both for manekins and human volunteers with and without MFMs and CFMs. The size range of the observed droplets was 150–600 μm. They found that the droplet count for masked test subjects was reduced by a factor of

1000 compared to the unmasked references. Based on this they conjectured that a person standing 2 m from someone coughing without a mask is exposed to over 10 000 times more respiratory droplets in that size range than a person standing 0.5 m away from someone coughing wearing a single-layer mask. This study shows that even simple face coverings are able to block the transmission of large droplets.

Milton et al. [77] studied source control provided by MFMs against the influenza virus using 37 volunteers. They sampled droplets in the size range 0.05–50 μm in the exhaled air from both masked and unmasked test subjects, and grouped the collected particles into two classes; smaller and larger than 5 μm, respectively. Their results showed that the use of MFMs reduced the viral copy numbers in the large fraction (droplets larger than 5 μm) by a factor of 25 (higher than 95% efficiency). For the smaller droplets (smaller than 5 μm), the corresponding reduction factor was 2.8 (approximately 65% efficiency). In other words, MFMs were highly efficient in removing larger droplets from the exhalation flow, but were less effective for smaller droplets. The 65% efficiency observed for the smaller particles may indicate that a substantial fraction of these follow the airflow through the gap leaks, but the FE may also be lower in this size range [147]. We have not found any other studies that address the size-dependent efficiency of MFMs or CFMs that consider a large size range from sub-micron to tens of micrometers. While there is some support in the literature that leakage accounts for 10–40% of inhaled air for MFMs [147, 191], we have not found similar data for exhalation. Due to the overpressure created during exhalation, it is, however, reasonable to assume that the leakage ratio is higher for exhalation than for inhalation.

Kolewe et al. [192] experimentally mimicked exhalation using an artificial head to emit particles. MFMs, CFMs (cotton) and N95 FFRs were tested. Particles in the 0.3-10 μm size range were measured directly in front of, above, and on the sides of the face coverings. Both MFMs and CFMs displayed significant leaks; MFMs primarily sideways and CFMs primarily to the top. As a sidenote, both loosely fitted N95 FFRs, MFMs and CFMs had a leakage of 35-70 times more particles than tightly fitted N95 FFRs. Nevertheless, the study concludes that even poorly fitted face coverings will help reduce the emission of respiratory droplets considerably compared to not wearing a mask.

The studies discussed above, consider only face coverings as source control. A number of studies have considered combined source/receiver experiments on facing manikins in enclosures with varying ventilation rates. Experiments with source/receiver configurations appear to have been first performed by Smaldone and co-workers (Diaz and Smaldone [193], Mansour and Smaldone [194], and Patel et al. [195]), who studied the effect of face coverings in ventilated and unventilated test chambers. They found that for both tidal breathing and coughing, separation between the source and receiver results in significant dilution of the concentration of exhaled droplets. When the distance between the source and receiver was 3 ft (0,9 m) and both were uncovered, the receiver inhaled approximately 1% of the total number of expelled droplets. Note that this dilution appears to be higher than the one reported by Abkarian et al. [106], who, based on a theoretical model of a speech jet, estimated a droplet concentration of approximately 5% at a distance of 1 m. For a ventilated test chamber (approximately 3 liters/s per person), all face

coverings used as source control were highly effective [193-195]. Furthermore, MFMs used as source control provided significantly better protection for an unmasked receiver than with an unmasked source and the receiver wearing a N95 FFR, unless the N95 FFR was perfectly sealed to the manikin [193, 194]. This effect is, however, less pronounced in Patel et al. [195]. The efficacy of face masks as source control for tidal breathing appear to be diminished in the absence of ventilation, possibly caused by build-up of background concentration over time [193]. For coughing, any mask provided significant source control, independent of ventilation.

In another source/receiver study by Ueki et al. [133], two manikin heads were placed 0.5 m apart in a small test chamber (0.24 m^3), and one manikin acted as a source of droplets (median size 5.5 μm) containing SARS-CoV-2 virions, whereas the other acted as a receiver. The results showed that when face coverings were mounted on the source, both MFMs and CFMs reduced the viral load experienced by an uncovered receiver by more than 50% and MFMs and CFMs (cotton) performed equally. Covering both the source and receiver did not seem to provide any extra protection to the receiver compared to only covering the source. In a similar study, with a significantly larger, unventilated test chamber (20 m^3), Brooks et al. [196] used source/receiver pairs located 6 ft (1.83 m) apart. They used NaCl particles in the 0.1–7 μm size range. When the source was covered by a MFM, the results showed a 41% reduction in inhaled particles by the receiver. They also considered knotted and tucked MFMs and double masking of the source using a CFM to cover the MFM. As source control, knotted and tucked MFMs showed a 63% reduction in inhaled particles by the receiver, whereas double masking showed a 82% reduction. When both the source and receiver were covered by MFMs, the reduction was 85%, and when both the source and receiver were covered with double masking as described above the reduction was 96%. Although the results in [196] do not explicitly state the amount of gap leakage, one may use the difference between the loose fitted and the knotted/tucked MFMs to provide an estimate of this. If we assume an average filtering efficiency of 80% for droplets over the entire size range, we can infer that gap leaks constitute 20% of the total flow rate for a knotted and tucked MFM and 50% for a regular (loose fitted) MFM.

Among the main differences between the works of Smaldone and co-workers [193-195], Ueki et al. [133], and Brooks et al. [196] are the size of the test chamber, the distance between the source and receiver, and the choice of tracer particles. These can all influence the experimental results and it is unclear to what extent these results can be compared and generalized. For example, the size of the test chamber will influence the background droplet concentration and thus the amount of droplets that can be inhaled by the receiver. Furthermore, the distance between the test subjects will determine whether the receiver will be exposed directly to the respiratory jet puff or to the background concentration. It is also not straightforward to reliably compare the viral titers reported in [133] and the droplet counts reported in [193-196].

Mask fit and outward leakage
Take-aways 1. In terms of source control, there is evidence that almost all exhaled large and medium-sized droplets are blocked by medical and community face masks. 2. For small droplets there is some evidence that almost half of the exhaled droplets are able to escape to the surroundings. 3. Measures to improve the fit of medical and community face masks can improve the source control efficiency by reducing the gap leakages along the perimeter of the mask.
Knowledge gaps 1. Experimental and numerical studies that provide quantitative information on flow velocities and droplets size distributions for different respiratory activities are needed for medical and community face masks. This is important to obtain a better description of the droplet concentrations in the vicinity of an possibly infective individual.

5.3 Answers to key questions in Chapter 5

- What is the spatial distribution of expelled respiratory droplets with and without face covering?

  In the *absence of face coverings*, respiratory activities generate turbulent jet plumes in front of the head. Sneezes are the most violent activitiy, and may lead to the transport of droplets up to 8 m. The jet plume of coughs, and therefore droplets, can reach up to 3 m. It has also been shown that regular speech can generate jets able to reach approximately 2 m. Whereas the latter activity typically occurs for extended periods of time and are very common, the two former are short time events that occur less frequently, especially in asymptomatic individuals. By wearing any type of face covering that offers some flow resistance, the contamination range from these jets are significantly reduced. A conservative estimate from the available literature suggest that for coughs, the jet puff length is reduced by at least 50% (from 2-3 m to 1-1.5 m) for MFMs. Some sources state that the reduction may be as large as 80% (from 2-3 m to 0.4-0.6 m). The plume length itself may be a conservative estimate of the

contamination range, since it does not take into account that droplets are filtered by the mask material. Hence, the contamination area may be smaller than the plume length.

- What is the size distribution of expelled respiratory droplets with and without face covering for different respiratory activities?

  Respiratory droplets has a tri-modal size distribution with the first two peaks between 1 and 2 μm, and a third peak at approximately 120 μm. Experiments show that almost all droplets larger than approximately 5 μm are captured by the MFMs. Smaller droplets are able to follow the airflow through gap leaks. Additionally, sub-micron droplets may penetrate the filter material. From the available evidence for inhalation, it can be estimated that approximately half of the small size droplets are able to escape during exhalation. However, the presence of the mask effectively reduces the momentum of the flow and the droplets. One is hence left with a situation in which small droplets are ejected with little momentum, and passively follow the airflow of the surroundings. Specifically, they are expected to be captured by the thermal plume rising from the wearer and mix with the surrounding air. A similar assessment can be made for CFMs. There is, however, less knowledge regarding the FE of CFMs over a wide range of droplet sizes, and this increases the uncertainty of the estimates.

- How much of the exhaled air passes through the filtering material and how much passes through the gaps between the face and the face covering?

  The amount of flow that passes through the gaps between the face and the face covering is highly dependent on the fit of the mask as well as on the flow rate of the exhaled air. We found one computational study that showed a 6% leakage for FFRs under standard exhalation conditions, but no direct studies on leakage flows for MFMs and CFMs. A rough estimate of the leakage can be deduced from the experiments of Brooks et al. [196], where they compared the performance of loose-fitted and tight-fitted MFMs. By assuming an estimated average FE of approximately 80% for small droplets, which is in line with litterature, we can infer an approximate 50% leakage for the loose-fitted MFM and an approximate 20% leakage for the tight-fitted MFM. We do, however, stress that this is a knowledge gap that needs to be studied using human volunteers and different mask configurations.

- How is the respiratory jet affected by the presence of different face coverings and for different respiratory activities?

  As discussed above, face coverings that offer some degree of flow resistance effectively reduces the flow velocity, and therefore obstructs the respiratory jet. Close to the face, MFMs may result in a three-fold reduction of the cough velocity. We have not found solid information on gap leakage velocities, but visualisations have shown that the flow escapes to the side, to the top, and even backwards.

6 Efficacy of face masks as respiratory protection against transmission of SARS-CoV-2

The level of protection offered by MFMs and CFMs against virus-laden respiratory droplets is, at present, not clearly determined [162, 173, 197-202]. While neither MFMs nor CFMs are classified as RPDs, some studies indicate that the use of MFMs may lower the wearer's risk of infection for diseases transmitted via respiratory droplets [198, 203]. In a randomized trial described by Loeb et al. [203], the use of MFMs and N95 FFRs were equally effective in preventing seasonal influenza in over 600 HCWs participating in the study. A recent Cochrane review [198] could not find sufficient experimental evidence to support the need for constant use of RPDs by HCWs during the COVID-19 pandemic. The necessity of using an RPD in a work environment should be based on a proper risk assessment. Furthermore, the Cochrane study seems to imply that MFMs can provide an adequate protection level when used in conjunction with non-respiratory PPE (e.g. face shields, gloves, aprons, etc.) and effective ventilation of indoor areas. Thus, it is difficult to derive any conclusions on the effectiveness of face masks from systematic review studies that do not take into account the underlying physical and biological mechanisms at play.

A key question in order to discuss the efficacy of MFMs and CFMs in terms of their ability to controll and prevent the inhalation of virus-laden respiratory droplets and droplet nuclei, is:

- How much of the *inhaled* air passes through the face covering/filter material and how much passes through gaps between face and face covering?

In this chapter, we address this question in light of the available scientific literature in order to describe the current state-of-knowledge and highlight some knowledge gaps.

6.1 Mask fit and inward leakage

Respiratory droplets suspended in air may penetrate the face covering both through the filter material and through gaps along the mask perimeter. The inhalation flow through such gaps is known as gap leakage. FFRs are designed and tested to minimize gap leakages, whereas loose-fitting MFMs and CFMs are more prone to gap leakage, causing unfiltered air to enter the respiratory tract.

As discussed in Chapter 2, the process of inhalation draws in air and droplets almost uniformly from a hemispherical region in front of the face. In the absence of gap leakage, simulations by Xi et al. [126] show that the pressure drop across the face mask slightly redistributes the inhalation flow pattern, and air enters the mouth and nose through the entire surface of the mask. Leakage at the mask perimeter will change the pressure drop characteristics of the face-face mask system and thus the inhalation flow pattern, but since we have not found any simulation studies that address this issue, we will solely consider experimental studies that have used particle measurements to quantify the performance of face coverings for respiratory protection.

The source-receiver experiments, discussed in Chapter 5.2 in the context of source control, can also be used to assess and compare the efficacy of face coverings in the context of respiratory protection?. The experiments of Smaldone and co-workers (Diaz and Smaldone [193], Mansour and Smaldone [194], and Patel et al. [195]), showed that MFMs when used as source control provided significantly better protection for an unmasked receiver than with an unmasked source and the receiver wearing an N95 FFR, unless the FFR was perfectly sealed to the manikin[193, 194]. In one of the studies, however, this effect was less pronounced [195]. Similar conclusions can be drawn from the study by Ueki et al. [133] who also used two manikin heads in a source-receiver setup. The difference in performance when used as source control and respiratory protection may be related to the asymmetry between the inhalation and exhalation flow patterns discussed in Chapter 2.2.2, and demonstrates that leakage appears to be more important in determining the efficacy of MFMs and CFMs as a mean for respiratory protection than for source control.

A quantitative approach, normally used for RPDs, can be employed to evaluate the faceseal leakage of MFMs and CFMs. The leakage is usually expressed in terms of TIL (total inward leakage), FF (fit factor), or PF (protection factor). Methods for measuring the leakage of RPDs are discussed in Chapter 3.1. There are no formal requirements regarding mask fit for MFMs and CFMs, but, with standard test procedures, their respiratory protection properties can be directly compared to the performance of FFRs. TIL measurements can be performed using either a panel of test persons or artificial heads. These artificial heads usually represent generalized anthropometric features but may impose an additional challenge in fitting the mask, as they are often manufactured in hard non-deformable polymers. Also for human test subject, there are a number of factors that affect the results of the tests: Breathing pattern, variability of facial dimensions, facial hair, gender, ethnicity, and user experience with face coverings [114, 139, 147, 204-209]. For instance, in a study by Oberg and Brosseau [147] where the FF of MFMs was measured for 20 human subjects without previous experience with MFM use, there was a statistically significant difference in the results depending on whether or not the test subjects were given assistance in donning the mask (head strap adjustments, nosepiece tightening), with an average FF of 4.4 and 5.7 for unassisted and assisted, respectively. Furthermore, the study concluded that even MFMs with a high FE had an FF less than 10 in all cases. These FF results are too low for MFMs to be used as a replacement for FFRs, for which the requirement is a FF larger than 100.

Lee et al. [134, 204] performed similar studies on different MFM models for several male and female volunteers. The authors measured PF using 93 nm to 1.61 μm NaCl particles [204] and 40 nm to 1.3 μm NaCl particles [134] and observed a large variation in PF results depending on particle size and MFM manufacturer. The PF was less than 10 in the entire size range tested and reached a minimum within the 40 nm to 0.3 μm particle size range. The size at which the minimum PF occurred, coincides with the size at which minimum FE was observed for MFMs. This indicates that the FE has a direct impact on the observed inward leakage results. Preferably the leakage tests should be performed for particle sizes where the FE is high so that the contribution of the gap leakage would be distinguishable from FE. It seems that for a majority of MFMs this particle size is likely in the range 3 μm and larger.

The effect of the particle size chosen for TIL measurement was also shown by Rengasamy et al. [132] on a manikin-based study, where TIL for two MFM models and two FFR models were compared. TIL measurements were performed for different sub-micron NaCl particles (20-800 nm) and airflows (8 and 40 L/min) delivered by a breathing simulator. MFMs and FFRs were either sealed on the manikin head (no leakage) or given different-sized artificial leakages to imitate an imperfect fit. One of the MFMs had a very high TIL in the absence of leakage of approximately 45-68% (depending on the flow rate) for 45 nm particles and 88-97% for 300 nm particles. This indicates a poor FE of the mask. In this case, there was virtually no impact on the TIL when adding an artificial leakage. The other MFM had a TIL in the absence of leakage of approximately 4-9% at 45 nm and 2-3% at 300 nm, indicating a high FE. In this case, once leaks were introduced, the TIL was mainly affected by particles entering via openings in the faceseal, resulting in a TIL of up to 37%. All particles in the studied size range were able to follow the flow through the faceseal leaks The observed results of TIL show a small dependence on particle size, which means that size-dependent FE may also play a role.

Grinshpun et al. [205] performed experiments with 25 human volunteers, donning both MFMs and N95 FFRs, during various exercises. Three measurements were performed for each subject. Additionally, the respiratory patterns were recorded and the measurements were replicated in a laboratory set-up using manikin heads. In total, the study comprised 5250 data points. For particle size range up to 1 μm, the number of particles entering via the faceseal leakage for MFMs was about five times the number of particles passing through the filter. Since this study explicitly state a FE (above 90%), one may readily estimate that this leads to a FF of 2.2, which corresponds to a leakage ratio of approximately 40%. Note that the amount of leakage varied only weakly with particle size, whereas this dependency was well pronounced for the N95 FFRs.

Large openings along the mask perimeter will be a major source of particles entering the face covering [132, 204]. Most of the available studies have focused on tight-fitting RPDs, such as FFRs, and the leaks in the faceseal have been simulated using slits, tubes or other devices to create a relatively small (milimeters or smaller) gap with a controllable size, shape and area [132, 210, 211]. In reality, the shape, size and the site of these gaps would depend on the individual facial features of the wearer and the mask form. To some extent, the variations among facial features can be reflected by using statistical data over a large number of individuals, such as the bivariate panel used by NIOSH based on the face breadth (bizygomatic) and length (Menton-Sellion) for several industrial workers in US [212]. These studies could be used for prediction of the perimeter leaks for larger groups of users (e.g. general public, HCWs etc). Nevertheless, some studies show that this approach may be somehow oversimplified [208, 209]. Therefore, it is unclear what impact the facial dimensions would have on the leakage for loose-fitting devices such as MFMs and CFMs.

Sickberg-Bennett et al. [213] tested a range of MFMs with elastic ear loops and ties by measuring a "Fitted Filtration Efficiency" (FFE)[4] on volunteers. Different models of MFMs and FFRs were tested for comparison. Volunteers (one male and one female) entered one by one a chamber filled

[4] FFE is a term not used outside this and other publications by the authors, and is in principle an equivalent of a TIL measurement with results given in terms of filtration efficiency rather than leakage.

with polydispersed 0.5 µm salt particles. The masks with ties provided much better protection than the ones with elastic ear loops (FFE of approximately 70% against less than 40%, or correspondingly a TIL of 30% versus 60%, respectively). A plausible explanation of this is that the masks with ties can be readily adjusted to the individual user's face, probably achieving better tightness and thus indicating the importance of the mask fit. In another study by the same group, Clapp et al. [148] conducted FFE measurements of CFMs, MFMs and FFRs under the same experimental conditions on one adult male volunteer. Several modifications such as adjusting the ear loops by tying them or fastening with a clip, increasing mask tightness by rubber bands or nylon hosiery, or inserting a metal nose bridge were introduced to investigate whether they improve the mask fit. The FFE of different CFMs tested on one adult male with no beard ranged from 80% to 25%, with the modified two-layer nylon CFM having the best results. The FFE of the unwashed nylon CFM of 45% was improved by adding a metal nose bridge to 55% and further to 75% when a filter insert was mounted. On the contrary, the unmodified MFM with elastic earloops yielded a FFE of approximately 40%, which could be improved to approximately 80% both when a nylon hosiery was worn over the mask, and when rubber bands were used for securing the mask. Even better results with improving the MFM fit was achieved by Runde et al. [214], who demonstrated that MFMs secured with three connected rubber bands could pass the N95 FFR fit test. A key take-away from these works is the importance of sealing any leaks in the face covering, which is especially true for loose-fitting devices such as MFMs and CFMs, if they are to provide sufficient respiratory protection. Another important observation is that the studies using human volunteers suffer from a small number of the test subjects with limited variations in their body composition and facial features relevant for fit goodness. For this reason, the results of many studies may not necessarily be representative for larger groups of society.

Mask fit and inward leakage

Take-aways

1. Medical and community face masks appear to be less effective for respiratory protection than for source control. This may, in part, be caused by the loose fit of these devices that enables leakage through the gaps along the mask perimeter. The size and shape of these gaps, depend on the facial characteristics of the user.

2. For medical and community face masks there are no formal requirements to determine the faceseal leakage.Standard testing procedures for filtering facepiece respirators are not necessarily suitable for community and medical facemask evaluation, since sub-micron particles are used and there is large variability in the filtration efficiency in this range for different face mask materials.

3. The reported fit factor for medical face masks is in the range 2-10, corresponding to a total inward leakage in the range 10-50%. These fit factor results are too low for medical face masks to be used as a replacement for filtering facepiece respirators, for which the requirement is a fit factor larger than 100.

4. Reduction of leakage through gaps in the faceseal can be achieved by simple means, such as knotting/tucking and mask braces, and leads to significant improvement in the respiratory protection offered by medical and community face masks.

Knowledge gaps

1. Studies assessing the total inward leakage and filtration efficiency independently, spanning a large particle size range, are scarce for medical and community face masks. Such studies would enable the quantification of gap leakages.

2. Standard testing procedures for respiratory protection devices are not suitable for the assessment of inward protection for medical and community face masks. Tailored testing procedures for these devices should therefore be developed.

3. Studies that quantitatively assess the leakage of medical and community face masks used by a larger and representative group of users should be undertaken. Such studies should include the effect of measures to improve the mask fit.

6.2 Answer to key questions in Chapter 6

- How much of the *inhaled* air passes through the face covering/filter material and how much passes through gaps between face and face covering?

  The available evidence suggests that 10–40% of the inhaled air passes through the gap leaks for MFMs. This range is based on fit testing both on human subjects and manikin heads that have reported FF values in the range 2–10, which correspond to a TIL of about 10–50%.

7 The effects of long term use, humidity, washing and reuse of face masks

To initiate a systematic discussion on the effects of long term use and humidity on CFMs and MFMs, and washing and reuse of CFMs, it may be useful to break the problem into sub-topics and formulate these as a set of key questions:

- How long can CFMs and MFMs be used before they get too humid or wet to wear? What is the definition of humid and wet face coverings?

- What is the effect of humidity on FE and fit of CFMs and MFMs?

- Do washing and drying cycles affect the FE and fit of CFMs? How many cycles can be performed?

In the following chapter, we will address these questions in light of the available scientific literature in order to describe the current state-of-knowledge, and to highlight some knowledge gaps.

It is difficult to generalize the effect of long term use on FE and fit of CFMs and MFMs since many of the fundamental properties will depend on the choice of materials (fabrics), the number of layers used, the combinations of these, and the general design [12, 173, 175]. CFMs have different designs, some of them very close to MFMs, whereas others are more similar to FFRs (e.g. duck-bill, horizontally folded). Nevertheless, no performance or evaluation requirements regarding the faceseal are given in the recommended testing procedures for CFMs or harmonized test standards for MFMs [150-152], and they are therefore both considered loose-fitting devices where gap leakages have to be expected.

The efficienty of MFMs and CFMs to remove droplets from the exhaled and inhaled air, depends both on the FE and gap leakage (Chapter 4-6). CFMs and MFMs become humid or wet from the human breath during use, and there is a limited number of studies that have addressed the effect of humidity on the FE of face coverings. In a recent study by Zangmeister et al. [215], the FE of different types of cotton were tested at low (55%) and high (99%) relative humidity. Under humid conditions (99%), the tested cotton fabrics increased their FE from 12% to 45%, with an average increase of 33% when challenged with a 300 nm NaCl aerosol. Synthetic fabrics, such as nylon, polyester and rayon performed poorly relative to cotton and their performance did not improve with increased humidity. The FE of MFMs and FFRs, which typically consist of plastic fiber materials such as melt-blown/non-woven polypropylene, was the same under both low and high humidity conditions. The increased FE of the 100% cotton fabrics can be explained by increased size of the particles due to H_2O uptake and the following increased capture of the particles.

The re-use of CFMs contaminated with SARS-2-CoV can potentially increase the risk for subsequent spreading of COVID-19. For this reason, a thorough understanding of the environmental stability and persistence of SARS-CoV-2 on contaminated masks may have impact on the handling of both reusable and single-use items during use and after wear. Kasloff et al. [216] studied experimentally the stability of SARS-CoV-2 on inoculated surfaces of face coverings used by healthcare workers and members of the general public. Of all the materials tested, cotton provided the lowest environmental stability to SARS-CoV-2. After one hour of drying, the inoculated infectious virus was disappeared almost completely from the input inoculum. However, infectious SARS-CoV-2 was recovered after 21 days on plastic, 14 days on stainless steel, 7 days on nitrile gloves and 4 days on chemical resistant gloves. In addition, significant quantities of infectious SARS-CoV-2 could be recovered from inoculated N95 FFRs for 14 days. Note that a a high titre inoculum (10^6-10^7) was used in the study to represent a worst-case scenario of SARS-CoV-2 persistence on a contaminated surface. However, it has been

argued that the use of high concentrations of SARS-Cov-2 inoculated on surfaces does not reflect the real situations (Chapter 2.1.1) [15].

The FE and the shape/fit of a CFM must be retained during the washing and drying cycles. The guidance from CDC (2020)[5] for cleaning says that the CFMs should be cleaned at 60 ºC with regular household laundry after each use. WHO refeers to the standard by AFNOR [151] and reconmmends that the materials used in CFMs must withstand at least five cleaning and drying cycles. Reusability without compromising the FE is crucial, but few studies have examined the influence of cleaning cycles on the FE of CFMs. In a study by Hao [217], eight fabrics were analyzed and the FE before and after 1, 5, and 10 cycles of washing and drying was examined. No measurable change in the structure of fabric materials and no impact on the FE of the fabrics was observed, unlike the FE of MFMs and respirator materials, which degraded drastically already after one cleaning cycle. This decrease may be due to the loss of charges attached on the fibers of the MFMs and respirator materials. However, it was observed that the FE of N95 FFRs and MFMs materials were still higher than many fabric materials used in CFMs (depending on the fabrics). A study by Clapp et al. [148] showed that washing of a two-layer nylon CFM slightly increased the FE from 74 to 79%, whereas Neupane et al. [218] observed that increasing the number of washing and drying cycles gradually decreased the FE of CFMs with a reduction in FE by 20% after the 4th washing cycle. Microscopic examination revealed that the pore size was increased and the shape of the pores were different after the washing and drying cycles.

The effects of long term use, humidity, washing and reuse of face masks

Take-aways

1. Increased humidity seems to increase the filtration efficiency of community face masks made of cotton. The filtration efficiency of synthetic fabrics, such as nylon, polyester and rayon did not improve with increased humidity. Increased humidity had no effect on filtration efficciency of medical face masks.

2. The effect of washing and drying cycles on the filtration efficiency of community face masks is contradictory. Studies have shown both increased and decreased filtration following washing and drying.

[5] How to Wash a Cloth Face Covering | CDC

Knowledge gaps

1. Experimental studies have not provided enough knowledge about the effect of humidity on filtration efficiency of community and medical face masks.

2. More knowledge is needed to estimate how long community and medical face masks can be used as face coverings before they become too humid or wet to be efficient (filtration efficiency and breathability).

3. There is a need for more studies investigating the effect of washing and drying cycles on the filtration efficieny of different fabrics, and the risk of increased faceseal leakage (fit) of community face masks

7.1 Answers to key questions in Chapter 7

- How long can CFMs or MFMs be used before they get too humid or wet? What is the definition of a humid or wet face covering?

  It is difficult to generalize if, and if so, how long it takes before face coverings become too wet or humid to be efficient. The face coverings will become humid from the human breath, but environmental conditions (weather conditions such as temperature, rain, sunshine) may also have an impact on humidity and efficiency of the face coverings. There is a lack of knowledge concerning how long CFMs and MFMs can be used before they become too humid or wet to be efficient, e.g. due to changes in filtration efficiency and/or breathability.

- What is the effect of humidity on filtration efficiency and fit (increased faceseal leakage) of CFMs and MFMs?

  Few studies have investigated the effect of humidity on the filtration efficiency and fit of CFMs and MFMs, and a broad generalization is therefore difficult. It is indicated that increasing the humidity from 55% to 99% increase the filtration efficiency of cotton fabrics, while no effect of humidity was seen for synthetic fabrics or MFMs (typically composed of synthetic fabrics). A possible explanation was increased droplet size due to H_2O uptake inside the fabric, followed by an increase in particle capture.

- Does washing and drying cycles affect the filtration efficiency and fit of CFMs? How many cycles can be performed?

  Few studies have investigated the effect of washing and drying cycles on the filtration efficiency of different fabrics used in CFMs, and the effects of washing and drying cycles

reported have been contradictory since studies have shown both increased and decreased filtration efficiency following washing and drying.

8 Discussion and conclusions

The benefit of using different types of face coverings to control and prevent the transmission of SARS-CoV-2 have been debated since the beginning of the COVID-19 pandemic. This study has reviewed the available scientific literature concerning the efficacy of medical fask masks (MFMs) and community face masks (CFMs), with a particular focus on experimental and numerical studies and results.

The basic idea behind using a face covering is to provide a filtering layer between the respiratory tract and the surroundings in order to prevent the inhalation and/or exhalation of pathogen-containing respiratory droplets while still allowing air to pass. The ability of face coverings to prevent the transmission of pathogens is closely connected to the underlying transmission mechanisms. Historically, and throughout most the COVID-19 pandemic, the main transmission guidelines for viral respiratory tract infections have referred to a contact route, a droplet route, and an aerosol (airborne) route. Recent updates to the main transmission guidelines have however redefined the transmission routes as inhalation of virus, deposition of virus on exposed mucous membranes, and touching mucous membranes with soiled hands contaminated with virus.

Respiratory activities such as breathing, talking, singing, coughing and sneezing expel droplets that span a vast size range from sub-micron to about 1 mm. In terms of droplet count, more than half of the droplets expelled are smaller than 10 μm. However, since the volume grows as the cube of the diameter, most of the expelled liquid volume is found in droplets larger than 100 μm. Droplets of all sizes can be ejected at high momentum during coughs and sneezes, and therefore deposit on a receiver, but only large and medium-sized droplets have sufficient mass to fall to the ground and contaminate surfaces. Likewise, only small and medium-sized droplets are light enough to stay suspended and be transported by the air currents. Both small and medium-sized droplets are inhalable, but only small droplets may penetrate into the lower airways. The specific cut-off between large, medium, and small droplets depends on several factors such as air currents, humidity, temperature, and salt/solid content of droplets, and is therefore difficult to assess. In this review, we have used the following classification: Small droplets are smaller than approximately 15 μm, whereas large droplets are larger than approximately 100 μm, with a size class for medium-sized droplets in-between. Since the importance of different droplet sizes on transmission of SARS-CoV-2 by inhalation is not well understood, it may be necessary to consider the efficacy of face masks in all three size categories.

Medical face masks are originally intended solely for use as source control, and typically in a clinical environment. During the COVID-19 pandemic, the use of medical and community face

masks have been advocated as source control, i.e. to control and prevent respiratory droplet emission from a wearer, and to some extent also respiratory protection, i.e. to protect the wearer from inhaling respiratory droplets an droplet nuclei. There is, however, a fundamental difference in face covering use for source control and respiratory protection. For source control the face covering is used to minimize the outward emission, with the most important features being to block the large and medium-sized droplets and to obstruct the respiratory jet. For respiratory protection, the face covering is used to protect against an airborne contamination that will be variable and context dependent both in terms of droplet and droplet nuclei size range and concentration level, which means that it is difficult to discern the practical/actual level of protection needed. Therefore, when testing face masks for respiratory protection, it is necessary to consider a large range of droplet sizes, including sub-micron droplets. In practice, for loose-fitting medical and community face masks, it is difficult to avoid gap leakages. As a consequence, about half of the air, and the particles contained within it, may be able to bypass the filter material.

In terms of source control, experimental studies have shown that both medical and community face masks can be effective in controlling and preventing the emission of medium-sized to large respiratory droplets. Recently, it has been shown that all exhalation events, such as breathing, talking, singing, coughing and sneezing produce warm, moist droplet clouds entrained in a turbulent jet that can propagate several meters. Sneezes may lead to the transport of droplets up to eight meters, whereas coughs can transport droplets up to three meters. It has also been shown that even regular speech can generate jets able to reach approximately two meters. There is evidence that the use of face coverings reduces the penetration length of these jets by more than fifty percent. This implies that the exhaled air will act as a low-momentum source of primarily small droplets. These droplets will, most likely, rapidly mix with the background concentration. This is in contrast to what happens when not wearing a face covering, where instead a strong directed jet flow is formed that contains a cloud of droplets of all sizes. Note that to achieve complete efficiency as source control, it is important both that the filtering efficiency is high enough for all particle sizes and that gap leakages are avoided. This is usually not achieved for loose-fitting face coverings such as medical and community face masks. In practice, gap leakage leads to the escape of about half of the small respiratory droplets. In addition to the obstruction of the respiratory jet, there are two external effects that contribute to the overall efficacy of face coverings: i) the ability of the ventilation system to reduce the background concentration in indoor environments, and ii) the time the virus remains infective in suspended droplets. Both these effects impact the transmission to individuals in the vicinity.

For respiratory protection, the filtration efficiency across the range of droplet sizes as well as the gap leakage of medical and community face masks is more important than for source control. For medical face masks, the filtering efficiency for droplets that are 3 μm or larger appears to be high (above ninety five percent). This is not surprising, since it is in line with the minimum performance requirements according to the applicable harmonized test standards. On the other hand, there is no guarantee that this performance will apply also to droplets that are smaller than 3 μm. The filtration efficiency for sub-micron droplets usually range from fifty percent to more than ninety percent, but some studies have shown filtration efficiencies close to zero percent. For community face masks, the filtration efficiency usually range from fifteen to more than ninty-five

percent for droplets that are 3 μm or larger, and from five to more than ninty percent for sub-micron droplets. There are no formal performance requirements for community face masks, but recent guidelines have proposed that such products should be capable of filtering at least seventy precent of particles that are 3 μm or larger. Gap leakages constitute a major concern for medical and community face masks, since both have a loose-fitted design. Gap leakages as large as forty percent have been reported. Most or all small, and possibly some medium-sized, droplets and droplet nuclei will be able to follow the inward airflow through the gap leakages. This may result in a significant inhalation exposure. It has been shown that simple measures, such as knotting/tucking or mask braces, can lead to a signicant gap leakage reduction for medical face masks.

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A Appendix

A.1 List of symbols and abbreviations

The list is given in alphabetical order.

ACE2	Angiotensin I converting enzyme 2
AFNOR	French Standardization Association
ASTM	American Society for Testing and Materials
APF	Assigned Protection Factor
BFE	Bacterial filtration efficiency
CDC	U.S. Centers for Disease Control and Prevention
CEN	European Committee for Standardization
CFD	Computational fluid dynamics
CFM	Community face mask
CWA	CEN Workshop Agreement
COVID-19	Coronavirus disease 2019
ECDC	European Centre for Disease Prevention and Control
EU	European Union
FDA	US Food and Drug Administration
FE	Filtration efficiency
FF	Fit Factor
FFE	Fitted Filtration Efficiency
FFR	Filtering facepiece respirator
HCW	Health care worker
ISO	International Organization for Standardization
MD	Medical Device
MFM	Medical face mask
NEN	Royal Netherlands Standardization Institute
OSHA	Occupational Safety and Health Administration
PAPR	Powered air-purifying respirator
PF	Protection Factor
PFE	Particle filtration efficiency
PHEIC	Public health emergency of international concern

PPE	Personal protective equipment
RPD	Respiratory protection device
SARS-CoV-2	Severe acute respiratory syndrome coronavirus 2
SCBA	Self-contained breathing apparatus
TIL	Total Inward Leakage
VFE	Viral filtration efficiency
WHO	World Health Organization

A.2 Terms and definitions

Fit factor, FF is calculated based on formula:

$$FF\ (\%) = \frac{C_{out}}{C_r} \times 100 \tag{A.1}$$

where C_{out} is the test aerosol concentration in the surroundings, C_r – test aerosol concentration inside the respirator

Total Inward Leakage TIL is calculated according to the formula:

$$TIL\ (\%) = \frac{P_1 + P_2 + \ldots + P_n}{n} \times 100\% \tag{A.2}$$

where P_n is FFR penetration by the test aerosol during n-exercise:

$$P_n(\%) = \frac{C_{r,n}}{C_{out,n}} \times 100\% \tag{A.3}$$

where $C_{r,n}$ – concentration of test aerosol inside the respirator during exercise n, $C_{out,n}$ – concentration of test aerosol during exercise n.

Table A.1 Chosen requirements for FFR filtration efficiency tests according to European and US/international standards.

standard	respirator class		requirement						
			Max. Filter penetration against		Aerosol particle size (count median diameter)		Challenge flow	Breathing resistance [mbar]	
			solid aerosol (NaCl)	liquid aerosol (EN paraffin oil, US dioctyl phtalate DOP oil)	solid	liquid		inhalation	exhalation
EN EN149	FFP1		80%	80%	0,06-0.1 μm	0.29-0.45 μm	95L/min	0.6 @ 30 L/min; 2.1 @ 95 L/min	3.0 @160 L/min
	FFP2		94%	94%				0.7 @ 30 L/min; 2.4 @ 95 L/min	
	FFP3		99%	99%				1.0 @ 30 L/min; 3.0 @ 95 L/min	
US NIOSH-42 CFR 84	N-class	N95/99/100	95/99/99.97%	n/a	0.075±0.020 μm	n/a	85 L/min	3.43 @85 L/min	2.45 @85 L/min
	R-class	R95/99/100	n/a	95/99/99.97%	n/a	0.185±0.020			
	P-class	P95/99/100	n/a	95/99/99.97%	n/a	0.185±0.020			

Table A.2 A comparison of TIL procedures given in EU and US standards used for FFR test and evaluation.

Table A.2 A comparison of TIL procedures given in EU and US standards used for FFR test and evaluation.

EN 149 (Europe)	NIOSH/OSHA (US)
NaCl aerosol	NaCl or oil aerosol
walking for 2 min without head movement or talking; 2) turning head from side to side (approximately 15 times), as if inspecting the walls of a tunnel for 2 min; 3) moving the head up and down (approximately 15 times), as if inspecting the roof and floor for 2 min; 4) reciting the alphabet or an agreed text out loud as if communicating with a colleague for 2 min; 5) walking for 2 min without head movement or talking.	While standing: eight exercises performed in the following order: 1) normal breathing, 2) deep breathing, 3) turn head side to side, 4) move head up and down, 5) speak out loud (recitation of the 'rainbow' passage), 6) reach for floor and ceiling, 7) grimace, and 8) normal breathing. The duration of time for each exercise is approximately one minute for a total of eight minutes for the test.
at least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall be not greater than 22% for FFP1 8% for FFP2 2% for FFP3.	n/a*

**NIOSH does not provide any specific numbers, but the respirator performance should comply with the legal national regulations in the US (42 Code of Federal Regulations §84).*

Table A.3 List of chosen European and international standards relevant for MFM testing.

Standards	Comments
EN 14683:2019+AC:2019 Medical face masks - Requirements and test methods	European standard. Used to assess BFE, pressure drop across the mask material, for blood penetration refers to ISO 22609
ISO 22609:2004 Clothing for protection against infectious agents — Medical face masks — Test method for resistance against penetration by synthetic blood (fixed volume, horizontally projected)	International. Used to assess blood penetration
ASTM F2100-19 Standard Specification for Performance of Materials Used in Medical Face Masks	International (US). Summarizes specifications and terminology used in F2299, F2101 and F1862

ASTM F2299/F2299M-03(2017) Standard Test Method for Determining the Initial Efficien cy of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres	International (US). Used to assess PFE of the medical face mask material
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*	International (US). Used to assess BFE
Mil-M369454C	US. Used to assess BFE
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)	International (US). Used to assess blood penetration.
MIL-M-36954C Differential Pressure Air Permeability - Respiratory Resistance Delta P Test	US. Used to assess pressure drop across mask material.

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FFI is the prime institution responsible for defence related research in Norway. Its principal mission is to carry out research and development to meet the requirements of the Armed Forces. FFI has the role of chief adviser to the political and military leadership. In particular, the institute shall focus on aspects of the development in science and technology that can influence our security policy or defence planning.

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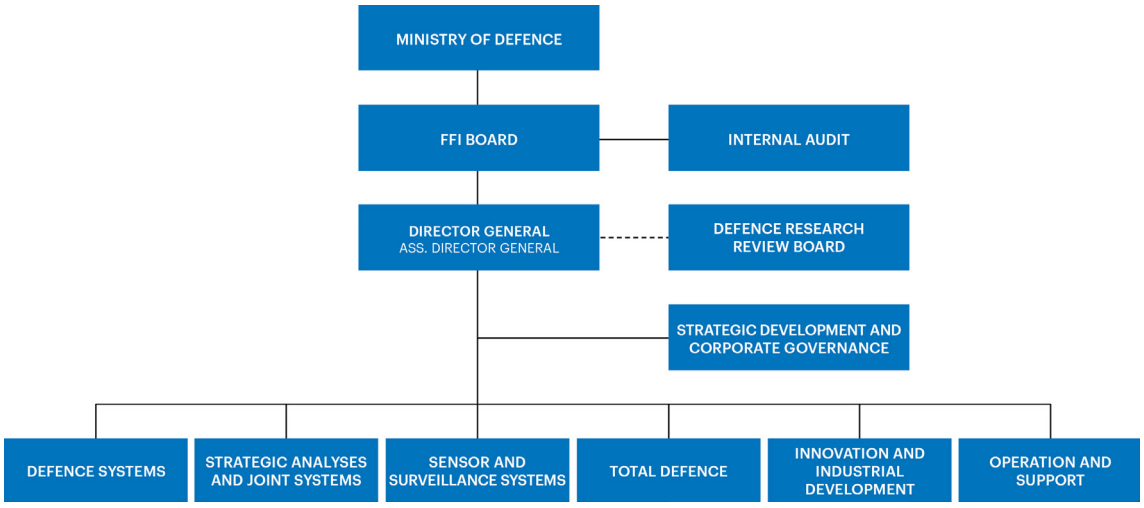

Forsvarets forskningsinstitutt
Postboks 25
2027 Kjeller

Besøksadresse:
Instituttveien 20
2007 Kjeller

Telefon: 63 80 70 00
Telefaks: 63 80 71 15
Epost: post@ffi.no

Norwegian Defence Research Establishment (FFI)
P.O. Box 25
NO-2027 Kjeller

Office address:
Instituttveien 20
N-2007 Kjeller

Telephone: +47 63 80 70 00
Telefax: +47 63 80 71 15
Email: post@ffi.no