Ingenuity during the COVID-19 pandemic: a controlled experiment for respirator mask efficacy testing

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INTRODUCTION
In early December 2019, the first COVID-19 pneumonia cases were identified in Wuhan, China.1 The virus quickly spread throughout the world and New York City became one of the major epicentres.2 For healthcare providers, one of the most effective modes of protection against infection is personal protective equipment (PPE).3–5 However many hospital systems did not initially possess sufficient PPE reserves, particularly N95 masks.6 7 Due to the severe shortage of respirator masks, healthcare organisations resorted to less conventional avenues of sourcing PPE.3 8–10 However, there was concern that N95 masks purchased from international markets may have undergone less stringent certification.11 12 During a time of low supply and high demand, these masks were the only available option for many healthcare workers. Unfortunately, the process of certifying the efficacy of respirator masks is lengthy and would delay distribution of masks to the frontlines by several weeks. Facing the impending shortage, our hospital located in New York City developed a novel device to serve as an affordable and fast screening tool for N95 masks acquired through alternative sources. Our hypothesis was that foreign-made N95 masks acquired through alternative resources would have the same particle filtration efficiency (PFE) as US-manufactured masks.

METHODS
Trial design
Particle filtration efficiency was carried out using a testing apparatus built from readily available supplies purchased at a local hardware store and pharmacy. This was used to evaluate two different mask types in a non-randomised controlled experiment. The first mask type was produced by a US-based manufacturer with an N95 designation meant to be used during sanding of drywall, wood and metal (control group). The second mask type was manufactured abroad and advertised as an N95 medical grade respirator (experimental group). The apparatus (figure 1) is assembled from 2-inch polyvinyl chloride (PVC) tubing (FORMUFIT, Lenexa, Kansas), drain, waste and vent couplers and two 2-inch PVC union couplers (Charlotte

Summary box
What are the new findings?
► Due to the severe shortage of N95 respirator masks during the onset of the COVID-19 pandemic, healthcare organisations resorted to less conventional avenues of sourcing personal protective equipment.
► There is concern that N95 masks purchased from international markets may have undergone less stringent certification.
► Facing an impending shortage of N95 masks, our hospital located in New York City developed a novel device to serve as an affordable and fast screening tool for N95 masks acquired through alternative sources.

How might it impact on healthcare in the future?
► We found that N95 masks from certain distributors did not efficiently filter particles and likely did not meet the standards of an N95 designation.
► This device design may be implemented at other institutions that are currently unable to ensure the quality of their N95 masks.
Pipe and Foundry Company, Charlotte, North Carolina). Threaded reducers and barb adaptors are placed at each end to allow for introduction of aerosolised particles and connection to a vacuum pump (figure 2). Bonding cement (Oatey Co, Cleveland, Ohio) was used to join the components of the apparatus together and eliminate air leaks. The two PVC union couplers were connected in series (figures 1 and 2) and can be easily disassembled to place filtration material. The more superior of the two couplers houses the mask to be tested for efficacy with the outer surface of the mask facing superiorly (online supplemental figure 1). The inferior coupler houses a ‘back up’ filter (mask) that is known to have an N95 equivalent PFE. This ‘back up’ filter captures any fluorescent particles that pass through the mask being tested, which is positioned upstream in the flow. A 2.5-inch circular sample of each mask is cut out and placed into their respective chambers. The apparatus is then fully assembled (figure 3). Two laboratory vacuum pumps connected in parallel were used to create unidirectional flow of approximately 74 LPM within the apparatus (Invacare, Elyria, Ohio and KNF Laboport, Trenton, New Jersey).

Testing uses Nile Red fluorescent microspheres measuring 0.25 µm and 0.5 µm (Spherotech, Inc, Lake Forest, Illinois) at a cost of US$135 per 2 mL vial. Each vial is sufficient for two test runs. Fluorescent microspheres are aerosolised with the help of a nebuliser purchased at a local pharmacy (DeVilbiss 3655LT Nebulizer with Compressor, Port Washington, New York). Microspheres arrive in a 2 mL suspension of 1% w/v per volume. For each test run 1 mL of the solution was further diluted with 1 mL of water and placed into the nebuliser cup. The experiment is run for 10 min (figure 3). After 10 min, the testing apparatus is disassembled to retrieve the samples, which are examined in a dark room under a blacklight. For reference, (online supplemental table 1) summarises the cost of the apparatus.

For the masks that successfully passed, two samples of a mask from each batch were challenged with 0.25 µm and 0.5 µm particles. Batch #1 of the foreign masks was only tested with 0.5 µm particle and the US-manufactured mask was tested and passed with 0.25 µm challenge only, due to nanoparticle resource constraints. For batch #2 masks that failed, the experiment was repeated with new mask samples challenged with 0.25 µm and 0.5 µm particles, both of which failed.

Analysis
Samples are qualitatively evaluated for presence of fluorescent signal. Individuals involved in the analysis were not blinded to the mask type. The ‘back up’ mask (from the bottom chamber) will exhibit fluorescent signal if the ‘test mask’ fails to capture the aerosolised particles. In our experience, masks that failed did so unequivocally, and the fluorescent signal on the ‘back up’ filter was easily visible to the naked eye. The tests with masks that successfully filtered the particles had no signal on the back up filter.

Finally, as an additional examination, the three different types of masks (control mask, passing mask and failing mask) were evaluated with the use of a compound microscope (Zeiss AxioImager Z1). Each mask was disassembled into its separate layers and each layer was examined under the microscope to determine the effective diameter of the pores.

RESULTS
The US-manufactured mask was able to filter out particles as small as 0.25 µm. The foreign-made masks had mixed results. Masks from the batch #2 failed to filter out particles of 0.25 µm and 0.5 µm. The remaining two batches were able to filter out particles at sizes of...
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Figure 3  Stepwise PFE testing instructions. Please note that in our testing two vacuum pumps connected in parallel were used. However, one pump appeared to be sufficient during test runs. PFE, particle filtration efficiency, UV, ultraviolet.

0.25 µm and 0.5 µm (table 1). Representative findings are shown in figure 4.

Microscopic evaluation of the ‘back up’ filter mask, the US-manufactured mask that passed, and the foreign-manufactured mask that failed our test confirmed our filtration test results. The foreign mask that failed had the smallest pore size measuring 11 µm. The masks that passed had smallest pore sizes that were much smaller than 11 µm, and in fact beyond the capability of the microscope to reliably resolve for measurement due to the tightly woven fibres and overall material density (table 2). These findings correspond with our PFE testing results. The 11 µm pores in the failing masks would easily allow submicron particles to pass through to the ‘back up’ filter, as was observed in our case.

**DISCUSSION**

Our department was able to successfully develop an affordable and fast screening device to evaluate PFE of N95 masks. One batch of masks was found to be dramatically ineffective, allowing particles measuring 0.5 µm through, which are larger than the 0.3 µm particles used by the National Institute of Occupational Safety and Health (NIOSH)-approved testing laboratories for PFE testing of N95 respirators. Normal PPE certification is an expensive and lengthy process taking approximately 2 weeks, possibly even longer depending on the demand. Standalone testing units are available, but the manufacturer quoted price is in excess of US$100,000 and the installation process can take several weeks to complete. Due to our results, none of the approximately 3000 foreign-sourced masks were used, as it was deemed too high of a risk. Had we given these masks to healthcare workers in the hospital, they may have been at an increased risk of infection.

It is important to recognise that this apparatus is meant to be used as a screening test to quickly identify inadequate PPE. It is not meant to replace the stringent certification process of NIOSH laboratories. Furthermore, we only performed a qualitative analysis of mask filtering efficiency. It is certainly possible that masks which ‘passed’ our screening tests may in fact let greater than 5% of particles measuring 0.3 µm through.

**Table 1  Summary of particle filtration efficiency testing results**

| Mask tested   | Testing condition | 0.25 µm | 0.5 µm |
|---------------|-------------------|---------|--------|
| Foreign-manufactured |                   |         |        |
| Batch 1       | Not tested*       | Passed  |        |
| Batch 2       | Failed            | Failed  |        |
| Batch 3       | Passed            | Passed  |        |
| US-manufactured |                  |         | Not tested |

*Note: 0.25 µm microspheres were not tested in batch #1 since we used up our available supply at the time.

**Table 2  The effective diameter (µm) of pores for each layer of three different masks based on reflected light images**

| Effective diameter (µm) of pores | Back up filter | Foreign-manufactured | US-manufactured |
|----------------------------------|----------------|----------------------|-----------------|
| Layer 1                          | 25.1           | 29.4                 | 27.2            |
| Layer 2                          | 23.7           | 11.0                 | 25.4            |
| Layer 3                          | Too small to measure* | 56.6          | Too small to measure* |
| Layer 4                          | 59.0           | 26.4                 | 17.5            |

*The masks that passed had smallest pore sizes that were much smaller than 11 µm, beyond the capability of the microscope to reliably resolve for measurement due to the tightly woven fibres and overall material density.
through. The testing apparatus was a quick, non-quantitative solution to an urgent question providing an answer to mask efficacy in less than 24 hours. This was essential during the peak COVID-19 infection period in New York City when supplies of PPE availability were uncertain. Future studies with the device should include a quantitative analysis of how the brightness of the backup filter correlates with filtering efficiency, as well as a more complex analysis of the individual layers of the passing masks.

In conclusion, we developed an apparatus to serve as an affordable and fast screening tool for PPE during the COVID-19 pandemic. We found that masks from certain distributors did not efficiently filter particles and likely did not meet the standards of an N95 designation. Therefore, these masks were only to be used in an emergency shortage scenario. This device design may be implemented at other institutions that are currently unable to ensure the quality of their N95 masks and would be helpful if a situation similar to the current COVID-19 pandemic were to arise in the future.

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