



# **The Major Role of Reusable Respirators in Increasing Respiratory Protection for Future Infectious Disease Emergencies: A Stakeholder Discussion**

Meeting report of a stakeholder discussion organized by  
the Johns Hopkins Center for Health Security

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## Executive Summary

The Johns Hopkins Center for Health Security convened an in-person, not-for-attribution stakeholder discussion on April 25, 2024, to: 1) examine how reusable respirators (RRs) used at scale would protect against supply chain shocks in large emergencies, cost less per respirator than single-use disposable respirators over the life of the product, and provide better protection for workers; and 2) inform a national strategy to promote stockpiling of RRs by the US government, encourage greater adoption of RRs by the healthcare sector, incentivize innovation in RR design, and create a stronger demand signal for industry.

The discussion included experts and practitioners from academia, healthcare, government, nongovernmental organizations, manufacturers, trade associations, and other private sector entities. Participants were encouraged to consider solutions to likely challenges arising with such a strategy, including funding, user acceptance, needed design innovation, and issues regarding RR decontamination, fit testing, and storage. Participants consistently expressed the importance and benefits of RRs for improving pandemic preparedness.

Key needs and opportunities identified during the meeting discussion include:

1. Adding RRs in personal protective equipment (PPE) stockpiles immediately, requiring new funding commitments for the Strategic National Stockpile (SNS).
2. Innovating and designing more comfortable RR models to accommodate the preferences and needs of the healthcare worker community and other potential users.
3. Addressing institutional challenges with managing and cleaning RRs through informed implementation practices.
4. Routinely using RRs in healthcare and beyond.
5. Fostering necessary education, training, and cultural change at the user level.
6. Generating a consistent industry demand signal from both government and the private sector.
7. Providing more support for US-based RR manufacturers, for example by prioritizing domestic purchases and upholding the Make PPE in America Act.
8. Determining the contributions of federal, state, local, and healthcare stockpiles.

Based on these takeaways, the Center for Health Security recommends several actions to achieve each, described in detail in this report. Overall, the Center recommends:

1. The Centers for Disease Control and Prevention (CDC) and/or the Administration for Strategic Preparedness and Response (ASPR) commission the creation of a new national pandemic planning scenario.
2. The US government create a substantial stockpile of RRs sufficient to protect essential workers in the event of a new respiratory disease emergency. An initial purchase of 200,000 RRs should be made, at a cost of approximately \$10 million,

to cover a large portion of frontline hospital workers who would be most at risk in the first several months of a severe disease outbreak. The Department of Defense (DOD) should also procure a substantial supply of RRs to protect DOD personnel.

3. Manufacturers and other research organizations develop and test innovations in RRs.
4. The federal government and/or Congress make funding available for research to identify solutions regarding RR fit, cleaning/disinfection, and storage/accessibility.
5. The Food and Drug Administration (FDA) and National Institute for Occupational Safety and Health (NIOSH) collaboratively establish a streamlined approval process for RRs.
6. Healthcare and research institutions continue to evaluate existing strategies for implementing RRs in healthcare settings.
7. Hospitals integrate RRs into their pandemic response plans.
8. ASPR and/or the Hospital Preparedness Program (HPP) require Regional Emerging Special Pathogen Treatment Centers and Special Pathogen Treatment Centers to have RRs in sufficient quantity for a new national pandemic planning scenario.
9. Professional organizations encourage the healthcare sector to use more RRs during interpandemic times. This should include the Healthcare Infection Control Practice Advisory Committee (HICPAC) examining the role of RRs and developing recommendations.
10. Congress allocate funding to advance research on PPE through centers of excellence established by NIOSH.
11. The Occupational Health and Safety Administration (OSHA), trade associations, and private sector and nonprofit leaders encourage businesses and organizations that employ critical workers to stockpile RRs.
12. Purchases of RRs for the SNS be spread over the timeframe of each product's shelf life to maintain a consistent and multiyear demand signal.
13. The demand signal generated by purchases for the SNS include specific details and specify the appropriate NIOSH and/or FDA approvals.
14. The federal government uphold the requirements of the Make PPE in America Act.
15. The government evaluate the effectiveness of incentives for purchasing US-made supplies.
16. The Department of Health and Human Services (HHS) develop an overall respiratory protection plan for infectious disease emergencies. The agency can provide clarity and advice to healthcare systems about the expectations of federal government responsibilities and hospital responsibilities for PPE.
17. ASPR clarify the functions and contributions of stockpiles at different levels.

## Background & Introduction

Personal protective equipment (PPE) can reduce pathogen transmission and saves lives during a pandemic. Several types of PPE can be used to limit respiratory transmission among the healthcare workforce, other essential workers, and the public. Respiratory protection includes disposable items, such as surgical masks and N95 respirators, and reusable items, such as elastomeric half-mask respirators (EHMRs) and powered air-purifying respirators (PAPRs).<sup>1</sup> Throughout this report, “reusable respirators (RRs)” refers to existing EHMRs and PAPRs as well as not-yet-developed innovative reusable products.

Major infectious disease pandemics over the past 20 years have required the use of PPE to minimize transmission risk, particularly for healthcare workers (HCWs) caring for patients. These events create high demand for PPE, often leading to local or even global shortages that leave HCWs less protected.<sup>2</sup> Shortages of respiratory protection were widespread during the COVID-19 pandemic. The majority of respiratory PPE both stockpiled and currently in use is single-use and disposable. Despite these lessons, the demands for respiratory PPE during another pandemic, particularly early on, likely will far exceed both the supply in the Strategic National Stockpile (SNS) and the amount that can be produced by scaling up manufacturing.

A growing body of literature and recommendations support the need for greater use and stockpiling of RRs in the US. In 2008, a US government interagency working group (Project BREATHE) was convened with the aim of developing consensus recommendations to improve respiratory protection for the healthcare workforce. This group identified recommendations for manufacturers, researchers, standards developers, respirator users, and employers. Areas for recommended action related to 4 desired characteristics: safety and effectiveness; lack of interference with occupational activities; comfort; and compliance with standards, guidelines, and policies.<sup>3</sup> In early 2019, the National Academies of Sciences, Engineering, and Medicine released a consensus study report on RRs for the healthcare workforce, focused on economic, policy, and implementation challenges and opportunities. The report presents 3 key recommendations: 1) increase research to improve respiratory protection, including for RRs; 2) ensure robust respiratory protection programs and training for HCWs; and 3) harmonize standards among authorities, from the international to the local levels, and clarify guidelines and responsibilities, including for stockpiles.<sup>4</sup> Actions are still needed to achieve these recommendations.

The benefits of RRs, along with recommendations for federal action to increase pandemic preparedness, also were outlined in a 2021 report by the Johns Hopkins Center for Health Security.<sup>1</sup> The report makes several recommendations regarding RRs in healthcare, including that the federal government purchase EHMRs for HCWs for inclusion in the SNS; the Assistant Secretary for Preparedness and Response (now Administration for Strategic Preparedness and Response; ASPR) encourage RR use in hospital respiratory protection programs and commission scenario-driven

modeling studies to inform stockpile plans; and the Biomedical Advanced Research and Development Authority (BARDA) support design innovation and domestic manufacturing of respiratory protective devices.<sup>1</sup> The criticality of ensuring adequate PPE availability for pandemic preparedness has since been recognized in the National Biodefense Strategy, which highlights the need for “a resilient and scalable supply of personal protective equipment.”<sup>5</sup> In order to achieve this aim, further actions toward the aforementioned recommendations are required.

Recent work by Gryphon Scientific (since acquired by Deloitte) has generated additional recommendations to improve the PPE ecosystem for pandemic preparedness. A key finding of the research is that EHMRs offer greater respiratory protection, higher cost-effectiveness over their lifecycle, and have better fit and usability characteristics when compared to N95 respirators.<sup>6</sup> While PAPRs are more expensive, the report suggests they are required for a proportion of the essential workforce for whom EHMRs are unsuitable. A resulting recommendation was therefore that government-managed stockpiles consist of 90% reusable EHMRs and 10% PAPRs. Gryphon Scientific also recommends that stockpiles hold sufficient respiratory protection for the essential workforce for 150 days, which equates to 58 million elastomeric units for the US, accounting for some loss or damage.<sup>7</sup>

In addition to government stockpiles, there is a growing case for use and storage of RRs within hospitals. According to research conducted in medical systems that adopted RRs, HCWs preferred RRs compared to N95 respirators in high-risk scenarios, such as caring for a patient with active pulmonary tuberculosis or during the H1N1 influenza or SARS pandemics. This preference existed despite challenges with comfort and communication.<sup>2</sup>

In light of this previous work, the Johns Hopkins Center for Health Security convened a not-for-attribution stakeholder meeting to discuss increasing the availability of RRs for the next pandemic on April 25, 2024. Participants included experts and practitioners from academia, healthcare, government, nongovernmental organizations, manufacturers, trade associations, and other private sector entities. A list of participants is provided in Appendix A. The meeting featured presentations on research supporting increased numbers of RRs in the SNS, challenges and opportunities for ASPR, experiences of HCWs with RRs, the benefits of government demand signals to manufacturers, and the National Biodefense Strategy. The rest of the meeting consisted of discussion, providing opportunities for participants to reflect on the presentations and respond to others’ comments. For this meeting, the discussion was confined to the use of RRs in healthcare settings.

This report provides an overview of key points raised by meeting participants, resulting needs and opportunities, and recommendations for actions by the federal government, the healthcare sector, including hospitals, trade associations, and business leaders.

## Meeting Summary

Participants from multiple sectors repeatedly emphasized the importance of RRs both in routine use and for pandemic preparedness. Widespread agreement on the benefits and cost-effectiveness of RRs was echoed throughout the meeting. Participants noted that the PPE shortages experienced during the early months of the COVID-19 pandemic exemplified the need for increasing the use and availability of RRs. They also underscored how adequate PPE is critical for responding to any type of pandemic event.

### Need for RRs in SNS

The meeting opened with an expert presentation on the need for RRs within the SNS. Using different pandemic modeling scenarios, the presenter showed that obtaining and sustaining a good fit of an N95 provides sufficient protection for workers in most scenarios except when they share a workspace for extended periods. However, many workers lack access to occupational health teams that can support them in finding a good N95 fit, and fit can be lost for many reasons. Participants noted that obtaining a good fit with EHMRs is easier than for N95s, but getting and maintaining that fit may be more challenging outside healthcare settings where occupational health support is limited. The presentation concluded that EHMRs offer greater protection across different scenarios due to reduced leakage around the sides of the device (rather than differences in filter penetration).

### Adoption and Benefits of RRs in Healthcare

A healthcare sector participant provided an overview of RR adoption at several US medical system sites, demonstrating both feasibility and acceptability. Trials of EHMRs and PAPRs found several benefits, including increased protection and comfort, fewer associated injuries, and more reliable availability during emergencies compared to N95 respirators. A 2016 survey of 1,152 HCWs found preferences for EHMRs over N95s in high-risk scenarios, indicating that user acceptance is not a barrier in healthcare settings.<sup>2</sup> A larger 2021 survey found that approximately half of HCWs preferred EHMRs or PAPRs to N95s, with communication challenges being the most cited disadvantage of elastomeric respirators.

### Waste Reduction and Sustainability

Waste reduction and sustainability were discussed as benefits of RRs. The reuse of RRs results in fewer total items required, and fewer RRs are wasted during fit testing since disposable respirators must be discarded after each test. This leads to greater cost-effectiveness of RRs compared to N95s over their lifecycle (with N95s estimated to cost \$62.50–\$392.50 per individual per year during a pandemic, compared to \$30–\$180 for an EHMR).<sup>6</sup> The difference in cost is further widened due to the greater amount of space required to stockpile sufficient N95s compared with EMHRs.



## Diversity and Availability of PPE

Participants frequently remarked on the value of having multiple PPE types available and noted the advantages of having both disposable and reusable options. PAPRs and EHMRs offer different benefits, including integrated eye protection and cooling airflow in PAPRs and an ability to better accommodate cultural, ethnic, and functional needs, such as beards or headwear. Notably, hospitals with diverse options in their respiratory programs, including EHMRs and PAPRs, were initially better able to handle their own needs during the early COVID-19 pandemic and did not require additional supplies from manufacturers until later.

## Call to Action

The meeting concluded with a strong call to action. Several participants emphasized that discussions on the need for more RRs have been ongoing for more than 2 decades. Numerous participants said immediate action is necessary and cyclical conversations without concrete outcomes must be avoided.

## Needs & Opportunities

Building on the discussions about the benefits and implementation of RRs, the meeting highlighted 8 fundamental needs and opportunities to enhance pandemic preparedness and ensure the effective use of RRs.

### Immediately add RRs to PPE stockpiles, requiring new funding commitments for the SNS

Despite broad recognition of the importance of federal PPE stockpiling, participants frequently discussed the challenge of securing sufficient and sustained funding. Historically, the mandate of the SNS has been to stockpile products that have no commercial alternatives, such as vaccines and therapeutics, with no specific mandate to include PPE. As a result, purchasing PPE relied on supplemental funding, which is no longer available. A key challenge identified is how to include PPE within the SNS while balancing the trade-off of stockpiling other items given limited funding. ASPR is currently exploring options for PPE stockpiling, including RRs.

### Innovate and design more comfortable RR models to accommodate the preferences and needs of the healthcare worker community and other potential users

Participants acknowledged several limitations in the design of current RR models, including the inability of EHMRs to meet all the cultural, ethnic, and functional needs of the diverse HCW and essential worker communities, communication challenges, and the inability to instantaneously assess fit and monitor for loss of fit. Given these design limitations, several areas for innovation were identified. For example, an expert

from the healthcare sector commented that measuring fit at the point of use would be groundbreaking, potentially eliminating the need for occupational health assistance with fit testing. An existing device that provides an immediate measure of the pressure differential across the mask was also discussed. Additionally, fit in combination with eye protection was noted as a challenge and an area for further innovation.

Innovation is needed to develop equipment that is more appropriate for the workforce, given the need for respirators to fit diverse faces and suit various workplace demands. This challenge was highlighted during the COVID-19 pandemic. In terms of communication challenges, speaking diaphragms and clear facemasks were discussed as examples of existing solutions. Ongoing innovation by manufacturers is crucial to address these limitations and improve the effectiveness of RRs in protecting the broad range of essential workers.

## **Address institutional challenges with managing and cleaning RRs through informed implementation practices**

Many participants identified implementation as the greatest challenge to increasing RR use but noted that it is not insurmountable, with valuable lessons learned from healthcare systems that have already adopted RRs. The 2 key implementation challenges discussed were decontamination and accessibility of RRs.

Different models of cleaning and decontamination practices have been trialed, including individuals being responsible for cleaning their own respirators and a centralized system where HCWs return respirators for disinfection at the end of a shift and later collect a different respirator. Research presented at the meeting found that cleaning and disinfection practices were inadequate when left to individuals.<sup>8</sup> Similar challenges have been encountered with accessing respirators when needed, often due to inconvenient storage.<sup>9</sup>

Potential solutions discussed included a shared supply system with a centralized disinfection process,<sup>10</sup> using a central sterile processing department or vending machines for depositing and collecting respirators. While protocols and solutions exist for decontamination, there is a need for more evidence and solutions to ensure ready access to RRs when and where needed.

## **Routinely use RRs in healthcare and beyond**

Participants identified a need to normalize the use of RRs outside of pandemics to increase familiarity, acceptance, and trust among HCWs. They also expressed the importance of establishing infrastructure and protocols for assigning, using, and cleaning elastomeric respirators prior to an emergency.

One participant suggested that without common use of RRs in the medical system, the devices would need to be 100% centrally stockpiled because low routine use would

prevent rotation through a supply bubble such as vendor-managed or distributor-managed inventories. Similarly, participants noted that incorporating RRs into routine use in healthcare settings would reduce pressure on stockpiles. Evidence from hospitals that have already adopted RR strategies shows the feasibility of this approach.

Strategies for achieving widespread use were discussed. For example, piloting elastomeric respirators in more healthcare settings could increase familiarity and recognition of their benefits. Several participants highlighted education settings as opportunities to introduce RRs, such as providing and fitting new RRs to every graduating medical, paramedic, nursing, or allied health student. This aligns well with the National Institute for Occupational Safety and Health (NIOSH) Safe, Skilled, Ready Workforce Program.

In addition to the challenges of disinfection and accessibility, there is a lack of incentive for hospitals to move away from N95s, which are often considered the gold standard despite providing lower protection than RRs. One participant suggested that educating HCWs about different respiratory protection options and incentivizing the use of all respirators, not only surgical N95s, are necessary actions. Another participant recommended funding or other incentives to promote the benefits of RRs at the hospital level.

Participants also noted the importance of providing and fitting elastomeric respirators for all essential workers—not only for those in healthcare or during pandemics—due to persistent respiratory hazards such as wildfire smoke, poor air quality, or cold and flu season. Although a few RR models have been used in healthcare settings for decades, the use of novel RRs in medical settings is currently only permitted under an Emergency Use Authorization (EUA). Full approval of these products by the Food and Drug Administration (FDA) and streamlining the approval process in collaboration with NIOSH would reduce the regulatory burden for innovative designs.

In addition to the disinfection and accessibility challenges discussed above, hospitals lack incentives to move away from N95s. One participant suggested that education about different respiratory protection options is needed for HCWs alongside incentives to use all types of respirators. Another participant mentioned that funding or other incentives, and promotion of the benefits of RRs, are needed at the hospital level.

## **Foster cultural change, education, and training at the user level**

Participants emphasized the need for cultural changes, education, and training at the user level to make progress toward the routine adoption of RRs. They expressed the importance of beginning this education and training now to normalize RR before another emergency arises. Additionally, they recommended developing just-in-time training for safe donning and doffing of PAPRs.

Participants discussed several specific cultural changes. For example, one participant noted the need to overcome the culture of individual ownership of specific items if a

centralized system is used for disinfection and cleaning. They pointed out that other industries, such as firefighting, have successfully implemented pooled equipment supplies and that a rigorous cleaning process can increase trust in the shared items. Another cultural shift discussed was using appropriate protective equipment based on an activity's level of risk, thereby acknowledging the complementary role of disposable and reusable respirators. Participants also suggested employing and clearly communicating the precautionary principle regarding the respiratory protection needed for a given activity, meaning more protective measures (including wearing respirators) should be taken in environments where risks are unknown and then potentially de-escalated when more information about a hazard becomes available. To employ the precautionary principle, one participant stressed the need to have a sufficient number of RRs prior to an emergency.

Participants also discussed the need to change the expectations that employees have for protection, drawing comparisons to other industries or activities where protective measures have become the norm, such as preventing forest fires and wearing seatbelts. They also raised the challenge of public opposition to respiratory protection and the need to restore public trust. Potential strategies to generate such cultural change included identifying younger change agents, implementing ad campaigns and other educational communication efforts from those outside of government, and taking action while the experiences of the COVID-19 pandemic are still fresh.

Another valuable area for change is in the measuring and reporting of fit and effectiveness. Participants expressed the need for an imperfect use index, similar to that used for birth control. This metric would recognize that people do not always use PPE correctly, provide metrics for protection in real-world conditions, and facilitate more informed choices and education about respiratory protection. One participant noted that such an index should include measures of effectiveness without fit testing or when minimal training is given. Another participant mentioned the value of conducting future studies to compare the effectiveness of N95 respirators to reusable types using an imperfect use index, which may provide additional support for RR use given that EHMRs are both more likely to pass an initial fit test and maintain fit over time.<sup>6</sup>

Several participants discussed the benefits that centers of excellence could generate. These specialized programs, which involve a high concentration of expertise and resources for specific medical areas<sup>11</sup> and are usually located at US academic institutions, could focus on: improving communications about PPE and the utility of RRs; educating healthcare institutions on leadership practices; supporting employers in the selection, use, and maintenance of RRs; and building trust. Although academic institutions are ready to take on this role and NIOSH has been working toward establishing centers of excellence for PPE for more than a decade, funding is not available.

Throughout the meeting, several participants highlighted the need to protect additional workforce groups beyond those typically considered. This includes groups other than

HCWs within the healthcare ecosystem, such as janitors and aides, but also the broader essential workforce. Participants mentioned workers outside healthcare should have access to respiratory protection, including those in vital industries that could consider their own stockpiling measures. Notably, however, cultural change is required in which additional groups have a stake in the issue and receive related education. One participant suggested government has a role to play in advancing this goal through open and honest communication about why respiratory protection is needed for the broader essential workforce to gain public trust.

## **Generate consistent industry demand signal from the government and private sector**

One participant with industry experience noted that manufacturers must take many steps to respond to increased demand, including obtaining manufacturing equipment, raw materials, and other supplies; hiring labor; conducting quality management; seeking necessary approvals; and distributing products. Participants explained that the demand signal, whether from the government or the private sector, needs to be specific, consistent, and standards-based. A specific demand signal should include details such as the number of facepieces and filter cartridges, sizes, and required approvals. Consistent orders with a multiyear commitment are essential for industry to sustain this capability, given the time needed to establish increased manufacturing. The demand also should be standards-based, pre-specifying the appropriate and necessary NIOSH and/or FDA approvals and other applicable standards. This approach would ensure that all manufacturers, distributors, users, and regulators have a shared understanding of the requirements, and market competition occurs on factors other than performance levels. Participants also discussed the success of previous user community involvement in generating demand and developing standards, citing the example of chemical, biological, radiological, and nuclear (CBRN) respirators following the terrorist attacks of 9/11.

While most demand comes from the private sector, participants emphasized government's important role, especially in safeguarding continuity of demand. They noted that the SNS could help establish and maintain this demand signal by spreading purchases over the timeframe of a product's shelf life, preventing the need for industry to surge and then shut down. The stockpile can also relieve pressure on industry during an emergency by providing RR supply while production ramps up.

## **Provide support to US-based RR manufacturers**

Several participants highlighted the importance of a reliable PPE supply chain. One participant emphasized the need for greater reliance on domestic PPE manufacturing to ensure a resilient supply, protect the public's health, and gain economic benefits such as job creation. Another participant cited the need for the federal government to uphold the spirit and statutory requirements of the Make PPE in America Act. They called for greater clarity regarding the Buy America and Made in USA provisions,

including whether all components need domestic sourcing and if assembly must occur within the US. Multiple participants noted that COVID-19 highlighted the fragility of the international PPE supply chain for the US, prompting support for US-based manufacturing. Notably, data presented showed some backsliding in this trend, leading to increased reliance on imports. The government has attempted incentives, such as a Centers for Medicare and Medicaid Services (CMS) payment adjustment to hospitals purchasing US-made surgical N95s, although participation rates remain unclear. Other incentives were mentioned as potentially valuable.

Participants also discussed roadblocks associated with group purchasing organizations (GPOs). These entities generate savings and improve efficiency for healthcare providers by aggregating purchases across multiple providers. One participant explained that GPOs are restrictive, often importing products from overseas to buy at the lowest prices, which ultimately hinders US products from reaching the market. Another participant noted that while hospitals can sometimes make purchases outside of their GPO, they may face penalties and/or higher prices.

## **Determine the contributions of federal, state, local, and healthcare stockpiles**

Participants stressed the necessity of a sustainable and continuously improving federal stockpile throughout the meeting. However, they also discussed the need for states, hospitals, and other vital industries to maintain their own stockpiles. They highlighted several current barriers to achieving this tiered system, especially determining an appropriate balance between different stockpiles.

The potential for state-level stockpiles to supplement the SNS was mentioned. However, ASPR lacks visibility regarding state stockpiles, and states vary widely in their degrees of preparedness. Conversely, one participant noted that the federal stockpile's tendency not to disclose its contents creates challenges for private healthcare systems' preparedness. In terms of hospital stockpiles, a participant expressed the need for clarity regarding the expectations and role of the healthcare system within the broader ecosystem of stockpiles. Areas for greater clarity include the number of items hospitals are expected to hold, the extent of the government's responsibility, delivery protocols, and who will make these decisions. There are obvious benefits to hospitals and health systems having RRs readily available in their own stockpiles, one of which could be an opportunity for healthcare workers to become familiar with the equipment. However, small and rural healthcare organizations may lack the space or funding necessary for sufficient stockpiles.

As mentioned previously, participants discussed the need to rotate items out of stockpiles and through health systems to reduce waste due to expiration,<sup>1</sup> which would require improved logistics for tracking that movement. One participant described challenges during the COVID-19 pandemic when stockpiled ventilators arrived but were missing parts and suggested that clear plans for distribution are required in the future.

## Key Recommendations

The Center for Health Security recommends the following concrete steps to address each of the 8 identified needs and opportunities identified during this meeting.

*Immediately add RRs to PPE stockpiles, requiring new funding commitments for the SNS*

1. CDC/ASPR should commission the creation of a new national pandemic planning scenario based on the transmissibility of the Omicron variant of SARS CoV-2 and the case fatality rate of the 1918 influenza pandemic. This scenario can guide pandemic preparedness by both the public and private sectors.
2. The US government should create a substantial stockpile of RRs sufficient to protect essential workers in the event of a new respiratory pandemic, with initial emphasis on the healthcare sector.
  - a. ASPR and the SNS, in coordination with the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), should establish a requirement for stockpiling RRs and request funding for procurement, maintenance, and replenishment of RRs in the stockpile.
  - b. Congress should authorize and then appropriate sufficient steady state funding for the SNS to purchase and maintain an RR stockpile.
  - c. The Office of Management and Budget (OMB) should prioritize the federal stockpiling of RRs.
  - d. The SNS should make an initial purchase of 200,000 RRs, at a cost of approximately \$10 million, to cover a large portion of the frontline hospital workers who would be most at risk in the first months of a new respiratory disease emergency.
  - e. ASPR should conduct or commission scenario-based modeling to determine the appropriate number of RRs to purchase in addition to the initial 200,000.
  - f. ASPR should determine target product profiles for RRs it will purchase based on needed innovation in several factors, including protection, fit, communication, and wearability.
  - g. The SNS should implement a multiyear program to gradually replace expiring disposable respirators with newly purchased RRs.
  - h. FDA should approve existing EHMRs for use in healthcare (not only through EUAs) and develop a straightforward process for approval of innovations.
  - i. CDC should develop pre-pandemic surveillance triggers for increased RR production and purchase in anticipation of need. Unused production can be bought by the SNS to offset future year's purchases.
  - j. DOD should procure a substantial supply of RRs to protect its military and civilian personnel.

*Innovate and design more comfortable RR models to accommodate the preferences and needs of the healthcare worker community and other potential users*

3. Manufacturers and other research organizations should develop and test innovations in RRs to meet the needs of the diverse healthcare and essential worker community, including addressing communication and other accessibility challenges and methods to assess and monitor fit.
4. The federal government and/or Congress should make funding available for research to identify solutions for ongoing challenges in RR fit, cleaning/disinfection, and storage/accessibility.
5. FDA and NIOSH should establish a unified and streamlined approval process that negates the need for 2 separate applications.

*Address institutional challenges with managing and cleaning RRs through informed implementation practices*

6. Healthcare and research institutions should continue to evaluate existing strategies for implementing RRs in healthcare settings, including protocols for disinfection and ensuring availability. Successful strategies should be implemented more broadly.

*Routinely use RRs in healthcare and beyond*

7. Hospitals should integrate RRs into their pandemic response plans.
8. ASPR and/or the Hospital Preparedness Program (HPP) should require the 13 Regional Emerging Special Pathogen Treatment Centers and 55 Special Pathogen Treatment Centers hospitals in the National Special Pathogen System to have RRs (EHMRs and PAPRs) in sufficient quantity for a new national pandemic planning scenario.
9. Professional organizations should encourage the healthcare sector to use more RRs during interpandemic times.
  - a. Healthcare settings should pilot RRs and use them more widely.
  - b. CDC should fund research to determine the optimal balance of reusable vs. disposable respirator use in interpandemic times.
  - c. The Society for Healthcare Epidemiology of America (SHEA) and the Association of Professionals in Infection Control and Epidemiology (APIC) should promote the use of RRs in healthcare settings.
  - d. CDC should promote RR use and encourage the use of its existing implementation guide for EHMRs in healthcare.<sup>12</sup>
  - e. The Joint Commission should promote the use of RRs.
  - f. HICPAC should examine the critical role of RRs, consider their role in protecting HCWs, and develop accompanying recommendations.



### *Foster cultural change, education, and training at the user level*

10. Congress should provide funding to advance research on PPE, including RRs, through NIOSH's Personal Protective Technology Program and new centers of excellence.
11. OSHA, trade associations, and private sector and nonprofit leaders should encourage businesses and organizations that employ critical workers to stockpile RRs, accompanied by efforts to train, educate, and communicate how to use them and their importance.

### *Generate consistent industry demand signal from the government and private sector*

12. RR purchases for the SNS should be spread over the products' shelf life to maintain a consistent and multiyear demand signal.
13. This demand signal should include specific details, such as the number of facepieces, filter cartridges, and sizes, and specify the appropriate and necessary NIOSH and/or FDA approvals and other applicable standards.

### *Provide support to US-based RR manufacturers*

14. The government should uphold the requirements of the Make PPE in America Act and provide clarity regarding the requirements of the Buy America and Made in America provisions.
15. The government should evaluate the effectiveness of incentives for purchasing US-made healthcare supplies and consider additional incentives.

### *Determine the contributions of federal, state, local, and healthcare stockpiles*

16. HHS should develop an overall respiratory protection plan for infectious disease emergencies that includes recommendations on RRs.
17. As part of that plan, ASPR should provide guidance to states and healthcare systems regarding PPE expectations for and responsibilities of the federal government and healthcare systems during infectious disease emergencies.

## **Conclusion**

The Johns Hopkins Center for Health Security held this stakeholder meeting to inform a national strategy regarding RRs for the next pandemic. Despite identified challenges, participants overwhelmingly recognized the need to move toward routine RR use and expand stockpiles. They discussed current needs and opportunities, identifying 8 key areas for action: 1) adding RRs to the SNS; 2) innovating RR design; 3) adopting informed implementation practices; 4) increasing routine use of RRs; 5) fostering user education, training, and cultural change; 6) generating specific and consistent industry demand signal; 7) supporting US-based manufacturing; and 8) determining stockpile contributions at different levels. Many concrete actions were suggested to move toward these goals, summarized in a list of recommendations from the Center for Health Security. Implementing these recommendations would meaningfully increase pandemic preparedness in the United States.

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