N95 Respiratory Masks for COVID-19: A Review of the Literature to Inform Local Responses to Global Shortages

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Abstract

The scale of the COVID-19 pandemic and subsequent stain on the global supply chain has led to an acute worldwide shortage of personal protective equipment for healthcare workers. In response, many groups around the world are seeking to develop novel solutions to ensure local supply. N95/P2 respiratory masks are one of the critical components for reducing the spread of COVID-19 and protecting frontline workers. This article reviews the most significant and up-to-date literature around N95/P2 filter fundamentals, manufacturing and reuse, with the aim to serve as an authoritative resource for the development of novel COVID-19 respiratory masks.
Introduction

The availability of personal protective equipment (PPE) is vital for healthcare workers during disease outbreaks. This is particularly the case during global epidemics such as the recent novel coronavirus COVID-19 pandemic [1]. Driven by the high transmission efficiency of the SARS-CoV-2 virus [2], its rapid spread has placed healthcare systems under extraordinary pressure. This has produced an acute shortage of PPE for healthcare workers worldwide which is largely due to three underlying factors; behaviour, demand, and supply. Firstly, during the early stages of the outbreak the high potential for healthcare worker infection, combined with the lack of a vaccine and high mortality, leads to behavioural changes such as stockpiling and PPE misuse and overuse [3]. Secondly, the exponential increase in infections rapidly overwhelms the established PPE manufacturing capabilities which are optimised to respond to seasonal influenza demand. Finally, reductions in economic activity, border shutdowns and export restrictions significantly disrupt global supply. With manufacturing primarily led by China [4], this delicate supply-demand balance may suddenly collapse leaving many countries struggling to develop local solutions. Personal protective equipment is a key intervention for preventing airborne or respiratory droplet viral transmission in occupational settings such as hospitals, where healthcare workers are routinely exposed to infectious patients [5]. Healthcare PPE includes gowns, aprons, gloves, safety glasses, hair nets, shoe covers and face protection and also includes surgical masks, face shields and/or filtering facepiece respirators (FFRs). Under typical operating conditions, much of this equipment is available in a range of sizes, is single-use and disposable in order to reduce contamination. FFRs, specifically, protect against inhalation of airborne bacteria, viruses and fungi via a physical barrier comprising graded filtration papers that selectively block polydisperse water- and oil-based aerosols greater than 0.3 μm [6]. There is also significant demand for FFRs outside of healthcare. For example, surveys have shown that over 200,000 workplaces in the US use disposable FFRs, totalling 3 million workers [7]. Given the importance of FFRs for protecting frontline healthcare workers from infection, reduced supply places both the workers and their patients at risk. This has been the case during the COVID-19 pandemic, where the global shortage of PPE has contributed to increased risks to healthcare worker, rising infection rates and reduced healthcare capacity throughout medical
and surgical practice [8]–[11], highlighting the limitations of relying on established supply chains. To redress this, affected healthcare systems must now examine the scientific literature to maximise current FFR stock usability and develop robust novel methods for local manufacturing and supply [12].

FFR global manufacturing capacity is approximate 40 million masks per day with Chinese manufacturing accounting for approximately half of total supply [13]. Notwithstanding disruptions to manufacturer capacity and supply chain logistics, universal use of N95 equivalent FFR for prevention of COVID-19 transmission through the general population would greatly outstrip global supply capacity [13]. In response, governments have implemented measures to prioritise healthcare worker access to N95 masks and increases production capacity [14]. Despite this, the security of supply chains remain of critical concerns with significant price increases and modelling from the World Health Organisation indicating that mask production must increase by 40% to meet rising demands [15].

The aim of this review is to serve as a resource for those involved in the urgent efforts to fabricate, reuse, and clinically implement N95/P2 masks. We discuss important research around mask fabrication, including industry standards, particle filtering, manufacturing, mask compliance, fitting, and respiration. We also highlight research around the preservation, reuse, and recycling of existing masks to extend the life of current stocks. Finally, we draw from the latest work around novel strategies for COVID-19 masks production, including very recent publications and selected pre-publication sources.

A Scopus search was performed (7/9/20) for “N95 AND filter”. Of the 158 returned results, 4 were in languages other than English and therefore excluded, 5 were excluded based on relevance, 3 were not accessible, and the remaining articles were categorised according to the subsequent topic headings based on their title, abstract and keywords. Figure 1 shows the annual number of publications related to this search, with global virus outbreaks indicated. Given the rapid evolution of the COVID-19 pandemic, the pre-print server medRxiv was also searched to identify relevant emerging research.
**Current state of the art: N95/P2 masks**

**Respirators and Particle Filtering**

FFR regulatory standards vary across different global jurisdictions; however, it is generally reasonable to consider N95/P2 equivalency between respirators manufactured to N95 (United States NIOSH-42CFR84), P2 (Australia/New Zealand AS/NZA 1716:2012), FFP2 (Europe EN 149-2001), KN95 (China GB2626-2006), DS (Japan JMHLW-Notification 214, 2018) and Korea 1st class (Korea KMOEL - 2017-64) standards for the for the purposes of emergency health care bioaerosol PPE. It should be noted that small variation in requirements are present between these standards, the most notable of which is filtering efficiency of 95% for N95 masks compared to 94% for P2 masks and variation in maximum pressure resistance for inhalation and exhalation between a number of standards.

In the United States of America, FFRs are certified by the National Institute for Occupational Safety and Health (NIOSH) through certification 42 CFR 84.181, *non-powered air-purifying particulate filter efficiency level determination* [16]. This certification details the protocols for testing the filtration
capacity of respirators. The protocols specify two polydisperse aerosols: sodium chloride (NaCl) for use against solid aerosols, and dioctylphthalate (DOP) for use against oil-based liquid aerosols at a flow rate of 85 L/min [17], [18]. These aerosols are intended to have a mass median aerodynamic diameter of approximately 0.3 µm. This diameter is predicted to be the “most penetrating particle size” for filters in accordance with filtration theory using classical mechanics [4], [19], [20]. The testing protocols are designed to represent the worst-case particle conditions during which an FFR must perform at compliant or better efficacy [21]. Additional tests under worst-case conditions such as heavy breathing, coughing and sneezing conditions, correspond to higher flow rates and are also used to verify the efficacy of standard FFRs [22], [23]. In the United States, in addition to NIOSH certification, FFRs must also be cleared by the Food and Drug Administration (FDA) which mandates additional requirements. Other countries mandate certification by their local regulatory bodies, such as Therapeutic Goods Administration (TGA) in Australia. As FFRs must often pass through two certification bodies, harmonisation of the testing protocols may expedite the availability of masks. This has been achieved in United States [24] and a number of products which had only undergone NIOSH certification have also been shown to pass FDA clearance in several studies [25], [26]. Additional computational and computer learning models have also recently been established to accurately predict filtration efficacy [27], [28]. In one such study, a library of experimental data was acquired for the penetration of 10.7–191.1 nm particles through an FFR filter at varying flow rates. A back-propagation algorithm was then used to train an artificial neural network to predict particle penetration based on particle size and flow rate. This network was then tested and validated on new data sets and demonstrated promising filtration efficiency prediction compared to experimental methods [27].

Graded FFRs are manufactured to comply with three standardised aerosol filtering efficacy levels, indicated as 95, 99 or 100, corresponding to the ability to filter 95%, 99% and 99.97% of aerosol particles greater than 0.3 µm, respectively. The degree of resistance to oil-based aerosols are indicated by non-resistant (N), resistant (R) and proof (P), giving nine different mask grades of each efficiency and level of resistance [29]. All 9 grades of filter were initially approved by NIOSH in 1995 [30] for use in healthcare facilities in response to the increasing concerns of healthcare workers about the
nosocomial acquisition of multidrug-resistant tuberculosis, *mycobacterium tuberculosis* [31]. N95 masks, also known as P2 respirators, were the cheapest masks that were shown to conform to the 42 CFR 84.181 standard for 95% efficacy at filtering 0.3 µm water-based aerosols with non-resistance to oil-based aerosols (Figure 2). These have become essential in healthcare settings to protect healthcare workers from exposure to bacteria, viruses and fungi that may be transmitted during their occupational tasks [32]–[35].

**Figure 2** Schematic diagram of an N95 FFR, including the use of four or more layers to provide external protection and internal filtration to satisfy the National Institute for Occupational Safety and Health (NIOSH) standards for 95% filtration of particles above 0.3 µm in diameter. Other materials may be used as alternatives to those listed in this figure. A tight-fitting seal is required to ensure there is no leakage around the face or ability for air to leak into the mask without passing through the filter. These masks vary significantly from surgical masks which do not contain a high-efficiency filter and only filter particles greater than 2 µm in diameter, as well as being loose fitting.

Airborne bacteria are typically 0.6-1.5 µm, larger than the “most penetrating particle size” tested during certification [31]. It can therefore, be expected that the filtration efficacy for bacteria is higher than the certified efficacy for the ‘worst case’ particles. For viruses, respiratory droplets generated whilst coughing or sneezing are typically 5-10 µm in diameter and act as the carrier for the nano-scale virons [36]. In the case of fungal spores, the typical diameter range has been reported to be 0.7-4 µm [37]. The use of a 0.3 µm particle diameter is therefore an acceptable lower threshold for particle filtration for
trapping respiratory droplets in a mask before they can make contact with healthcare workers [4]. In addition to mitigating the transmission of aerosols to the wearer, filters are also designed to reduce re-aerosolization when the mask wearer coughs or sneezes and thereby prevent reintroduction of viral or bacterial particles back into the air [38]–[40].

Following the outbreak of severe acute respiratory syndrome (SARS) in 2002-2003, several studies reflected on the healthcare procedures and practices that increased the risk of SARS transmission. Intubation, non-invasive ventilation, tracheotomy and beds in <1m proximity to one another were identified as hazardous and substantially contributed to super-spreading events in hospitals in Hong Kong and China. The use of properly-fitted N95 masks, on the other hand, was found to be vital to protecting healthcare workers [2], [41]. In another study demonstrating the efficacy of N95 masks, one of the first victims of the SARS outbreak, a World Health Organisation physician, was reported to be seen by 129 attending healthcare workers before he died of respiratory failure after 19 days in a hospital in Thailand [42]. Of the 112 healthcare workers that were subsequently surveyed, 95% reported using a correctly fit-tested N95 mask and 80% compliance with the recommended PPE. None of the attending healthcare workers contracted the virus despite their proximity to the patient during treatment[42]. Later during the outbreak in Canada, 91.5% of healthcare workers were reported as using N95 masks, with the most commonly reported impediment to their use being a lack of availability [43].

**Surgical Masks vs N95/P2 FFRs**

In addition to N95/P2 FFRs, surgical masks are also commonly used PPE for mitigating exposure to airborne pathogens. However, their particle filtering ability is limited by comparison and only rated to filter particles greater than 2 µm. A comparison of the primary purpose and filter composition is shown in Table 1 [44]. Surgical masks typically comprise three layers; a melt-blown filter layer to prevent the emission of respiratory particles sewn between two layers of non-woven fabric. These soft masks cover the nose and mouth and are tied behind the head and neck or around the ears to secure it to the wearers face. Due to their superficial similarity, surgical masks can often be mistaken by the general public as N95 FFRs and are often worn with the intent of reducing the spread of contagious diseases. However, they provide limited protection against pathogens [45]. Furthermore, research suggests that when worn
by the general public, N95 FFRs do not offer superior protection against virus transmission compared to surgical masks and are also more expensive and uncomfortable [46], [47].

Table 1 Comparison of surgical masks (SMs) with N95 masks of soft or cone-style design. Example images are reproduced from [48]–[50].

<table>
<thead>
<tr>
<th>Mask Type</th>
<th>Purpose</th>
<th>Composition</th>
<th>Schematic</th>
<th>Example</th>
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<tbody>
<tr>
<td>Surgical Mask</td>
<td>Protect others from wearer’s respiratory particles</td>
<td>3 layers: 1. Outer hydrophobic layer to repel fluids, including blood 2. Filter for particles &gt;2 µm 3. Inner hydrophilic layer to absorb fluids, sweat and spit</td>
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<tr>
<td>FFR (N95, soft)</td>
<td>Protect wearer from airborne pathogens</td>
<td>4+ layers: 1. Outer layer to filter particles &gt;0.5 µm 2. Filter for particles &gt;0.3 µm 3. Inner hydrophilic layer to absorb fluids, sweat and spit</td>
<td></td>
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</tr>
<tr>
<td>FFR (N95, cone)</td>
<td>Protect wearer from airborne pathogens</td>
<td>4+ layers: 1. Outer hydrophobic layer to repel fluids, including blood 2. Activated charcoal filter to remove contaminants, impurities and chemicals 3. One or more high-efficiency filters for particles &gt;0.3 µm 4. Soft inner layer for comfort</td>
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For healthcare workers, the superiority of N95 FFRs over surgical masks for protecting against bacteria, viruses and fungi has been conclusively demonstrated in several studies [51]–[57]. This extends to multiple layers of surgical masks, with up to 5 layers being found to have inadequate leak protection or filtration against airborne particles in studies seeking alternatives to scarce N95 FFRs during outbreaks [52].

In addition to protecting patients against respiratory emissions by the clinicians during procedures, surgical masks may be used by contagious patients to limit the spread of pathogens [58], [59]. A number of studies have compared the effectiveness of protecting healthcare workers from exposure by fitting a
patient with a surgical mask compared to an unmasked patient seen by a healthcare worker with an N95 mask [47]. Given the improved availability and cost effectiveness of surgical masks compared to FFRs, the wearing of surgical masks by all contagious patients may reduce demand for FFRs which is critical in pandemic scenarios. Studies involving simulated particle emissions and masks secured on manikins showed that a surgical mask placed over the source (a model contagious patient) are more effective at minimising the transmission to a healthcare worker than a healthcare worker using an N95 mask, even when sealed with Vaseline [60], [61]. However, it should be noted that the inferior fit of the N95 masks on manikins compared to healthcare workers may have led to the poor comparative performance of N95 masks in this study. Regardless, the combinational approach of patient surgical mask use and healthcare workers’ N95 use remains the best clinical practice where availability permits [60]. In addition, retrospective evidence from hospitals in Hong Kong during the SARS outbreak, as well as during simulations, suggest that the use of an N95 mask on a patient may be more effective than surgical masks at reducing the amount of expelled air by the patient during coughing, however leakage around the face was found to extend up to 15 cm [62], [63]. Despite this, surgical masks are still recommended for the patient in preference to N95 masks due to their superior comfort [2], and may be more suitable in paediatric patients due to their better fit and minimal leakage [64].

Filter Manufacturing

The filtration component within N95 masks is a non-woven textile, typically produced from a combination of synthetic polymers such as polypropylene and regenerated cellulose [65]. Details of the manufacturing processes for the fabrication of such textiles, however, are not readily available in the literature, and remain propriety information of several global manufacturers such as 3M Innovative Properties Co (Maplewood, MN, USA) and TrioMed Innovations Corp (South Burlington, VT, USA). Select details can be gleaned from a number of patents which describe the manufacturing and material selection process [66], [67]. For example,

“The filter body is preferably comprised of a substrate, preferably a nonwoven fabric. Nonwoven is a type of fabric that is bonded together rather than being spun and woven into a cloth. It may be a manufactured sheet,
mat, web or batt of directionally or randomly oriented fibers bonded by friction or adhesion; it may take the form of a type of fabric. Preferred nonwoven filter media include but are not limited to nylon, polyethylene, polypropylene, polyethylene terephthalate, polyester, etc. or any other polymer suitable for a filter substrate. In such cases, it is preferable that the filter media be prepared from a meltblown process, which provides for optimum filtration performance. Additionally, the filter body can be made of materials other than polymer fiber. For example, the filter body may be made from alternative substrates, which include glass fibers and fibers, such as cellulose, that are ultimately formed into a paper-based filter media. Cellulose fibers may be appropriate where the mask is designed for single use.”

Given the commercially-sensitive nature of filter manufacturing, it is challenging to deduce specific composition and manufacturing guidelines from the literature. However, similar filters have been described elsewhere for applications in desalination and water treatment [68] and protein ultrafiltration [69] which could be adapted and up-scaled for manufacturing towards respiratory filters if supply was compromised.

**Mask Compliance, Fitting and Resistance to Respiration**

To ensure optimal performance of NIOSH-certified masks, including N95 masks, fit-testing is required in clinical practice to ensure the mask completely seals around the face, particularly over the bridge of the nose and mouth [70]. Initially, a self-administered fit check is performed by the healthcare worker. This is performed by placing the mask on their face and securing the ties. The mask is then compressed into the face and positive pressure is produced by gently exhaling. The healthcare worker can then feel any air that escapes around the seal and adjust the mask to improve the fit. Next, negative pressure is created by inhaling to check for complete sealing. In Australia, formal fit testing, training and assessment is required annually [70]. Fit testing is used both as a frontline assessment of healthcare worker safety while donning and wearing FFRs, as well as in research, development and retrospective clinical studies for assessing the safety and efficacy of PPE. The importance of fit testing has been
extensively verified [51], [71]–[73]. Systematic evaluations have shown that that with fit-testing, N95 masks can achieve the expected 95% efficacy, however, without fit-testing, filtering performance dropped to 6-88% [74].

Filtering facepiece respirators of various grades of filtration efficacy proportionally restrict flow during normal breathing cycles [75]. High grade FFRs such as P100 exhibit up to double the resistance to flow than N95 FFRs. This can lead to face-seal leakage [54], [76], as well as wearer discomfort and non-compliance [77], [78]. The proportion of leakage present in P100 masks compared to N95 under different leakage conditions has been studied using a certification standard aerosol system running at various flow rates through the masks fitted to a manikin [79], [80]. One study concluded that when significant leakage occurs due to flow restriction with P100 masks, the filtering capability drops to below that of N95 masks which have less flow resistance [79]. Another study corroborated these results and additionally found that once the leak is greater than 0.1% of the mask surface area, a N95 mask no longer performs at 95% efficacy [81]. In fact, many studies have quantitatively ascertained that the face seal is more of a critical indicator of filtering performance, rather than the performance of the filter itself [82]. These findings have motivated research into optimising mask design, increase minimise leakage and increase their effectiveness [83].

A comparison of three mask designs (shown in Figure 3) was undertaken to assess their fit-factor following routine fit-testing and during seven common head and facial movements [84]. For most activities, no significant difference in fit quality was measured between the three masks. However, for some of the participants certain masks exhibited poorer fitting during some activities. Similar results have been reported elsewhere, providing consistent recommendations that healthcare workers should understand which masks provide superior performance for a given scenario in addition to ensuring optimal comfort and functionality [84]–[88].
In addition to initial fit-testing, a three-year study evaluated the change in fit factor for 134 subjects whilst monitoring weight changes [89]. On average, the risk of an unacceptable fit after 3 years climbed from 25%, with those losing more than 20 lb (~9 kg) in a year more likely to have an ill-fitted mask than other weight change groups [89], corroborating other studies which have recommended the implementation of robust training and workplace verification of mask wearing, as well as frequent follow up, particularly for healthcare workers experience weight change [87], [90]–[93].

**Strategies for existing masks: preservation, reuse and recycling**

**Decontamination for Reuse**

In the event of major public health crises, including pandemics, the shortage of FFRs poses a significant strain on healthcare workers on the frontlines treating infected patients. In the event of disruption to manufacturing, alternative approaches for using existing FFR supplies can be considered. The NIOSH and CDC have published guidelines and recommendations on mask reuse towards improving clinical practice in compromised environments [94]. Before masks can be reused, they should be decontaminated to control the growth of microorganisms and prevent the spread of pathogens between
patients. Considerations for reuse include the availability of decontamination resources, space and expertise, as well as the introduction of control measures to protect against potentially harmful decontamination reagents [95]. Additionally, the impact of decontamination on the mask and its filtering performance must be established to ensure the masks are not damaged or compromised which may impact the safety of healthcare workers [96]–[98].

Several strategies have been developed and evaluated for decontamination and reuse of existing masks to increase their longevity (Table 2). Ultraviolet germicidal irradiation (UVGI) and bleach have been proposed and the efficacy of the masks was validated using certification standard protocols, however degradation of the mask itself was noted in some instances [99], [100]. Furthermore, alcohol is not cleared by the FDA as the primary active ingredient in liquid chemical sterilants since it does not completely eliminate bacterial spores. While ethanol and isopropanol could be more suitable for this purpose, they remove the electric charges present on filter fibres which are crucial to their efficacy [101].

Table 2 Summary of recommendations made by four studies on the use of various decontamination methods to enable reuse of N95 masks.

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<tr>
<td>Lin et al. 2018 [95]</td>
<td>F</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>−</td>
<td>−</td>
<td>−</td>
<td>−</td>
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<td>−</td>
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<tr>
<td>Bergman et al. 2010 [99]</td>
<td>−</td>
<td>M</td>
<td>✓</td>
<td>−</td>
<td>−</td>
<td>M</td>
<td>−</td>
<td>F</td>
<td>✓</td>
<td>✓</td>
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<td>Lore et al. 2012 [102]</td>
<td>−</td>
<td>−</td>
<td>✓</td>
<td>−</td>
<td>✓</td>
<td>M</td>
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<td>−</td>
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<tr>
<td>Lin et al. 2017 [104]</td>
<td>F, M</td>
<td>−</td>
<td>−</td>
<td>F, M</td>
<td>✓</td>
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<tr>
<td>Grinshpun et al. [105]</td>
<td>F, M</td>
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✓ = recommended

F = filter degradation/non-compliant performance after treatment

M = mask degradation/non-compliant performance after treatment

− = did not test
Other strategies involve the use of bleach at various concentrations, autoclaving which is a common high temperature and pressure sterilization method commonly used for medical supplies and medical devices, as well as using a rice cooker to apply dry heat for up to 3 min [95]. A recent study from 2018 compared the survival of bacteria on N95 mask filters after exposure to ‘worst case’ high humidify environments for 24 hours. Using the five methods listed above, the biocidal efficacy of each decontamination technique was compared against preservation of mask integrity, concluding that bleach, ultraviolet germicidal irradiation, autoclave and rice cooker were the most effective methods which could be readily translated to a clinical setting [95]. Additional studies have corroborated evidence to suggest that ultraviolet germicidal irradiation, along with ethylene oxide, dry heat via rice cookers and hydrogen peroxide (H₂O₂) vapour, are a promising, cost effective and readily-introducible technique [99], [102], [103], including pre-print articles published on medRxiv detailing methods for using UV [106] and hydrogen peroxide [107] for rapid PPE sterilization amidst the COVID-19 pandemic. Notably, on the 29th March 2020, the FDA issued Emergency Use Authorization for a commercial hydrogen peroxide vapour-based sterilization system with capacity up to 80,000 N95 masks per day [108]. The initial authorization has been approved for 10,000 masks, however additional social and governmental pressure may see additional capacity approved as well as additional systems from other providers as the pandemic progresses [109].

**Surgical & N95 Mask Combination Strategies**

Another strategy proposed to increase the longevity of existing supplies of N95 masks involves the concurrent use of a surgical mask overlayed on a fit-tested N95 mask [110]. Surgical masks, which are considerably cheaper, could be readily worn over the N95 mask and replaced many times between patients during a given shift. The surgical mask would, therefore, act as a barrier to preserve the efficacy of the N95 mask while reducing exposure to multiple patients for which new N95 masks would have otherwise been required. Although beneficial in principle, additional considerations require further investigation such as the increased burden on healthcare workers do to increased resistance to breathing and difficulty communicating through the double mask combination. It is also possible that the additional layer of material would induce premature N95 mask failure due to accumulation of heat and
perspiration which is known to reduce the filters ineffectiveness [111]. During the SARS outbreak, a combined approach of wearing an N95 mask and protective eyewear underneath a powered air-purifying respirator which covered the entire head (including a clear face shield) was reported [112]–[114], however the authors note that rigorous scientific studies were lacking to confirm its efficacy [115].

Storage and Shelf-Life

While N95 masks are certified to have a specific shelf-life, studies have demonstrated that the efficacy of masks, when stored properly, may extend for many years after their ‘use by’ date [116]. This provides the opportunity to store masks in stockpiles for longer so more can be deployed for use in the event of a shortage. The key aspect which must be preserved during storage is the filtration performance. Specifically, electrostatic charges are imparted onto the filtration textile during manufacturing which play a critical role in attracting and capturing particles. This approach enables the filtration material to be lighter and more comfortable than with purely mechanical filtration mechanisms [116]. The conditions under which N95 masks are stored are, therefore, fundamental to preserving the critical material properties. Masks are required to be stored in humidity-controlled conditions between 15°C to 27°C is locations which minimise physical damage, contamination, dust, and exposure to sunlight and damaging chemicals. For example, exposure to solvents (ethanol, isopropanol etc.), radiation and heat [117], [118] have been shown in laboratory experiments to significantly decrease the efficacy of N95 mask filters. UV radiation and water, however, were not shown to compromise functionality [119].

Manufacturers often specify a shelf life or use-by date, but they are not required to specify the storage conditions needed to ensure maximum efficacy of the filters. A number of studies have, therefore, sought to compare the longevity of a range of commercial masks under ‘ideal’ and ‘worst-case’ scenarios. These studies followed a certification process using particle filtration measurements to determine compliance with filtration efficacy standards [116]. In one notable study comparing 21 models of N95 masks, the storage time before the masks failed filter certification tests was found to be between 6 and 10 years, with an average of 7.3 years (N=21 mask brands) [116]. However, a key limitation of this study was the inability to perform the filtration efficacy test on a given masks both
before and after storage, since the masks were sourced from existing stocks and already in storage. Further studies are required to definitively examine mask degradation rates to determine their maximum practical storage period.

**Novel COVID-19 masks: alternative filtration & rapid manufacturing**

**Translation of masks and filters from non-medical industries**

N95/P2 masks are also routinely used in a number of other industries beyond healthcare, with many studies demonstrating their effectiveness in various contexts. Examples include community response to volcanic eruptions [120], [121] and combustions [122], [123], long-term exposure to engine and smoke emissions [124], [125], dust exposure during construction [126], welding [127], and pathogen exposure in animal facilities [128], [129]. In the emerging field of nanotechnology, N95 masks have been found to offer protection during the fabrication and handling of nanomaterials such as carbon nanotubes [130]–[133]. N95 masks are also recommended by the Centre for Disease Control and Healthcare Infection Control Practices Advisory Committee for use by immunocompromised patients when exposed to construction or maintenance works which may generate dust and particulate matter in the air [134]. While the focus of these studies relates to the use of N95 masks in industrial contexts, few articles exist that investigate alternative sources of filtration devices.

One such device is high-efficiency particulate air filters (HEPA). These are efficient and widely used air filters which are commonly installed in domestic appliances such as vacuum cleaners [135], as well as air filtration systems including in cars [136], airplanes [137] and laboratories [138]. HEPA filters are rated to the N100 standard, filtering 99.97% of particles and non-resistant to oil, as per NIOSH certification. Given their widespread availability, it is likely that these filters are not subjected to supply interruptions during health crises and, as such, may offer an potential alternative filter material for manufacturing novel masks [139]. Recently, full-face snorkel masks have also been suggested as readily adaptable and potentially more comfortable alternatives to filtration respirators with demonstrated success following fit-testing and minimal excess CO₂ accumulation compared to regular N95 masks [140], [141].
Household Materials for Community Mask Use

Although out of scope for this article discussion FFRs for healthcare workers, many countries around the world have mandated the use of face coverings in public during the COVID-19 pandemic, including in shops, workplaces and public transport. This has motivated research into the filtration efficacy of a variety of household materials and fabrics which are used as home-made face coverings and masks [142]. Widespread misunderstanding exists, in parallel to the aforementioned confusion surrounding the role of surgical masks versus FFRs, as to whether mandatory face covering legislation is designed to stop potentially-infectious mask wearers from spreading the disease (consistent with the role of surgical masks) or to stop the general uninfected population from becoming infected (consistent with the role of FFRs) [143]. In general, the widespread use of face coverings may intend to achieve both imperfectly, encouraging the reduction in disease transmission through a combination of physical barriers to reduce viral particle accumulation in public spaces, filtration of airborne particles, and encouraging behavioural changes such as reducing face touching frequency and maintaining physical distancing. Therefore, the efficacy of fabrics both in reducing the spread of respiratory droplets from coughing or sneezing as well as filtering airborne particles for the wearer is of interest [144]. Materials tested included coffee filters, quilt fabric, leather, tea towels, toilet paper, paper towel, bandanas, scarfs, pillow cases and dust cloths, showing a range of filtration compliances which is often has a trade-off with pressure drop [142], [143], [145]. For example, leather exhibited 100% filtration efficiency of 0.3 μm particular but had a pressure value more than an order of magnitude higher than surgical masks and 3M N95 masks [142].

Novel Rapid Manufacturing Considerations

Several novel manufacturing methods have been suggested to employ more readily available materials for. For example, meshes have been fabricated by producing nanofibers using combinations of materials such as cellulose acetate (CA), polyvinylidene fluoride (PVDF), [146]–[148], polyurethane [149], polystyrene [150], and have demonstrated NIOSH requirements for N95 filtration. With the availability of suitable industrial electrospinning manufacturing facilities, it could be possible to produce N95-grade filtration using these readily available materials. Several other materials commonly found in hospital
settings, including sterilization wrap (e.g. Halyard H200-H600, available in a variety of strengths) have been proposed for use as filtration textiles, however recently literature has not reached consensus on whether these materials satisfy NIOSH standards for N95-compliant filtration efficacy [151], [152].

Softwood and hardwood kraft pulp have also used in a “wet beating” manufacturing process to achieve a high surface fibrillation. The samples were then partially freeze dried to retain surface fibrillation into the dry state to ensure they met the criteria for N95 NIOSH certification using the standardised measurement of less than 5% penetration of NaCl aerosols [153].

Approaches for the advanced manufacturing of reusable masks are also undergoing intense research and development [154], [155]. Some reusable mask designs propose the use of several different materials to ensure comfort, fit and robustness combined with a disposable filter component, as illustrated in Figure 4. The use of a 3D printable elastomeric polymers or moulded silicone components can be used for the skin interface to reduce irritation and provide a suitable seal. This skin interface component is then attached to a 3D printable or injection moulded rigid body. Single-use disposable filter cartridges consisting of a rigid polymer framework containing the N95 (or equivalent) filter material can then be attached and removed by healthcare workers as required. After each shift, the reusable component of the mask may be cleaned before the next use [155].

Figure 4 A schematic design for a reusable N95 facemask for healthcare workers within the hospital. (a) a side view showing the skin interface material (red) attached to a rigid framework, into which is attached the disposable filter. (b) a 3D computer render of the mask design showing the three main components.

The COVID-19 pandemic and this critical shortage of FFRs has driven a substantial increase in local capacity to test novel FFR solutions. Recently in Australia, a new testing facility has been established
to enable compliance testing of FFRs to international standards for synthetic blood penetration (ISO 22609:2014), pacterial filtration efficiency (BFE) (EN 14683:2014 Annex B) and pressure differential (EN14683:2014 Annex C) [156]. This offers local manufacturers the ability to rapidly produce essential medial equipment including FFRs and gain accreditation for novel and alternative solutions, reducing costs and reliance on international testing facilities during periods of supply chain and global transport disruptions.

Other than the technical compliance factors, including filtration efficiency, fitting and resistance to liquids, other psychosocial considerations have been strongly encouraged for inclusion in novel mask manufacturing. For example, transparent masks would greatly increase accessibility for patients with hearing impairment who strongly rely on lipreading for communication, as well as allowing facial expressions to be more readily observed which is known to be critical to providing high quality care [157], [158]. Additionally, recognisability of healthcare workers in full PPE is also limited and therefore incorporating the names on masks, especially when personalisation can be readily incorporated into mask manufacturing, has been suggested to improve communication [154]. Customisation, colour and creativity could also be enabled through the use of 3D printing where accessories and decorations to PPE could be incorporated, increasing accessibility and lessening the confronting visual impact of PPE-donned healthcare workers for children.

While the goal of this article was to specifically collate relevant findings from published scientific literature for the development and production of FFRs during the COVID-19 pandemic, an additional source of information should also be noted. Social media is now integrated into the global socio-political landscape and, during times of global crisis, is widely used to rapidly communicate news, ideas and experiences. In the context of the current situation, innovations in new PPE, alternatives for N95 masks, and mask reuse approaches are being shared online. Although not peer-reviewed, some of these findings may be useful as starting points more rigorous studies. For example, strategies including storing masks overnight in dry paper bags have been suggested to minimise exposure to the hot, humid conditions that accelerate pathogen proliferation. Other social media posts suggest spraying masks with a commercial disinfectant, Lysol® for reuse. Homemade fabric mask covers have also been proposed as an alternative
to surgical masks to be worn over and protect N95 masks from contamination. Many groups and agencies around the world are also establishing website-based 3D model repositories for the purpose of 3D printing PPE components, including face shields and masks for the COVID-19 pandemic. Although promising, caution is required before adopting do-it-yourself (DIY) approaches, as they can often lack clinical governance and rigorous evaluation frameworks and are not performed with regulatory oversight. Subsequently, they may be unable to comply with safety requirements when tested using standard certification procedures, and therefore be ineffective and pose risks.

Conclusion

Experience drawn from recent epidemics such as SARS and MERS, combined with ongoing research into the fundamental science, manufacturing, and clinical use of N95/P2 filters, can inform local COVID-19 mask solutions and ensure they are evidence-based, safe and effective. To enable optimal designs, minimise production timelines, and extend the life of current stocks, a number key findings should be noted. Firstly, a wealth of modelling, simulation, clinical and retrospective case studies have demonstrated the importance of effective N95 mask fit-testing to ensure correct functionality. In addition, evidence suggests wearing surgical masks or face shields over N95 masks can extend their useful life. Beyond this, several decontamination methods are available to extend mask usage including the recently FDA approved hydrogen peroxide vapour decontamination method, UV irradiation, ethylene oxide sterilisation, and the use of dry heat in a rice cooker. N95 masks have also been shown to perform at certification standards for up to 10 years following manufacturing, provided they were carefully stored in cool, dry conditions away from sunlight. Novel approaches are also possible for the production of N95/P2-grade filter materials using electrospun polyurethane or cellulose acetate (CA) and polyvinylidene fluoride (PVDF) combination nanofibers, although further research and certification of these approaches is still needed. Additionally, filter materials such as high-efficiency particulate air (HEPA) filters may also be a suitable if N95 stocks become unavailable. The challenges stemming from the unprecedented demand and limited supply of PPE during the COVID-19 pandemic has generated
significant research and development activity. An evidence-based and clinically driven approach, supported by the expansion and diversification of local solutions, will ensure that the results of these efforts provide the best possible protection for frontline healthcare workers.
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**Author Contribution Statement**

NCP, SKP and MAW performed the literature review and wrote the manuscript, DPF, MD, MK, SB, CS provided significant inputs, edits and proof-reading assistance.