

Developing Regulatory Framework and Performance Criteria for Children's Respiratory Protective Devices – a White Paper

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ABSTRACT

This White Paper is a call to action for the development of a regulatory framework and performance criteria for children's respiratory protective devices. The unique physiological and developmental characteristics of children make them very susceptible to inhalation hazards. Almost all respiratory protective devices (RPDs) are designed for adult occupational use and rarely address the needs of pediatric populations. Studies in National Academies of Sciences, Engineering, and Medicine (NASEM) proceedings indicate that, while respirators can reduce children's exposures, they are generally less effective than when designed for, and properly used by, adults (NASEM, 2022). Challenges such as lower inspiratory and expiratory pressures, discomfort due to filtration (breathing) resistance, and cognitive limitations in younger children make respirator usage more complex. In addition, the facial dimensions vary greatly. These factors highlight the necessity for specialized design frameworks that ensure safety, usability, and accessibility (NASEM, 2022).

The International Society for Respiratory Protection (ISRP) has been a collaborating partner with the FACE-UP (Factors Affecting Childhood Exposures to Urban Particulates) project, which aimed to establish the efficacy of children's use of respiratory protection to reduce their exposure to particulate air pollution.

As part of this effort, ISRP and FACE-UP conducted two workshops in 2024 to give an overview of existing information and identify knowledge gaps surrounding respiratory protection for children. The intent of the workshops was to address priorities for the development of regulatory frameworks, including recommendations for design and performance criteria, the design of a global consensus standard, manufacturing and distribution considerations, product registration requirements, selection and use guidance, education and training, ethical considerations, and recommended next steps. This White Paper lays out these recommendations.

A worldwide standard for pediatric respirators should be established under the leadership of a global consensus standard development organization, such as the International Organization for Standardization (ISO) or ASTM International, ensuring adaptability to diverse populations and regional needs. This requires standardized testing protocols that incorporate child-specific physiological and ergonomic considerations; regional flexibility within global standards to account for variable demographics and cultures and environmental exposures, and alignment with existing national regulatory frameworks to streamline certification and adoption.

Developing pediatric RPDs necessitates a nuanced approach which integrates filtration, breathability, fit, comfort, and accessibility. By leveraging insights from recent research and establishing age-appropriate

performance standards, manufacturers can create effective solutions tailored to children's respiratory protection needs.

Additionally, there is a need for comprehensive regulatory frameworks, which include guidance for families on when, where, and how respirators should be used by children, including references to the worldwide consensus standard as part of clear selection guidance. Continued interdisciplinary collaboration will refine these guidelines and enhance protection for pediatric populations amid evolving health and safety challenges.

Keywords: pediatric respiratory protection; global consensus standards; respirator design and performance; air pollution exposure; child health vulnerability; filtration efficiency and fit; respirator regulatory frameworks

INTRODUCTION

There is a recognized need for an effective regulatory framework, including a global consensus standard, to be developed to help protect the respiratory health of children. There are currently discussions to develop such standards by the International Organization for Standardization (ISO) and ASTM International. This White Paper aims to guide that standard making process.

Children are particularly vulnerable to airborne hazards, including air pollution and infectious diseases. The World Health Organization (WHO, 2018) estimates that 93% of children under 15 years old live in areas with air pollution exceeding safe guidelines, contributing to 543,000 deaths in children under five due to respiratory illness in 2016 (WHO, 2018). Similarly, UNICEF reports that air pollution was the second leading risk factor for child mortality in 2021, accounting for 709,000 global deaths (UNICEF, 2021).

Higher respiratory rate, increased activity, and ongoing lung development make children more susceptible to airborne pollutants (NASEM, 2022). Their higher respiratory rate per kilogram of body mass increases exposure to airborne toxicants, while their higher activity levels and rapid craniofacial development before age 10 complicate proper respirator fit (NASEM, 2022). Holm (2022) underscores these factors, emphasizing that children inhale more air per kilogram of body weight than adults.

Short- and long-term health effects are a concern for children. Exposure to polluted air and respiratory pathogens increases the risk of infections and respiratory distress in children (EPA, 2019). Long-term exposure can impair lung development, contributing to chronic conditions such as asthma and cardiovascular disease (WHO, 2018).

It is essential for governments to prioritize the introduction and enforcement of policies aimed at reducing and ultimately eliminating air pollution, particularly emissions generated by combustion processes. While these systemic changes will take time to implement and achieve measurable results, it is of paramount importance to ensure that children grow into productive and healthy adults. In the interim, especially in regions with consistently poor air quality—such as densely populated cities or areas affected by agricultural burning and wildfires—personal protective measures have become a necessary and proactive mitigation strategy, rather than a last resort.

Regulatory frameworks will play a crucial role in shaping the pediatric respirator market by enforcing safety and performance standards and clarifying the circumstances in which pediatric respirators may be needed. These future regulations would drive demand for higher-quality, certified products and significantly influence manufacturer strategies. However, variations across regional regulatory systems create challenges for manufacturers seeking to operate globally.

The COVID-19 pandemic has increased public use of respiratory protection and boosted the production of certified respirators and non-certified facemasks (MacIntyre, 2025; OSHA, a; Toner 2021). During the pandemic, respirators emerged not only as personal protective equipment (PPE) but also were shown to be a source control product, capable of preventing respiratory droplets from escaping infected individuals

and reducing the spread of airborne pathogens (MacIntyre, 2025). Unlike facemasks designed primarily for source control - for which standards are still evolving - respirators offer dual protection, shielding the wearer and mitigating the transmission of infectious agents to others. This functionality underscores the necessity to develop, for respirators and source control devices, their own distinct standards, tailored to their respective roles.

It is now more socially acceptable to use respiratory protection for reducing children's exposure to particulate air pollutants compared to before the pandemic (van der Westhuizen, 2020). However, due to the lack of design standards for pediatric respiratory protection, existing respirators are variably effective. This, and the need for further scientific evidence on their efficacy, has created a lack of trust in current products which has hindered governments and international humanitarian organizations from implementing policies or guidelines to protect children from air pollution through personal interventions (McDonald *et al.* 2020).

The International Society for Respiratory Protection (ISRP) is collaborating with the FACE-UP (Factors Affecting Childhood Exposures to Urban Particulates) project, which aims to reduce children's lifetime vulnerability to non-communicable diseases by minimizing exposure to particulate air pollution during childhood. FACE-UP is a research consortium funded by the UK Research and Innovation Global Challenges Research Fund Programme. It investigated factors affecting children's exposure to urban pollution and the efficacy of respiratory protection for children. The project examined the fit and filtration efficiency of children's respiratory protection, potential health benefits in various exposure scenarios, and behavioral, social, ethical, contextual, and policy drivers influencing its effectiveness and sustainability (Sleeuwenhoek, 2025; Gudgin Dickson, 2025). It also looked at community motivation, opportunity, and capability for behavior change required for successful uptake (FACE-UP, 2023).

As part of this initiative, ISRP and FACE-UP conducted two workshops, the first to give an overview of existing information, and the second to identify knowledge gaps related to children's respiratory protection. The goal was to prioritize information required for the development of global consensus standards for such protection, including recommendations on design and performance criteria, manufacturing and distribution considerations, education and training, ethical aspects, and future steps.

The first workshop was held online on 26 June 2024, and included keynote presentations on the state of knowledge on children's respiratory protection to the ISRP community, followed by a question and answer session and discussion (recording available: <https://www.youtube.com/watch?v=IEUVRUfSqiM&t=10s>). The second workshop took place on 26 September 2024, at the ISRP Conference in Oxford, UK. The workshop was open to all interested conference participants and included the keynote speakers from workshop 1. It involved round-table discussions that contributed to the outline of this White Paper. The table discussions focused on: 1) designing respirators for children; 2) development of design standards; and 3) supply chains, access, and affordability. Each table addressed pre-defined questions and topics (Appendix I), with five or six conference attendees per table, including a chair/rapporteur and one or two note takers (see Acknowledgements for attendees).

This White Paper follows on from the workshops and is a call for the development of global consensus performance standards and accompanying guidance on children's respiratory protection. It aims to offer recommendations and insights on key considerations for developing a global regulatory framework, including a consensus standard for respiratory protection for children exposed to environmental and public health hazards, including infectious particles and particulate pollution. The scope of this paper does not include child labor protections.

EXISTING INFORMATION AND DATA

Standards are guidelines developed by experts, offering best practices for performance, quality and safety. Establishing a global standard for pediatric respiratory protective devices (RPDs) is essential, as adherence to standardized criteria enhances product safety, interoperability, and overall system efficiency (ANSI, n.d.; ISO, 2021). Standards help to ensure that products are safe for their intended use, reliable, and compatible

across markets. In an increasingly interconnected global marketplace, alignment with international standards benefits manufacturers, developers, distributors, and consumers alike. Conversely, a lack of global coordination can lead to inconsistent regulations, trade barriers, and compromised health and safety outcomes (ANSI, n.d.).

Regulations, distinct from standards, are mandatory requirements imposed by governments to achieve policy objectives such as safer products and workplaces (Litan, n.d.). Although regulatory goals may align across nations - and standards greatly enhance this alignment - their implementation often varies due to differing legal, cultural, and administrative contexts (ENHESA, n.d.). Regulatory frameworks serve several key functions. They establish clear, enforceable rules that promote fair competition and protect consumers by ensuring that products meet baseline quality and safety standards. Additionally, they safeguard public health through guidelines that address safety and environmental risks (Abogado, n.d.).

Current standards predominantly focus on respirators for adults and their use in occupational settings. Certain ISO RPD standards extend to the general public (ISO, 2022). Wang *et al.* (2022) provide a summary of the performance requirements for some commonly used international standards for RPD. At the time of writing, there exists only one standard specifically for child respirators: China's GB/T 38880-2020 "Technical Specifications of Children's Masks" (Standardization Administration of China, 2020), which is applicable for children aged 6 to 14. Products conforming to this standard filter particulates in the air, including microbes, pollen, airborne droplets, etc. There are no global (e.g., ISO, ASTM) consensus standards for pediatric respirators.

Although there is an increasing volume of published work relevant to the design of child respirators (Seo *et al.*, 2017; Sucipta *et al.*, 2023; Zhang *et al.*, 2023; NASEM 2023; Goto *et al.*, 2021; Realmuto *et al.*, 2023), this knowledge has not been translated into practice by manufacturers because there is no country or regional regulatory framework available for child applications of RPDs. However, some countries such as China and South Korea, do provide regulatory approvals for respirators designed for children (NASEM, 2023).

Few studies have specifically measured the performance of respirators claiming to fit children. Seo *et al.* (2023) and Gudgin Dickson *et al.* (2025) recently studied pressure drop and filtration efficiency in children's respirators and various non-respirator masks, such as surgical and cotton or cotton-blend cloth masks. All of the respirators in Gudgin Dickson *et al.*'s study met N95 pressure drop requirements but two (out of eight) did not meet the penetration requirements. Additionally, two studies assessed wearability parameters of selected N95/FFP2 respirators for children, including self-reported comfort, measured fit, and gas exchange during rest and light exercise (Goh *et al.*, 2019; Smart *et al.*, 2020; Sleenwenhoek *et al.*, 2025). Sleenwenhoek *et al.* (2025) also assessed the fit of respirators on sixty children (30 in Nepal and 30 in Indonesia) using six different earloop respirators (3 in each country) in two combinations (with and without an additional adjustable earloop clip). The fit factor for each respirator was determined using a modified fit test protocol (Appendix II) for filtering facepiece respirators using a TSI PortaCount™ Respirator Fit Tester Model 8048. Most fit factors were less than 10, i.e. less than 90% reduction in exposure. Using an additional earloop clip was associated with increases in fit factor of 42% and 50% for Indonesian and Nepalese respirators, respectively, compared to not wearing an earloop clip.

The physiological effects of wearing respiratory protection at higher activity levels typical of active children have not been systematically examined. However, Smart *et al.* (2020) recorded discomfort due to heat buildup within the respirator during running activities. Sleenwenhoek *et al.* (2025) found that children who underwent a limited exercise fit test rated the respirators positively across comfort, heat, breathability, perceived fit, embarrassment, and appearance.

The style of a respirator can also influence uptake and use in children. Nila *et al.* (2025) conducted focus group discussions with children in Indonesia and Nepal and asked them to rank respirators in order of their preferred styles and features. Children preferred respirators with earloops rather than headstraps. Younger children tended to prefer coloured and patterned materials whereas older children tended to prefer plain

masks (white or black). This suggests that manufacturers could offer a variety of designs to improve uptake in different age groups.

Anthropometric studies offer valuable facial measurement data that could inform the design of pediatric respirators. Using anthropometric data obtained using digitalized 3D face analysis, Kim *et al.* (2016) classified Korean children's facial dimensions to define three appropriate facepiece sizes for protection against yellow dust and fine particulates using anthropometric data obtained using digitalized 3D face analysis. Lin *et al.* (2017) developed and evaluated respirator fit test panels for small-to-medium facial features in young adults (age 21-30) and found that fit improved with larger facial dimensions. Sleenwenhoek *et al.* (2025) also measured facial dimensions: face width (Bizygomatic breadth) and face length (Menton-Sellion length) of sixty children in Nepal and Indonesia. They found that, for each mm increase in face length, there was a 2.9% increase in log fit factor, for the Indonesian children.

DEVELOPING GLOBAL STANDARD(S)

The need for a comprehensive approach to pediatric RPDs is increasingly evident. Establishing a standardized global framework that focuses on performance standards, fit assessments, and equitable access is vital. This paper aims to provide general considerations and a framework that a future standards development committee should address.

Aligning international consensus standards with existing conformity systems, such as those of National Institute for Occupational Safety and Health (NIOSH) in the United States, the Conformité Européenne (CE) certification and marking in Europe, and Canadian Standards Association (CSA) in Canada, can streamline the approval, manufacturing, and distribution processes, reducing barriers to adoption. Regional conformity assessment systems, like NIOSH's, could require regional regulatory changes to allow the use of existing frameworks. International efforts like the ISO 16900, 16976 and 17420 series on RPDs provide a framework for this alignment by offering performance-based criteria that can be adapted regionally without compromising safety (ISO, 2021). Each ISO standard number includes a prefix ("ISO"), a series identifier, an optional part number, and a publication year — all of which communicate its scope and industry focus.

If one or more new standards for children's respirators were developed, it would not necessarily render existing products obsolete. Many of the child-sized respirators currently on the market, such as those labeled KN95, FFP2, or KF94, have already been tested against established performance benchmarks for filtration efficiency and, in some cases, breathability. However, while these products may meet technical criteria, the broader regulatory framework needed to ensure appropriate design, labeling, fit, and use for children is often missing. To manage the transition, regulatory authorities could adopt a phased approach: recognizing existing products that meet core technical requirements, while simultaneously setting timelines and guidance for full conformance with the new standard. This would avoid unnecessary waste and supply disruptions, especially given the high volume of products produced by a wide array of manufacturers. The regulatory authority or agency responsible for the new standard could issue a statement acknowledging that certain previously certified respirators remain acceptable for use, provided they meet specified interim criteria. This approach would support continuity in protection while gradually shifting the market toward more rigorously defined and comprehensive child-specific respirator standards.

A comprehensive standardization effort for pediatric RPDs should begin with the development of globally recognized performance requirements, established through an international consensus process involving multidisciplinary experts in respiratory protection, pediatric health, materials science, and human factors engineering. Once developed, these standards guide the design and engineering phase, where manufacturers translate the performance requirements into manufacturing product specifications. This includes the selection of materials, structural components, and features to ensure compliance with the defined pediatric-specific needs. Prototypes should undergo rigorous laboratory testing to verify conformance with performance requirements.

Following successful testing, the certification process—often involving third-party conformity assessment

bodies—is used to validate that products consistently meet the standard. Certification should include initial type testing, factory audits, and ongoing quality control monitoring to maintain product integrity throughout the production lifecycle (NIST, 2023). Manufacturers must establish robust quality management systems to ensure repeatability and consistency in mass production, including documentation of production procedures, raw material sourcing, and inspection protocols.

Once in production, regular post-market surveillance, including random batch testing and user feedback collection, is necessary to detect performance degradation or emerging risks. The regulatory framework should also require periodic updates to the standards and certification criteria to incorporate technological advances, updated research data, and improved materials or manufacturing techniques. This full lifecycle approach—from standards development through design, testing, certification, manufacturing, and post-market oversight—ensures that pediatric RPDs remain safe, effective, and responsive to changing needs.

Moreover, it is essential to consider socio-economic factors that impact access to high-quality protective devices. This is particularly important in low to middle income countries where children's exposure to air pollution may be significantly higher than air quality guidance (UNICEF, n.d.[a]). Implementing subsidies or financial assistance programs can ensure that all communities, regardless of economic status, have access to effective pediatric respiratory protection. Collaborative efforts between governments, non-profit organizations, and private sectors could further enhance research and development, addressing specific needs such as fitting adjustments for various age groups and conditions.

A well-rounded and universally accepted framework for pediatric RPDs will not only standardize quality and safety measures but also promote inclusivity and innovation in this critical field.

DESIGN AND PERFORMANCE CRITERIA

Pediatric RPDs require sophisticated engineering to achieve an optimal blend of filtration efficiency, breathability, fit, and comfort. Ensuring effective respiratory protection for children necessitates outlining crucial performance factors. The balance between high filtration efficiency and breathability is essential, as highlighted by ISO (2021), indicating that respirators must not only filter particulates effectively but also allow for easy breathing.

Pediatric RPDs should at least meet these measurable performance requirements: filter efficiency, breathability, and fit. A satisfactory balance of breathability, filtration, and fit is specified by the many global respirator performance standards which are currently referenced in the certification and approval of respirators for adult workers - including N95, FFP2, KN95, and others (3M, 2021). Striking the right balance between these factors is essential for ensuring both safety and wearability. Public health respirator standards, including for pediatric respirators, should be as similar as possible to those existing standards, in the interest of scalability, availability, and elasticity of supply during public health crises.

Other design factors that should be addressed include comfort and acceptability; shelf-life; marking, instructions for use and storage; and reusability, stability, and durability. Respirators with good fitting characteristics are paramount to the effectiveness of respiratory protection. Developing a sizing grid based on studies, such as the Korean study identifying three respirator sizes (Kim *et al.*, 2016), could establish a baseline for pediatric respirator sizing. Additionally, sizing may need to be done in different geographical regions to address differences in facial anthropometry, to ensure a respirator fits a person's unique facial dimensions well enough so that the respirator is offering the optimal level of protection for which it was designed (Hasni *et al.*, 2023; Hobbs-Murphy *et al.*, 2025; O'Kelly *et al.*, 2021; Yu *et al.*, 2014).

When designing pediatric respirators, physiological differences need to be considered. Age-appropriate designs should accommodate children two years and older (CDC, 2025). In addition to the above mentioned measurable performance requirements, effective pediatric respirators should prioritize comfort, usability, and inclusivity. Materials used should minimize discomfort while maintaining protective integrity, as noted by Holm (2022). Furthermore, inclusive design should ensure that devices meet the needs of children with

developmental challenges and hearing impairments (ISO, 2021).

Safety considerations are critical to guarantee effective and safe respiratory protection for children. Pressure drop analysis indicates no significant physiological effects on heart rate, oxygen saturation, or respiratory rate while wearing surgical masks or FFP2 respirators, according to Happerneegg *et al.* (2023). Most studies report no adverse effects from product use; however, further evaluation of CO₂ retention in child-sized respirators is necessary to ensure safety, as highlighted by Lubrano *et al.* (2021), Weigelt *et al.* (2024), Mull *et al.* (2021) and Goh *et al.* (2019).

Several key areas must be addressed in a global standard, to optimize the real-world effectiveness of pediatric RPDs:

Particulate Filtration Efficiency

Filtration efficiency measures how effectively a respirator can filter out particles from the air. High-efficiency respirators, such as N95 filtering facepiece respirators (FFRs), are designed to capture at least 95% of airborne particles, including harmful pathogens, dust, and particulate pollutants (Rengasamy *et al.*, 2017; NIOSH, 2021). This effectiveness is achieved by employing multiple layers of advanced materials such as melt-blown polypropylene, electrostatic filters, or nanofiber technology. However, higher filtration efficiency often comes with increased resistance to airflow, which can make breathing more difficult. For example, respirators that offer protection against oil-based aerosols or smaller particles may have denser filter media, thereby reducing breathability. To optimize protection from both particulate pollution and pathogens, children's RPDs should meet the same filtration efficiency performance standards as adult respirators. For pediatric respirators, flow rate and aerosol loading are essential parameters in particulate filtration efficiency testing because they ensure the device can provide consistent protection under realistic and worst-case use scenarios for children. Flow rate should be adjusted to reflect pediatric breathing patterns, which vary by age and activity level, but still need to account for elevated exertion during play or physical activity (Gudgin Dickson *et al.*, 2025). Testing at appropriately scaled higher flow rates helps ensure the respirator maintains filtration performance even when a child's respiratory rate increases. Similarly, aerosol loading evaluates how filter performance changes as particulates accumulate during extended wear. Some filter media may initially perform well but degrade as they load, particularly in designs that rely on electrostatic charge. Understanding how pediatric respirators behave under both high-flow and loaded conditions ensures that they maintain protective efficiency throughout their intended duration of use and supports the development of performance standards that are appropriately scaled for children's unique physiological and behavioral characteristics.

Breathability Optimization

Breathability refers to the ease with which air passes through the respirator and reaches the wearer. It is dictated by factors such as the structure of the respirator, the materials used, and the overall design, including fit. Lightweight and low-resistance non-respirator products, such as surgical masks, may provide better breathability but may compromise on filtration efficiency. Manufacturers assess breathability using measurements like pressure drop, which quantifies the resistance of airflow across a respirator's material. Lower pressure drop values correspond to easier breathing, making the respirators more suitable for prolonged use, particularly in physically demanding environments or for individuals with respiratory conditions.

The relationship between breathability and filtration efficiency is often inversely proportional. As filtration efficiency increases, breathability tends to decrease due to the denser material makeup required for high-level filtration. Balancing filtration efficiency with breathability is crucial for comfort and extended wear. Recent advances in filtration media enhance protection while simultaneously offering low airflow resistance. Innovations in materials science also promise to create lightweight yet durable facepieces, which could be pivotal in promoting wider acceptance and usage. Further research could explore alternative manufacturing techniques incorporating porous membranes and microstructure adaptations to improve breathability without compromising filtration efficacy.

Breathability-focused modifications, such as specialized exhalation valves or adjustable airflow features, might be designed specifically for respirator applications, although these present challenges in child respirators due to the reduced area of filter medium (Goh *et al.*, 2019). Additionally, ergonomic designs, like horizontal fold FFRs, that consider facial structures and movement patterns could further optimize the breathability, comfort and usability of pediatric respirators, ensuring effective use in varied environments and conditions.

Gudgin Dickson *et al.* (2025) suggest that, due to the physiological and anthropometric differences between children and adults, further work to help define requirements and standards appropriate for specifically testing children's respiratory protection is warranted. For example, they evaluated test flow rates representative of typical children's breathing patterns. Child-specific flow rates should be considered in performance testing of filtration efficiency and pressure drop.

Fit Capability

Ensuring proper respirator fit is vital for protecting children. Respirator fit is a critical consideration because effective contact between the respirator and the wearer's skin, around the full perimeter of the respirator, including the bridge of the nose, directs air through the filter rather than allowing it to flow around the respirator and directly into the child's airways. The effectiveness of a respirator seal can be compromised by gaps between the face and the respirator, which underscores the necessity for fit data that better represent children's facial features (Hasni *et al.*, 2023; Xu *et al.*, 2021).

Pediatric respirator fit needs to be addressed in two ways. First, the capability of the respirator design needs to be addressed by the performance standard - this is explored in this section. Second, the fit of a particular respirator that is selected for use by a particular child needs to be confirmed before the child wears the respirator into a hazardous environment, since no one respirator model effectively fits every single face. This is explored in the Regulatory Framework section of this White Paper. It is important to note that, usually, fit and comfort are opposing factors. Often, masks and respirators that fit poorly are perceived to be the most comfortable, because they allow more air to enter freely around the sides of the respirator. A proper balance must be established between fit and comfort.

Measurements of respirator fit are called fit factors. A lower fit factor on a respirator indicates a weaker or incomplete seal between the facepiece and the wearer's face. This compromised seal allows for an increased level of leakage, diminishing the respirator's overall effectiveness in filtering harmful contaminants. In practical terms, this means that the child wearing the respirator may inhale a greater proportion of airborne particles, which the device is intended to block.

Several factors can contribute to a lower fit factor, including an ill-fitting design that does not adequately contour to the face, as well as anatomical variability and compliance considerations (Sleeuwenhoek *et al.*, 2025; Brosseau, 2010), improper donning of the respirator, or wear-and-tear over time. A low fit factor is a clear signal that adjustments are necessary, whether through selecting a new or better-fitting respirator model, using accessories to improve fit (such as earloop clips), or educating the child and caregiver on proper use.

A test to measure a fit factor is called a fit test. Ideally, fit test protocols simulate real-world use conditions, such as speaking or head movements. Conducting a series of fit tests on a variety of wearers is called a fit study. Fit studies must be conducted using human subjects - no researcher has to date developed a headform, static or dynamic, that yields fit measurements that correlate with fit measurements on human faces. If the wearers in a study are selected methodically, to be representative of a broader population, that study is called a fit panel. Typically, for adult respirators, fit panels are assembled based on face sizes typical for that adult population, with a certain number of participants from each face size, distributed according to the whole population face size distribution. For children, a similar practice could be effective, and should include children who must use various head-worn items such as glasses, hijab, turbans and orthodontic equipment. However, given the wider range of face sizes due to the fact that children grow and

develop at different rates, it is possible that a child panel would be assembled based on ages rather than face sizes. This method of assembling a panel has been used when a face size grid was not available for a child population (Sleeuwenhoek *et al.* 2025).

Developing anthropometric face measurement databases for children is of paramount importance, as they can be used to develop facial dimension grids representative of specific child populations, which are essential for designing protective equipment, such as respirators, that fit securely and function effectively (Zhuang *et al.*, 2007). Nemeth *et al.* (2025), found facial shape and size in children vary significantly with age from ages 2 to 18, and offered guidance on how qualitative analysis can be used for the design of pediatric RPDs. In designing children's respirators that are both effective and equitable, global standards should incorporate regional flexibility to address the demographic variability (e.g., facial anthropometry, age, sex, and facial features) specific to different populations. Pediatric respirators designed for one demographic may not fit or function optimally for another; for instance, studies have shown that standard respirators often fail to provide an adequate seal for individuals with smaller or flatter facial profiles, which are more common in some Asian populations (Zhuang *et al.*, 2010).

Anthropometric face measurements could also be used to inform respirator labeling to guide consumer size selection. Non-invasive optical scanning technology, like using an app on a cellphone, presents an opportunity for manufacturers to improve pediatric respirator designs before they reach the market.

A comprehensive standard would need to specify fit performance criteria. The standard should allow maximum innovation in product design by dictating performance requirements, not specific design elements. A key consideration in respirator design is the difference in performance between earloops and head straps. While elastic head straps have shown to provide improved fit and stability (Bergman *et al.*, 2012), most children's respirators, especially in low-resource settings, rely on earloops due to ease of use, manufacturing constraints, and the preference of users who prefer comfort but lack awareness of the differences in performance between earloops and headbands. Novel head suspension systems, such as adjustable harnesses or hybrid configurations that combine earloops with an optional overhead strap, may be alternatives to consider for improving fit. Including fit performance criteria in the product standard would compel manufacturers to develop well-fitting child respirators via a wide range of solutions.

Manufacturers should consider design elements that can help ensure good fit across the full spectrum of face sizes in pediatric populations. Standards and user instructions could, and arguably should, include information on improving respirator fit through additional methods, particularly for children. For example, Sleeuwenhoek *et al.* (2025) demonstrated that the use of an earloop clip, connecting the earloops at the back of the head, significantly improved fit for particular child respirators by reducing gaps and enhancing seal integrity. The research in Sleeuwenhoek *et al.* (2025) was part of the FACE-UP project which subsequently incorporated such findings into its informational products (an animated video for children and a booklet for parents/carers), recommending practical accessories like earloop clips and, in their absence, alternatives such as hair clips to tighten the facepiece effectively. Fit improvement techniques such as these could vary in effectiveness by respirator and should be evaluated, perhaps by manufacturers (FACE-UP, 2025).

One could look to occupational FFRs as a model to establish the fit capability requirements for child respirators. In workplaces, employers must measure the concentration of the hazard and then ensure that a respirator provides enough protection to reduce the concentration that is inhaled by a worker to an acceptable level that will not damage their health. For workers, fit factors of 100 are typically required during a fit test, in order for an FFR to be considered sufficiently well-fitting for that workplace use. A fit factor of 100 typically means the respirator is capable of providing a 100-fold reduction in the amount of particles inhaled by the wearer - or 99% reduction (1/100). However, because fit tests are very controlled measurements, regulators apply a research-supported safety factor of 10 to estimate the actual protection provided when the worker wears that respirator during work. Therefore, a fit factor result of 100 is interpreted to mean that when a fit-tested worker wears that FFR in their workplace, they are assumed to receive overall protection of at least a 90% reduction (1/10) in contaminants. Therefore, if workplace concentrations do not exceed 10 times the acceptable concentration, the worker is assumed to be effectively protected by the FFR.

Typically, fit capability performance criteria are expressed in terms of a percent pass rate at a specific fit factor. For example - for an adult workplace respirator design, a reasonable acceptance criterion could be “a 65% pass rate at a fit factor of 100.” If a design has a lower pass rate than that, it might not be well accepted by customers, since many wearers would fail fit tests. However - for pediatric respirators, since most children cannot be expected to be fit tested, it is reasonable for the pass criterion to include a higher pass rate. Regulators would want to be sure that a design has a high probability of providing a certain level of protection, when used correctly.

Significant questions that need to be addressed by standard developers and regulators are: What is an acceptable fit factor criterion for child respirators? What reduction in contaminant concentration is acceptable? As mentioned earlier, fit and comfort are often inversely related - as fit improves, there is a decrease in comfort; as fit deteriorates, comfort can seem to increase, due to air flowing freely around the edges of the respirator. A balance must be struck, where child wearers are adequately protected but not over-protected at the possible expense of comfort and uptake (or effective use). Section 4, below, explores features that impact comfort and acceptability.

It is perhaps reasonable for the acceptance criterion to specify a lower fit factor than 100. Factors that must be considered are: typical particulate matter concentrations and levels that are considered to be acceptable for a given population or individual. The ratio of concentration to acceptable level is the reduction that is needed. For example, the World Health Organization (WHO) recommends that 24-hour average $PM_{2.5}$ levels should not exceed $15 \mu\text{g}/\text{m}^3$ more than 3-4 days per year. $PM_{2.5}$ concentrations routinely reach $100 \mu\text{g}/\text{m}^3$ in parts of the United States affected by wildfire smoke (Childs *et al.*, 2022). To reduce $100 \mu\text{g}/\text{m}^3$ to below $15 \mu\text{g}/\text{m}^3$, a reduction factor of 6.7 is needed. With a safety factor of 10 applied, the fit test fit factor should be at least a 67. Therefore, a possible acceptance criterion to consider, based on this logic, could be at least an 80% pass rate at a fit factor of 70. It is also possible to set multiple performance criteria - such as, the design must achieve at least an 80% pass rate at a fit factor of 70, and at least a 95% pass rate at a fit factor of 5. A fit factor of 5 represents an 80% reduction in exposure (1/5). A historical precedent to consider is the FDA-approved public health respirators, for which the DeNovo (new product) application specified a fit performance of a 100% pass rate at a fit factor of 2 (a 50% exposure reduction, 1/2).

Finally, a fit study protocol needs to be designed. Since children are not likely to have access to individual fit testing, one way to meaningfully assess a respirator design's ability to fit in real-world use is to conduct an unassisted study (3M Personal Communication) (Appendix II).

Manufacturers that have developed and commercialized child respirators, and that have internal acceptance criteria and testing procedures, should be consulted in the development of at least the fit performance portion of the pediatric respirator standard.

Ideally, individual fit tests would be conducted on children needing respiratory protection. The availability of such fit testing services might result in changes being made to the fit performance criterion specified by a pediatric respirator performance standard.

Comfort and Acceptability

Comfort in pediatric respirator design extends beyond functional aspects and breathability; it also encompasses careful consideration of design elements that directly impact user experience. Ensuring that respirators lack sharp edges or coarse materials is imperative to prevent irritation or discomfort during prolonged use. Rough textures can lead to skin chafing, particularly on sensitive areas of a child's face, such as the nose bridge and cheeks. Similarly, the use of staples to attach straps, while seemingly negligible, may pose risks if exposed or ingested, causing discomfort or potentially injuring the user.

Manufacturers should instead opt for seamless, padded, or ergonomically contoured designs that evenly distribute pressure and minimize localized strain (Smart *et al.*, 2020). By integrating these thoughtful design elements alongside functional performance, pediatric respirators can achieve a balance of safety, usability,

and comfort, which is critical for encouraging consistent use among children.

To enhance comfort for extended pediatric use, it is essential to consider several factors. Firstly, using hypoallergenic materials can significantly reduce skin irritation, which is particularly important for individuals with sensitive skin or allergies (Smith, 2022). This choice of material ensures that the respirator remains comfortable over prolonged periods, minimizing discomfort and potential allergic reactions. Secondly, incorporating moisture-wicking and ventilated layers aids in temperature control (CDC, 2025a). These features help manage perspiration and heat build-up, making the respirator more suitable for long-duration wear, especially in warmer environments. Facial seal pressure is another important attribute for comfort that should be considered.

For children, more than adults, how they appear while wearing a respirator or facemask will influence their willingness to use the intervention (Le et al., 2023). The shape, color, and pattern of the facepiece are all, likely, influential (Smart *et al.*, 2020; Sleeuwenhoek *et al.*, 2025; Nila *et al.*, 2025). A global standard should be sufficiently flexible to allow for varied designs, potentially including non-typical respirator designs such as gaiter-style coverings (also known as snoods or buffs). With conventional styles, there is evidence that horizontal-folded facepieces fit better on children than vertical-folded facepieces, which often are too large around the nose and chin areas (Sleeuwenhoek *et al.*, 2025). However, vertical-fold facepieces are more commonly available (and are worn more frequently by adults, with children modelling adult behavior; Kendal *et al.*, 2018) in some parts of the world.

Designs should also prioritize usability and intuitiveness, ensuring that children can easily adjust and wear the respirators without complex instructions or external assistance. Features such as simple strap mechanisms, clear markings for proper orientation, visual cues for fit adjustments like forming the nose clip, and ability to accommodate a variety of hairstyles, eyewear, and headwear accessories can make respirators more user-friendly for children. It is important for a design standard to encourage designs that are most likely to fit, and be appealing to, a wide range of children (Nila *et al.*, 2025).

Pediatric respirators should also be acceptable to parents and caregivers, particularly of younger children, as their willingness to purchase such devices directly influences compliance and effectiveness. Acceptability hinges not only on functional attributes but also on cost, availability, and design aspects (ease of adjustment, visual appeal, perceived comfort, and packaging design). Providing clear instructions and educational materials tailored for caregivers ensures proper usage and maintenance, fostering a positive experience and promoting consistent use among young users (CDC, 2025).

By designing children's respirators that fit well and distribute pressure evenly, users can avoid areas of discomfort that may develop during continued use. These combined strategies create a more practical and user-friendly respirator experience, promoting health and safety without sacrificing comfort.

Marking, Instructions for Use, Storage and Shelf-life

Improving compliance and effectiveness through clear and accessible usage guidance is crucial. To aid children and caregivers, package marking should incorporate pictorial representations in conjunction with culturally appropriate instructions for use. Manufacturer instructions should provide guidance for reuse and care in the instructions. Consideration should be given to the role that carers must play in helping the child wearer put on and check the fit of the respirator. It is essential that the manufacturer instructions be specifically written to be understandable and executable by carers and children, including how to put on the respirator, limitations, and how to conduct seal checks. Checking and troubleshooting the seal of a respirator is vital to helping optimize the protection that the respirator delivers, and it is important for manufacturers to recognize and address the fact that seal check procedures for adults likely need to be modified or explained differently to be understood and done effectively by children and their carers.

It is best practice for regulatory authorities to evaluate the effectiveness of manufacturer user instructions during the approval process, to help ensure that the instructions document is complete and understandable by the end user. Standardizing fit adjustment accessories and instructions across different pediatric

respirator models, if practicable, can ensure consistency and facilitate ease of use for all users. An example of this would be the inclusion of earloop clips. Furthermore, public health education programs should provide comprehensive instructional materials that detail the procedures for selecting, maintaining, and disposing of children's respirators. These measures can enhance understanding and proper usage, ultimately contributing to better health outcomes and overall safety.

Improper storage such as exposure to extreme temperatures, high moisture, or UV light, can lead to degradation of filter media and loss of electrostatic charge, compromising filtration efficiency, as well as degradation of elastic/rubber straps. NIOSH has documented several cases where expired or improperly stored respirators failed to provide adequate protection, highlighting the importance of adhering to manufacturer-recommended storage conditions and shelf lives (NIOSH, 2025). These reports have shown that expired or improperly stored N95 respirators experienced increased fit failures and decreased performance, emphasizing the need for routine inventory checks and adherence to stock rotation practices. Ensuring proper storage in a clean, dry environment and within the manufacturer's specified temperature and humidity range is essential to maintaining respirator integrity and user safety.

Respirator shelf-life and proper storage conditions are critical to ensuring the effectiveness and safety of all RPDs, including those for children. Shelf-life varies by manufacturer and model but is generally affected by environmental factors such as temperature, humidity, light exposure, and packaging integrity (NIOSH, 2020). Typical shelf-life for currently available RPDs range from 2-5 years.

Shelf-life is an important consideration in respirator performance and inventory management, although its treatment varies across regulatory frameworks. For example, in the United States, NIOSH does not specify shelf-life and storage method as part of its certification process under its regulation, 42 CFR Part 84, apart from identifying a shelf-life requirement for escape respirators used in mining and chemical, biological, radiological, and nuclear (CBRN) applications (NIOSH, n.d.). It is the responsibility of manufacturers to determine and label shelf-life based on internal testing (NIOSH, n.d). EN 149 requires labeling indicating that the shelf-life should be provided in the marking, but it does not give any requirement for shelf-life length (BSI, 2001).

Reusability, Stability, and Durability

Pediatric respirator designs need to be robust enough to maintain their functionality through the period they are in use. Some respirators are designed to be used for a short period (like FFRs), and some, like elastomeric respirators, are designed to be more durable and robust, with facepieces made of plastic, rubber, or silicone (which can be cleaned/disinfected) and replaceable filters (which cannot be cleaned). FFRs are not intended to be cleaned or disinfected; however, they may be reused. Both FFRs and elastomeric respirators are intended to eventually be discarded when they no longer pass inspection according to procedures which should be recommended by the manufacturer. Features to be inspected may include rips or tears of the facepiece, stretching or breaking of the head straps or earloops and, for FFRs, ensuring the noseclip is intact and bendable and that the inside of the facepiece is not dirty or otherwise contaminated.

Particle filters in most particulate respirators become more efficient as they collect particles during use. Eventually, as the filter accumulates more particulate matter, however, the user might notice that it is harder to breathe through and discard and replace the filter or FFR.

Ideally, children's respirator designs and/or packaging would incorporate clear indicators of wear-and-tear to signal when they need replacing. By doing so, users and caregivers could ensure optimal protection and timely replacements. Manufacturing strategies should also prioritize affordability, to make pediatric respirators accessible to families across different socioeconomic backgrounds. This approach will help more children, regardless of their financial situation, have access to reliable respiratory protection.

MANUFACTURING AND DISTRIBUTION

Efforts to improve the accessibility and affordability of children's respirators require strategic coordination among multiple stakeholders, including manufacturers, public health authorities, and governments.

The creation of selection guidance by local, regional, or global public health authorities, which references scientifically sound children's respirator performance standards, such as those that are currently queued for development by ISO and ASTM, will help to create favorable market conditions for high-performing new pediatric respirator products, designed and manufactured using sound quality control practices by reputable manufacturers.

The global children's facemask market, which includes respirators, is experiencing robust growth. It is projected to reach \$2.5 billion in 2025, with a compound annual growth rate of 8% extending through 2033 (Archive Market Research, 2025). This growth is driven by heightened awareness of respiratory health and air pollution, an increase in allergies and infectious diseases among children, and stringent public health regulations. Technological innovations, such as enhanced filtration capabilities and the use of eco-friendly materials, are further fueling this market expansion. While non-certified facemasks and FFRs currently dominate due to convenience and affordability, the elastomeric style is gaining popularity, largely due to environmental concerns and long-term cost savings (Archive Market Research, 2025).

The 2–6-year-old age group represents the highest demand segment, with market concentration primarily in North America and the Asia-Pacific region (Archive Market Research, 2025). These areas benefit from high population density, rising disposable incomes, and elevated health awareness (Archive Market Research, 2025). However, demand is expected to grow across all global regions, particularly in developing economies with expanding middle-class populations. Despite the positive market outlook, challenges remain. These include fluctuations in raw material costs, seasonal demand variations, and stringent regulatory compliance requirements in certain jurisdictions (Archive Market Research, 2025).

Cost instability, driven by unpredictable demand spikes, is a concern in the production and scalability of pediatric respirators. Emergency preparedness plans must include scalable production mechanisms to respond rapidly during health crises. There is a potential for international child and health-focused humanitarian agencies to support market stability through agreements with RPD manufacturers, to ensure availability of sufficient unexpired RPDs during air pollution and public health crises. Collaboration between governments, manufacturers, and public health agencies can help align standards and improve access to high-quality pediatric respirators (UNICEF, 2021a). These partnerships can also facilitate knowledge sharing and promote innovation. Equitable distribution is essential, especially in low- and middle-income countries, where children face disproportionate barriers to accessing respiratory protection (McDonald *et al.* 2020). Supply chain disruptions can significantly limit availability, making it crucial to build resilient logistics networks and harmonized global standards, so that products from one market can easily be applied to a different market. Additional strategies to improve accessibility include offering pediatric respirators through online marketplaces, distributing them at local community events, and implementing subsidy programs for underserved populations.

Governments face complex decisions when allocating limited public health resources, particularly when balancing the need for children's respiratory protection against other pressing priorities such as vaccination programs, mental health services, nutrition, and chronic disease prevention (McDonald *et al.* 2020). The manufacturing and distribution of pediatric respirators require a coordinated, multisectoral approach involving manufacturers, public health agencies, policymakers, and communities. Stockpiling is an essential component of disaster preparedness planning. However, without a standard defining the performance requirements for pediatric respirators and regulations requiring that products meet those standards, stockpiling organizations lack the guidance needed to create effective specifications in bids.

LOCAL REGULATORY FRAMEWORK

A robust local regulatory framework is essential for ensuring that children's respirators meet the necessary

safety and performance requirements, using existing, well-established respirator standards, with the ability to incorporate child-specific standards as they are published. Such a framework should be implemented locally, at the country or region level, and should include these components:

- Pediatric respirator performance requirements
- Approval or registration requirements
- Selection and use guidance
- Consideration for equitable distribution, access, and education

Two framework options that incorporate these components are given below.

Pediatric Respirator Performance Requirements and Approval or Registration Requirements

Option 1 - Approval Program

Lawmakers in each country would designate a regulatory authority or agency responsible for overseeing approvals of pediatric respirators to acceptable performance standards (see Design and Performance Criteria, above). This agency, ideally one with existing expertise in PPE, aerosol science, and inhalation protection, would be tasked with setting and enforcing performance criteria. For example, for occupational respirators in the United States, approval is currently overseen by NIOSH's National Personal Protective Technology Laboratory (NIOSH, n.d.). The regulatory framework considered for a children's respirator standard should, at a minimum, require that an accredited testing lab (one that meets international quality rules under ISO/IEC 17025), which is independent of the manufacturer, evaluates the respirators against a standard. Independent validation ensures that products meet standardized performance thresholds, which is especially vital for protecting children. Third-party testing - by either the approval agency or independent laboratories - also fosters consumer and institutional trust, which is essential for public acceptance and widespread adoption. Incorporating certified testing laboratories into the regulatory approval process helps mitigate risks associated with substandard or counterfeit products and aligns with best practices observed in adult respiratory protection standards.

The regulatory authority would either develop its own performance regulation or, preferably, adopt or reference a high-quality international consensus standard (like an ISO or ASTM standard) tailored to pediatric respiratory protection. In some jurisdictions, suitable standards already exist. For instance, China's KN95 standard allows children to be used in Total Inward Leakage (TIL) testing if the manufacturer designates children as the target user group (Standardization Administration of China, 2019). Similarly, Korea's KF94 consumer respirator standard provides performance benchmarks relevant for children's respirator products (Korea Ministry of Food and Drug Safety, 2020). A global standard could be adopted by regions that have established regulatory frameworks and actively support participation in the global marketplace, promoting consistency, safety, and trade efficiency across borders.

Regional adaptation within harmonized global standards is key - for example, defining required facial panels representative of local populations. The World Health Organization's (WHO) guidelines allow for context-specific implementation while maintaining core safety principles (WHO, 2021). Incorporating modular design features, such as adjustable straps or interchangeable filter media, and promoting local production with certified materials can also support regional adaptability while maintaining compliance with overarching certification requirements. This approach is exemplified by India's BIS-certified FFP2 standards, which align with European norms but include provisions for local high-dust environmental conditions by including a clogging test using coal dust or dolomite (Bureau of Indian Standards, 2002).

To ensure compliance, the agency should define conformity assessment procedures. This includes requiring manufacturers to submit test data from accredited laboratories and possibly verifying the qualifications of these labs. Where feasible, the agency may also perform independent testing. The burden of proof requirements should be transparent and consistent.

A comprehensive approval program should extend beyond initial product testing to include:

- Verification of manufacturing site qualifications (to reduce counterfeit risks)

- Product marking and labeling requirements
- Review of user instructions
- Assessment of product-specific quality plans
- Manufacturing site audits
- Post-market surveillance and performance verification

These elements ensure sustained product quality and performance over time.

Option 2 - Registration Program

Another feasible model that countries could consider is a product registration approach, where a country would recognize the approval or certification of another country, requiring manufacturers selling in their country to provide documentation of the approval or certification they hold from the approving country. This is an especially advisable option for smaller countries with little or no domestic respirator production or smaller market sizes. Creating a unique approval program in such countries could discourage established, reputable manufacturers from selling into those markets altogether; a registration program is a more appropriate regulatory approach.

Selection and Use Guidance

In parallel with performance regulation, guidance for the selection and use of pediatric respirators should be developed by regional public health authorities in alignment with global health (e.g., WHO or UNICEF) respirator selection recommendations, as they become available. These agencies should collaborate with occupational health experts as well as pediatricians and public health experts to provide evidence-based, accessible user guidance, potentially based on international guidelines (there are plans for their development). Ideally, the agency or agencies responsible for issuing such guidance would have a) authority related to environmental airborne contaminants, b) expertise on environmental health principles, and/or c) responsibility for population health - such as the Environmental Protection Agency or Center for Disease Control and Prevention in the United States and similar agencies in other countries.

Selection and use guidance for pediatric respiratory protection should include, at a minimum:

- When - Under which circumstances should caregivers consider having children use respirators - e.g., what environmental conditions or circumstances, identifying precise thresholds when possible
- Who - Which children should use respirators and which should not use respirators
- Which - What is the correct respirator type for the hazards that are present in a given situation
- How - How to correctly put on a respirator, with acknowledgement of model-specific user instructions, how to confirm that a respirator is well fitted and positioned, to optimize the likelihood that the respirator is providing the expected degree of exposure reduction

When to Use Respirators

Families and caregivers need clear, consistent, actionable guidance regarding when children should wear respirators. Air quality events may be caused by natural events such as wildfires or volcanic eruptions, or may be caused by humans, such as vehicle- and industry-generated particulate matter. Weather patterns influence the severity, duration, and geographic range of air quality events. Air quality is measured and air quality indexes (AQI) are calculated and reported in countries around the world. Some programs forecast AQI days into the future. Ratings and unhealthy thresholds are identified by environmental health authorities, and many countries have established systems for issuing Air Quality Alerts, often via weather alert systems, typically disseminated via web applications, television news, and radio. Ratings, threshold, and alert systems often include guidance to the public, such as reducing vehicle traffic, avoiding spending time outdoors, etc. Such guidance should also address whether and when (at what concentration thresholds) respiratory protection should be worn by sensitive populations if they cannot avoid spending time outdoors, for example children traveling to school, doctor appointments, or unavoidable family errands.

Which Children Should Use Respirators

Agencies should provide guidance to families regarding which children should not wear respirators. For example, the UK Health Security Agency (formerly Public Health England) and the US CDC had recommended against the use of respirators and non-respirators in children under two years of age or in individuals with conditions that prevent proper use (CDC, 2025a; PHE, 2020). Some experts have recommended that anyone - children or adults - who do not have the ability to remove the respirator should they want to - such as individuals with physical or mental impairment - should not wear a respirator. Guidance should also emphasize the importance of avoiding exposure, if possible, and only relying on respiratory protection when it is not possible to avoid exposure - e.g., to travel to school, but not to attend sports practices that could be canceled during an air quality crisis.

Which Respirator Type

As part of the reporting and guidance provided by agencies, there should be recognition that certain respirators are effective against certain hazards - and the limitations of, for example, an FFR should be communicated to families. It is important for parents and caregivers to understand that particulate respirators, such as N95s and other FFRs, provide protection against particulate hazards such as PM_{2.5}, but not against gases and vapors. A majority of environmental airborne hazards are particulate hazards - PM_{2.5}, pollens, mold spores, etc. However, there are gases and vapors that are present in air pollution - carbon monoxide, ozone, nitrogen dioxide, sulfur dioxide, and VOCs - that are not captured at all by the filter material in FFRs but may be reduced if the respirator features activated carbon. Families must fully understand the limitations of the respirators available to them, to make informed decisions about risk; this is an important consideration for education, as addressed in the next section of this White Paper, as well as for the regulatory framework. Agencies reporting air quality should highlight the hazards that are present on a given day.

How to Use Respirators

Finally, the authoritative agency or agencies should issue guidance on how to correctly put on respirators and assess their effectiveness. Guidance should be coordinated, aligned with, and amplified by the education efforts described below. Respirator fit capability is tested with the respirators worn correctly, and so it is important for users to wear respirators according to the manufacturers' recommendations. It is important for respirators to contact the wearer's face around the full perimeter, to help ensure that inhaled air travels through the filter rather than around the respirator. Therefore, caregivers must be advised of the importance of assessing the fit of the respirator on their child's face.

Ideally, every child needing a respirator would undergo a fit test to confirm that their particular respirator can seal well enough to their particular face to provide the expected level of protection. However, fit tests are not typically available to children. Public health agencies should consider developing community-accessible fit test services. Individual fit testing would need to be repeated at some frequency - likely annually - given how quickly children grow. Previous successful public health and safety programs that can serve as examples for this include vaccination programs and child safety seat assessment programs. Suggestions for child respirator fit testing programs have included making them available for free or for nominal fees at fire stations, provided by emergency responders (similar to a child car seat assessment in some countries); at schools, provided by school nurses; and at pharmacy clinics, provided by pharmacy technicians (similar to annual vaccines).

If child respirator fit testing services are not available, children can and should perform self-evaluations of a respirator's seal with guidance from, and close observation by, their caregiver. User guidance should instruct caregivers on how to identify and troubleshoot possible poor fits. Instructional videos can be extremely helpful.

Considerations for Equitable Distribution, Access, and Education

At-risk and disadvantaged populations consistently have less access to effective health interventions (Bright *et al.*, 2017). Public health authorities should consider the cost and availability of effective pediatric respirators in their countries for the populations who need them. The regulatory framework described in this section, once in place, will help ensure that pediatric respirators sold within a given country will be tested to science-based, effective standards. Cost and convenient access could still be challenging. Community stockpiles should be considered - purchase requests to supply the stockpiles should specify reputable standards or national approval programs. During acute air quality events, stockpiles should be distributed to impacted populations. Additionally, free or subsidized distribution via public schools could be an effective means to ensure that families have access to affordable pediatric respirators.

EDUCATION, TRAINING, AND COMMUNICATION

Public education is crucial for improving respirator use compliance. Effective methods for educating children on respirator use should be engaging, age-appropriate, and involve caregivers in their design and dissemination, as well as educators and health professionals.

One of the best practices for teaching children about respirator use is to provide age-appropriate instruction that aligns with their cognitive and emotional development. Educational strategies that incorporate visual aids, storytelling, and simple analogies can effectively convey the importance of pediatric respirators in a way that resonates with young learners. Interactive activities such as role-playing, games, and hands-on demonstrations allow children to practice using respirators in a fun, engaging, and memorable manner. These types of developmentally appropriate teaching practices must be adapted to age, development, individual characteristics, and the family and social and cultural contexts of each child served (National Association for the Education of Young Children, n.d.; National Center on Safe Supportive Learning Environments, 2025). By fostering familiarity and comfort with respirator use early on, children are more likely to adopt these practices during times of heightened health risk, such as during influenza season or in the event of a public health emergency.

Hands-on demonstrations should show the proper use of pediatric respirators with step-by-step guidance, allowing supervised practice to ensure correct fit and comfort. Guidelines provided by NIOSH and OSHA on fit testing and seal checks in occupational settings can be very useful as a template for these demonstrations. (NIOSH, 2018; NIOSH, 2025a; OSHA, b.)

Integrating respiratory protection education in health education and advocacy from pediatricians to help educate caregivers and children to introduce the concept of respiratory protection can also be highly beneficial. By including such education in science and health curricula, schools can link it to broader topics such as air quality and respiratory health. Regular reinforcement from teachers and school nurses can further solidify this knowledge. For example, Christiansen *et al.* (1997) conducted an evaluation of a school-based asthma education program for inner city children which showed that child-centered asthma education can be successfully conducted in the school setting.

Parental and caregiver involvement is critical to effective pediatric respirator use education. Educating parents on the proper selection and fitting of children's respirators, as well as conducting training sessions to help caregivers ensure correct usage, is vital. Families should be encouraged to practice putting on and taking off the respirator, following the manufacturer user instructions, including forming the nose clip and conducting a seal check.

Digital and media resources can enhance learning experience. Videos, including animations, offer engaging demonstrations of respirator use, while child-friendly infographics highlight key concepts. For example, the FACE-UP project has created a children's 90-second animation about air pollution and how to fit a respirator, co-designed with children who suggested the characters that they would best learn these public health messages from, thus incorporating their social learning strategies (Kendal *et al.*, 2018; FACE-UP, 2025). The project also co-designed (with parents, teachers and agencies) a detailed booklet for caregivers

and educators on protecting children from air pollution (FACE-UP, 2025).

Educational programs should also inform caregivers and children that different types of face coverings and respiratory protection offer different levels of protection. Without this knowledge, people can use face coverings with low protection ability, thereby producing a false sense of security (Mueller *et al.*, 2018; McDonald *et al.*, 2020).

Finally, addressing common concerns about pediatric respirator use is important. Providing reassurance regarding the comfort and effectiveness of pediatric respirators can reduce apprehension. Peer modelling can encourage adoption among children (Kendal *et al.*, 2018), and countering misconceptions with science-backed information from trusted sources such as UNICEF helps establish confidence in pediatric respirator use.

Incorporating comprehensive and interactive educational approaches within public and school health programs, involving caregivers, and leveraging digital resources might significantly improve respirator use compliance among children. An example of this approach used in another setting was a systematic review of pediatric asthma management which showed that digital interventions, like apps, text reminders, and websites, when combined with educational content and behavioral strategies, significantly improve children's adherence to inhaler use and overall asthma control. These interventions often involve both caregivers and clinical support (Ramsey *et al.*, 2020).

ETHICAL AND CULTURAL CONSIDERATIONS

Pediatric respirators are intended for general health protection rather than occupational use. Guidelines should clearly state their purpose to prevent misinterpretation and misuse in workplace settings. International standards by organizations such as ISO should reinforce this distinction by emphasizing appropriate application scenarios for RPDs (ISO, 2021).

Parents and caregivers should be provided with clear, transparent information regarding the benefits, limitations, and potential risks of pediatric respirators. Ensuring informed decision-making prevents misuse and fosters trust in regulatory guidelines (World Health Organization, 2021, McDonald *et al.*, 2020). Additionally, privacy and data protection, including anthropometric data capture and data collected during trials, are crucial considerations. Some advanced respirators incorporate sensors or monitoring technologies, which necessitate ethical guidelines addressing data collection, storage, and user privacy concerns to prevent unauthorized access or exploitation (European Data Protection Board, 2022).

RPD manufacturers should adhere to fair labor practices, avoiding exploitative working conditions or environmental harm. Ethical sourcing of materials and responsible production methods are essential to maintaining consumer trust (International Labour Organization, 2023). Furthermore, regulations should ensure that pediatric respirators are accessible to vulnerable populations, including children in low-income communities and those with disabilities. Policy interventions should address market-driven disparities (UNICEF, 2022).

It is also critical to respect cultural preferences, including considerations for facial coverings in different communities. Aligning protective devices with cultural norms can improve adoption rates (CDC, 2025).

Another point of importance is the environmental impact. FFRs contribute to waste accumulation, so ethical considerations should include sustainable production, biodegradable materials, and recycling programs to minimize environmental harm (United Nations Environment Programme, 2023). Sustainability in pediatric RPD design should prioritize environmental responsibility. One approach is to utilize biodegradable materials, which can significantly reduce the ecological footprint of these devices. Additionally, incorporating eco-friendly substances and advocating for responsible disposal methods in pediatric respirators can further enhance sustainability. Another key aspect is the development of reusable pediatric respirators equipped with modular, replaceable filtration units and clear maintenance and use guidance ensuring that the devices can be used multiple times.

Transparent reporting on production processes and supply chains enhances consumer trust and regulatory oversight, mitigating risks associated with substandard manufacturing conditions (International Labour Organization, 2023). Moreover, governments and manufacturers should maintain transparency in regulatory approvals to ensure that pediatric respirators meet safety standards without undue influence from commercial interests (World Health Organization, 2021).

Children's respiratory protection has historically received insufficient attention in strategic public health planning. One significant barrier is the just allocation of limited resources. As McDonald *et al.* (2020) argue, ethical considerations must inform how public health interventions are prioritized, especially when vulnerable populations such as children are involved. Ensuring equitable access to pediatric respiratory protection involves not only producing suitable devices but also addressing disparities in awareness, education, distribution infrastructure, and price sensitivity across socioeconomic and geographic divides.

McDonald *et al.* (2020) and the FACE-UP team have been actively researching the ethical and policy challenges related to the public's (children and adult) use of respiratory protection. Their work underscores the critical need for an ethical framework that guides decision-making in this area. Their ongoing research highlights gaps in regulatory policies, the need for pediatric-specific certification standards, and the importance of inclusive policymaking that considers the rights and needs of children in emergency preparedness and health system planning.

While governments must weigh competing health priorities, the provision of effective respiratory protection for children, especially in the face of respiratory pandemics and air quality crises, should be recognized as a foundational element of public health preparedness. Through ethical resource allocation and coordinated action, it is possible to close the protection gap for children and improve long-term public health resilience.

ADDITIONAL GAPS IN RESEARCH AND STANDARDS

There are several notable gaps in pediatric respiratory protection research and development. One significant issue is the lack of data concerning children's facial measurements across various demographics and ages. Differences in facial shape and size among different populations complicate the creation of standardized respirator designs (Nemeth *et al.*, 2025). Another gap pertains to the lack of data surrounding respirator fit in children. Ensuring that these devices provide a snug fit without compromising breathability remains a key obstacle, according to Holm (2022). Additionally, there is a dearth of information on physiological effects experienced by children during respirator wear (both acute and long duration), as well as children's comfort and tolerability of different RPDs.

Further gaps include the absence of standardized pediatric-specific testing protocols, which limit the ability to ensure consistent and reliable performance across different designs and manufacturers. Research is also limited regarding behavioral aspects of respirator use in children, such as compliance, correct usage, and the tendency to adjust or remove the respirator due to discomfort, fear, or misunderstanding.

Additionally, child- and carer-appropriate seal check procedures should be informed by data. Research is needed on: a) which modified seal check procedures are effective for children and their carers; and b) how those procedures should be described in manufacturer user instructions. Similar research on the effectiveness and understandability of written instructions and education to support children and carers in correctly putting on respirators would also be valuable.

Moreover, minimal study has been conducted on communication barriers created by respirators, including challenges with speech clarity and interpreting facial expressions, which are crucial for children who rely on adult instructions and emotional cues (Nobrega *et al.*, 2020). There is also scarce research on the impact of respirator use on learning and cognitive function, particularly during prolonged use in educational settings.

The compatibility of respirators with other equipment or medical devices - such as eyeglasses, hearing aids,

orthodontic appliances, head coverings, and hair styles and accessories - is another area that remains underexplored. Lastly, there is insufficient research into socio-cultural context and equity considerations, including differences in acceptance, accessibility, and effective use of respirators among diverse pediatric populations. Addressing these gaps is essential for advancing effective pediatric respiratory protection.

RECOMMENDATIONS AND NEXT STEPS

Advancing pediatric respirator standards require global cooperation. New pediatric RPD standards can build on the adult occupational standard model, but further evidence collection and testing protocols incorporating child-specific physiological and ergonomic considerations are needed. Given the differences inherent in public health guidance - as opposed to enforceable workplace standards - educational and cultural factors will need to especially be considered in the development of the framework for use of children's respirators.

Based on current research and expert guidance, the following performance and design criteria are recommended for consideration by standards developers for children's respirators intended for protection against particulate matter and airborne pathogens:

- **Filtration Efficiency**

Pediatric respirators should achieve a minimum of 95% filtration efficiency for particles $\geq 0.3 \mu\text{m}$ in diameter, which is consistent with recommendations for adults (EPA, 2018; WHO, 2023; UNICEF, n.d.[b]), but at child-specific flow rates.

- **Breathability**

The acceptable pressure drop in children's respirators should be low enough to minimize breathing resistance, but high enough to maintain effective filtration. Pediatric respirators should have breathing resistance pressure drop less than 50 pascals (Pa) at child-specific flow rates (Verma *et al.*, 2019; Hasni, 2024; Gudgin Dickson *et al.*, 2025).

- **Fit Capability (including size and shape)**

Research activities are needed to establish a fit capability requirement including developing robust anthropometric panels, generating evidence to support appropriate fit capability criteria that could be evaluated in a laboratory setting, and leveraging existing laboratory methods.

- **Comfort and Acceptability**

Pediatric respirators should eliminate coarse elements, use ergonomic designs, prioritize hypoallergenic materials, design for visual appeal, ensure ease of use with intuitive features, enhance caregiver acceptability, and be accompanied by educational materials.

- **Marking, Instructions for Use, Storage, and Shelf-life**

Pediatric respirators should incorporate pictorial guidance, use culturally appropriate instructions, integrate usability features (like earloop clips), and develop educational materials in multiple formats. Pediatric respirators should be designed to be stored in a range of conditions and include instructions on recommended storage conditions. Manufacturers should provide a shelf-life, and respirators need to be designed to accommodate various storage conditions.

- **Reusability, Stability and Durability**

Pediatric respirators should ensure they are fully functional for their duration of use, they should be built with high quality materials, and inspection instructions - allowing the user to identify when a respirator is not going to be protective - e.g., when a strap is broken.

The next step in developing pediatric RPDs is to prioritize the creation of one or more global consensus standard(s), supported by robust evidence gathering, and research to fill identified gaps, to inform performance requirements, particularly around fit, breathability, and usability for children.

Effective implementation will require coordinated action among governments, manufacturers, and health agencies. Public-private partnerships should establish multi-stakeholder working groups to align design, testing, and distribution. Equitable access, especially in low- and middle-income countries, should be ensured through policy-driven subsidies, procurement strategies, and health system integration.

A report by UNICEF emphasizes the role of primary health care in achieving universal health coverage and highlights strategic partnerships between governments, manufacturers and health agencies to strengthen health systems (UNICEF, n.d. [c]). Strengthening supply chains, integrating community health workers, and implementing targeted policies can significantly enhance access to pediatric respiratory protection.

Advancing innovation is also critical. Research and development priorities include:

- Incorporating affordable, high-performance materials to improve breathability and filtration.
- Conducting large-scale usability, comfort and fit studies specifically with pediatric populations.
- Developing standardized training tailored to different literacy levels and cultural contexts.

Educational outreach, through both public health campaigns and digital platforms, should support correct use among caregivers and medical professionals. Embedding respirator education within broader pediatric respiratory health initiatives will further support safe and effective adoption.

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Appendix I. Topics Discussed during Workshop 2**Group 1: Designing respirators for children**

1. How do we encourage better design of children's respirators?
 - a. Better fit characteristics
 - b. Better filtration efficiency
 - c. Better design for acceptance
 - i. Comfort
 - ii. Low breathing resistance
 - iii. Communication
 - d. Reusability
 - e. Simplicity
2. What information do we need about children?
 - a. Face shape around the world
 - b. Safety of respirators for children
 - c. Disbenefits of respirators for children (e.g. impact to learning and communication)
 - d. Ethical/cultural considerations?
3. What information do we need about respirators to effectively inform stakeholders of the appropriate path forward in the development of respirators for children?
 - a. Who collects this data?
 - b. How do we encourage the collection of this information?
 - c. Who are the major stakeholders?

Group 2: Supply chains, access and affordability of children's respirators

4. How do we educate on how respirators can reduce particulate exposure and their efficacy? (not including poor fit of some products currently on the market)
5. Would better education drive demand? Could demand drive innovation?
6. How can it be ensured that children's respirators are of high quality, i.e. certified, with high filter efficiency and good fitting characteristics.
7. What would it take to increase supply and decrease cost, globally? (demand essentially driven by regulation)
8. How can we increase access in low and middle income countries?

Group 3: Standards and regulations for children's respirators

9. What standard information is already available/in development?
10. What sort of standard is most appropriate?
 - a. What would the scope of such a standard be?
 - i. Is it a performance standard?
 - ii. Does it include selection and use?
 - iii. What is the intended use/applicability?
 - iv. What age groups?
 - b. How do we develop it?
11. Do we need harmonization, globally? If so, how/in what way?
12. What policies can countries do to spot insufficient devices coming to market and to stop false claims by manufacturers?

Appendix II. Example Protocols for Fit Testing Children

Modified Protocol for unassisted fit testing child respirators

(3M Personal Communication, 2025)

- Subjects are novice users - no training on how to use a respirator, have used a respirator fewer than 5 times in the past year, preferably have never undergone a fit test
- Subjects are not coached on correct use. They are given the user instructions and packaging as references and are asked to put on the respirator to the best of their ability.
- Study staff must not guide or correct the donning of the respirator.
- Study staff must not direct participants to read the user instructions or urge participants to “read more” or “read more closely” the references provided.
- The child subject’s parents, guardian or responsible adult must be present and should assist the child in donning.
- If the respirator slides off the subject’s face during the fit test, the test should be stopped, the subject should re-don the respirator, and the test should be re-started from the beginning.

Protocol for fit testing child respirators

Modified Ambient Aerosol CNC Quantitative Fit Testing Protocol for Filtering Facepiece Respirators (OSHA (c), App A, Table A-1).

Exercises ¹	Exercise procedure	Measurement procedure
Bending Over	The test subject shall bend at the waist, as if going to touch his/her toes for 50 seconds and inhale 2 times at the bottom ²	A 20 second ambient sample, followed by a 30 second mask sample.
Talking	The test subject shall talk out loud slowly and loud enough so as to be heard clearly by the test conductor for 30 seconds. He/she will either read from a prepared text such as the Rainbow Passage, count backward from 100, or recite a memorized poem or song	A 30 second mask sample.
Head Side-to-Side	The test subject shall stand in place, slowly turning his/her head from side to side for 30 seconds and inhale 2 times at each extreme ²	A 30 second mask sample.
Head Up-and-Down	The test subject shall stand in place, slowly moving his/her head up and down for 39 seconds and inhale 2 times at each extreme ²	A 30 second mask sample followed by a 9 second ambient sample.

¹Exercises are listed in the order in which they are to be administered.

²It is optional for test subjects to take additional breaths at other times during this exercise.