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## Brief Report

# Novel manufacturing of simple masks in response to international shortages: Bacterial and particulate filtration efficiency testing

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## Key Words:

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Many healthcare systems have been forced to outsource simple mask production due to international shortages caused by the COVID-19 pandemic. Providence created simple masks using surgical wrap and submitted samples to an environmental lab for bacterial filtration efficiency testing. Bacterial filtration efficiency rates ranged from 83.0% to 98.1% depending on specific material and ply, and particulate filtration efficiency rates ranged from 92.3% to 97.7%. Based on mask configuration, specific surgical wrap selected, and ply, the recommended filtration efficiency for isolation and surgical masks of 95% and 98%, respectively can be achieved. These alternative masks can allow for similar coverage and safety when hospital-grade isolation masks are in short supply.

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## INTRODUCTION

In January of 2020, the first COVID-19 case in the United States was identified. The patient was cared for at Providence Regional Medical Center Everett (PRMCE) in Everett, WA, near Seattle. PRMCE is part of Providence, a much larger integrated care network, including 51 hospitals, over 1,000 ambulatory care settings, and many long-term and home care programs. As COVID-19 spread in the Puget Sound area, many Providence facilities were required to quickly respond to an exceptionally rapid increase in COVID-19 cases and reports of patients under investigation. At the same time, personal protective resources became scarce, following many interruptions along the complex network that makes up the healthcare supply chain.

Healthcare facilities rely on personal protective equipment (PPE) in order to protect their staff from disease transmission. PPE is often manufactured outside of the United States in order to reduce cost, and much of the PPE used in the United States is produced in Asia. During the COVID-19 pandemic, a perfect storm interrupted the supply chain at multiple points—reduced manufacture, shipping, and distribution, alongside significantly increased demand. When it became apparent that some facilities were at risk of running out of

masks within days and that replacement stock was unavailable throughout the United States, Providence leaders partnered with local manufacturers to quickly convert their production lines to produce simple masks.

Healthcare quality masks are rated based on bacterial and particulate filtration efficiency as well as fluid resistance, differential pressure, and flammability. ASTM Standards are widely accepted as the routine standards for production and testing of healthcare quality face masks. ASTM F2100-e1<sup>1</sup> groups masks into three performance levels (Level 1, 2, and 3) based on bacterial filtration efficiencies (BFE) of  $\geq 95\%$ ,  $\geq 98\%$ , and  $98\%$ , respectively and sub-micron particulate filtration efficiency (PFE) of  $\geq 95\%$ ,  $\geq 98\%$ , and  $98\%$ , respectively. Inclusion in each performance level also requires specific rankings in differential pressure, resistance to penetration by synthetic blood, and flammability which were not considered as part of this study. ASTM Level 1 masks are considered appropriate for low barrier precautions in short procedures and exams that do not involve aerosols, sprays or fluids. ASTM Level 2 masks are considered appropriate for moderate barrier protection for low to moderate levels of aerosols, spray and/or fluids. ASTM Level 3 masks are considered appropriate for maximum barrier precautions for heavy levels of aerosols, sprays, and/or fluids. ASTM Level 1 masks are generally used for isolation and ASTM Level 3 masks are routinely used as surgical masks.

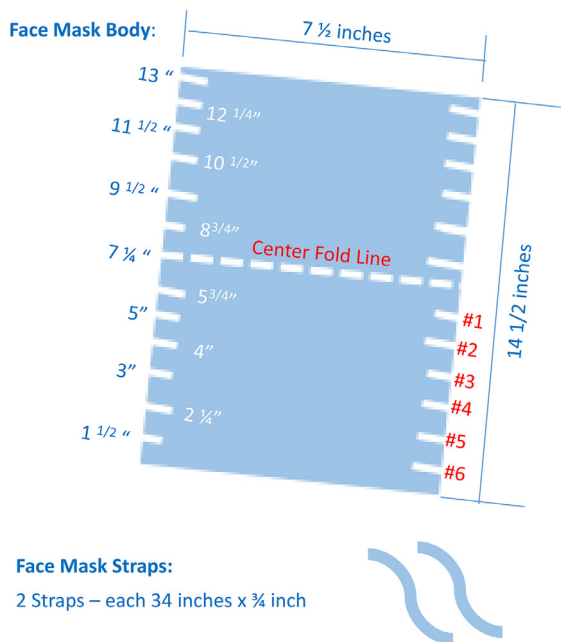
In the absence of ASTM certified masks at the beginning of the 2020 COVID-19 pandemic, health systems were forced to investigate other options for respiratory protection. Very few studies were

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Conflicts of Interest: None to report.

## Face Mask Piece Patterns



## Face Mask



Fig 1. Face mask design specifications.

available to help guide those decisions. Davies et al (2013) assessed several household materials to determine which would be the safest alternative to commercial facemasks.<sup>2</sup> In measuring filtration efficiency, the researchers found a mean % filtration efficiency of 96.35 for a surgical mask, with the next best material efficiency rating being that of a vacuum cleaner bag at 94.35. T-shirts and scarfs demonstrated filtration efficiency of 69.42% and 62.30%, respectively. Though not ideal, Providence leaders attempted to identify materials with the highest filtration efficiency possible prior to beginning

mask manufacture. Mask prototypes were created using surgical wrap because it was known to have already been tested for bacterial efficiency and carried a published rating of 98.4% or greater. This provided an immediate advantage to other mask materials in which filtration efficiency might be more variable. Many healthcare facilities had access to large supplies of surgical wrap products at this time because many facilities in the U.S. stopped conducting elective surgeries in light of rising COVID-19 rates.

## MATERIALS AND METHODS

Four different surgical wraps, all from the Medline GEM Series, were used due to availability. Eight mask prototypes were constructed in a consistent tri-fold design from each type of GEM wrap and single or double material layers (see Fig 1). All eight prototypes were sent to an environmental lab for bacterial filtration efficiency testing, latex particle filtration efficiency testing, and delta P testing. Due to communication issues at the environmental laboratory, BFE/delta P was tested on only four prototypes and PFE was tested on the other four.

## RESULTS

BFE results ranged from 96.3% to 98.1% in two ply masks produced with Medline GEM 1, 2, and 3 materials (see Table 1). BFE results ranged from 83.0% to 97.7% in one ply masks produced with Medline GEM 1, 2, and 3 (materials are distributed as single ply and were separated prior to mask manufacture). PFE results were similar to BFE results and ranged from 92.3% to 97.7% for one and two ply masks produced with Medline GEM 2 and GEM 3. Of note GEM 3 one ply mask (prototype H) had a PFE rating of 97.7% which is the only 1 ply mask that demonstrating filtration efficiency >95%.

## DISCUSSION

The massive global shortages of PPE supply that arose in early 2020 during the COVID-19 pandemic clarified the need for larger strategic caches and back-up methods for generating PPE during a future event. The rapid creation and manufacture of simple surgical masks with similar bacterial filtration efficiency as ASTM 1 rated masks illustrates one method for future planning in the event that mask shortages arise again. Although the masks distributed to staff at Providence were created using an assembly line and professional seamstresses, the same product outcome could be achieved using a simple sewing machine. Although not ideal, the use of surgical wrap to quickly produce a high quality isolation mask does offer a feasible solution when mask supplies are critically low to ensure healthcare services can continue to be provided while keeping healthcare workers safe.

User feedback was gathered regarding original design and comfort by direct caregiver application and trial. Prototypes were hand-delivered to hospital units where nursing staff donned the masks and provided specific feedback for consideration and adoption, directly to the designer, who in-turn influenced future patterns and manufacturing. Healthcare worker reception was very positive to the novel manufactured masks. Feedback was received regarding design and breathability, and users felt that both aspects were equal to or better than traditional masks.

PPE supply is critical to the health and safety of healthcare workers. Investments in growing adequate and appropriate caches of materials are critical, as are investments in identifying methods for quickly generating PPE locally during times of low supply. The method described in this paper could be easily replicated at other sites for use when supplies are critically low and use of locally

**Table 1**  
Bacterial and particulate filtration efficiency (BFE and PFE) ratings table

Mask test identifier	Material color	Ply	Medline GEM series #	Published medline mean % BFE of raw material	Mean % BFE in mask form	Mean % PFE in mask form
A	Light blue/light pink	2 Ply	GEM 1	98.6%	96.9%	NA
B	Light pink	1 Ply	GEM 1	NA	83.0%	NA
C	Sky blue	2 Ply	GEM 1	98.6%	98.1%	NA
D	Sky blue	1 Ply	GEM 1	NA	91.7%	NA
E	Medium blue	2 Ply	GEM 2	98.6%	NA	96.3%
F	Medium blue	1 Ply	GEM 2	NA	NA	92.3%
G	Dark blue/dark pink	2 Ply	GEM 3	99.20%	NA	96.6%
H	Dark blue	Used 1 Ply	GEM 3	NA	NA	97.7%

manufactured masks with known BFE ratings are logically superior to alternatives (like cloth masks or scarves).

Limitations of this study include assessment of other ASTM criteria, including flammability and fluid permeability. Although some data is likely available regarding these characteristics of surgical wrap, that information was not explored as part of this study due to the urgency of need for rapid production. Utilizing a full face shield over the surgical wrap mask can reduce the risk of fluid exposure. Masks produced outside of normal distribution processes also lack necessary regulatory approvals. These masks were not labeled as healthcare quality and were only used for limited periods of time while ASTM rated masks were unavailable.

### Acknowledgments

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