

[High Priority] - H0597 : [COVID-19] Strategies for the Use of Homemade Facemasks [ECRI Exclusive Hazard Report] Medical Device Hazard Report

Published: Thursday, April 30, 2020

UMDNS Terms:

- Masks [12447]

Geographic Regions: Worldwide

Suggested Distribution: Anesthesia, Clinical/Biomedical Engineering, Critical Care, Dialysis/Nephrology, Emergency/Outpatient Services, Infection Control, Nursing, Obstetrics/Gynecology/Labor and Delivery, Oncology, OR/Surgery, Pulmonology/Respiratory Therapy, Diagnostic Imaging, Risk Management/Continuous Quality Improvement, Facilities/Building Management, Ophthalmology, Internal Medicine, Point-of-Care Coordination, Pain Clinic, NICU, EMS/Transport, Perfusion, Pharmacy, IV Therapy, Central Sterilization Reprocessing, Materials Management

Problem:

Extensive community transmission of the SARS-CoV-2 virus has caused a patient surge, which has contributed to a worldwide shortage of facemasks.

1. [WHO](#) and [CDC](#) report that SARS-CoV-2 virus is primarily transmitted between people through respiratory droplets.
 1. Droplet transmission occurs when a person is in close contact (<1 m) with someone who has respiratory symptoms (e.g., coughing or sneezing) ([WHO](#)).
 2. Droplets can land in the mouths, noses, or eyes of people who are nearby or possibly be inhaled into the lungs of those within close proximity ([CDC](#)).
2. [CDC](#) reports that SARS-CoV-2 virus may be transmitted by people who lack symptoms or have not yet developed symptoms.
3. Increased facemask use by healthcare workers and the general public during the COVID-19 patient surge will likely exceed the available supply, resulting in shortages at many healthcare facilities.
4. Healthcare personnel may be exposed to SARS-CoV-2 during the COVID-19 pandemic.

ECRI Recommendations:

1. ECRI recommends that healthcare personnel and the general population wear a facemask of the type most suited to their level of infection risk and to do so in combination with good hand hygiene, proper social distancing measures, and respiratory etiquette (i.e., sneezing into your elbow).
2. Facilities should first conserve personal protective equipment (PPE) by using ECRI's guidance on strategies for addressing [respirator](#) and [facemask](#) shortages.
3. Maintain your stock of masks in a secure, monitored site.

For the General Population

1. Wear a homemade facemask (also called a cloth face covering) in public, especially in places where social distancing is difficult to maintain (e.g., grocery stores) ([CDC](#)).
2. Some states now require face covers be worn in public while doing certain activities and by essential workers who come into direct contact with the public. Check with your local and state representatives for guidance.
3. If you have N95 or surgical masks, use them as needed, but consider donating surplus supplies to healthcare personnel who are at higher risk for being exposed to the virus.
4. Face covers should not be placed on children younger than two years of age, anyone who has trouble breathing, or is unconscious, incapacitated, or otherwise unable to remove the cover without assistance ([CDC](#)).
5. Facemask use should not replace proper social distancing or hand hygiene. Remember that the facemask is meant to protect other people in case you are infected, even if you do not feel sick.
6. If you are caring for someone with known or suspected COVID-19, wear a surgical mask. As a last resort, if no other masks are available, a homemade face mask should be worn.

For Patients with Known or Suspected COVID-19

1. If you are sick and must go out in public, wear a surgical mask or, if surgical masks are unavailable, a homemade facemask.
2. [CDC](#) recommends that healthcare facilities consider maintaining a supply of homemade facemasks for patients with known or suspected cases if FDA-cleared facemasks are not available. These should be made available upon check-in at entry points.
3. Have patients cover their coughs with a tissue or towel if they cannot wear a mask.

For Healthcare Personnel (HCP) at a Low Risk of Contact with COVID-19 Patients

1. First consider addressing supply shortages by finding alternative sources or changing current practices, as discussed in previous ECRI reports.
2. Prioritize mask types based on activities and exposure risk. The [CDC](#) emphasized that surgical masks, which are FDA-cleared, are designed to protect against splashes and sprays. Homemade facemasks are not regulated by the FDA and may not provide the same protection.

3. Homemade facemask use is not recommended but may be worn if no other options are available.
4. If a homemade facemask is worn, supply the HCP with multiple to switch if the mask becomes soiled or damp, and launder after each use.

For HCP in Direct Contact with COVID-19 Patients

1. A homemade mask is insufficient because their capability to protect HCP is unknown. An N95 respirator offers the greatest protection. See [ECRI's previous guidance](#) .
2. In a crisis situation, when no other facemask is available, homemade facemasks may be worn. However, they should ideally be used in combination with a face shield that covers the entire front (that extends to the chin or below) and sides of the face.
3. Use caution and consider breathability and gas exchange when attempting to utilize homemade facemasks as debris protection for N95s, although there is [some evidence](#) that the risk of clinically significant adverse effects is low.

ECRI Recommendations for Homemade Mask Design

1. The [WHO](#) recommends that the following features related to nonmedical masks should be taken into consideration:
 1. Numbers of layers of fabric/tissue
 2. Breathability of material used
 3. Water repellence/hydrophobic qualities
 4. Shape of mask
 5. Fit of mask
2. [Public Health England](#) and [Wake Forest](#) suggest that masks be made with good quality cotton, such as quilter's cotton, or cotton blend. Closely woven (thread counts of 150 or higher) are better.
3. Surgical wrappers are untested for use in facemasks, but their bacterial filtration and breathability may make them suitable for this use.
4. Multiple layers significantly increase protection. You should not be able to see light through the fabric
5. If using a filter material, place the filter between two layers of fabric to reduce the risk of inhaling fibers ([New York Times](#)).
6. Masks should have a secure fit to your face, with no gaps around the nose or cheeks.
 1. A flexible metal wire may be added at the top of the mask to conform the fabric to your face.
7. Refer to the [Open Source COVID Medical Supplies Facemask Guide](#) for professionally reviewed and approved designs.

Proper Mask Use

1. Always use a mask in combination with good hand hygiene, proper social distancing measures, and respiratory etiquette (i.e., sneezing into your elbow).
2. Before putting on a mask, wash your hands with soap and water or use an alcohol-based hand sanitizer.
3. Put the mask on carefully, ensuring that it covers the mouth and nose, and tie it securely to eliminate gaps between the material and your face.
4. If the mask has a metal nosepiece, press the wire to form it to the bridge of your nose to create a tighter fit.
5. Avoid touching your face or the mask while wearing it.
6. If the mask becomes damp, change it. Moisture may reduce the filtration efficiency of the fabric and may make the fabric more likely to retain viruses.
7. To remove the mask, remove it from behind by holding the straps. Do not touch the front of the mask.
8. After removing the mask, immediately wash hands with soap and water or use an alcohol-based hand sanitizer.

Cleaning Homemade Masks

1. Wash cloth masks after each use in a laundry machine using standard household detergent. Masks made of paper (e.g., paper towel) or other materials should only be worn once and then discarded.
2. Consider replacing your mask or adding filtration after several uses. There is [some evidence](#) that filtering efficiency of cloth masks may drop after the 4th washing and drying cycle.
3. If not laundered, store masks in a breathable container (e.g., paper bag) for at least three days (72 hours).

Background

1. There is evidence of asymptomatic transmission of SARs-CoV-2.
 1. [Nasal and throat swabs](#) obtained from 18 patients in Zhuhai, Guangdong, China showed a similar viral load in the asymptomatic patients to the symptomatic patients, which may suggest the transmission potential of asymptomatic patients.
 2. A [case study](#) from Munich, Germany traced back four positive COVID-19 patients to a business associate who visited Germany in January but did not show symptoms until her return to China.
2. Large, community-based studies of [influenza](#) and [SARs](#) show that public use of facemasks combined with frequent handwashing was

effective in reducing the risk of transmission.

3. [Click here](#) for a table that describes the differences between N95 respirators, surgical masks, and homemade cloth masks.

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Comments:

- This alert is a living document and may be updated when ECRI receives additional information.

Source(s):

- 2020 Apr 28. ECRI researched report
- 2020 Apr 30. Table 1 [Download](#)