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<b>[COVID-19] Strategies for Addressing Expected or Known Facemask Shortages [ECRI Exclusive Hazard Report]</b>		

## Problem

1. The coronavirus disease (COVID-19) patient surge has contributed to a worldwide shortage of facemasks.
2. WHO and CDC report that SARS-CoV-2 virus is primarily transmitted between people through respiratory droplets (1,2).
  1. Droplet transmission occurs when a person is in close contact (<1 m) with someone who has respiratory symptoms (e.g., coughing or sneezing) (1).
  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 (2).
3. Facemasks that meet specific ASTM standards are used to protect healthcare personnel (HCP) from respiratory droplets; single-use procedure and surgical masks are the most common types of facemasks used in healthcare.
4. Increased facemask use during the COVID-19 patient surge will likely exceed the available supply, resulting in shortages at many healthcare facilities.
5. The potential consequence of this problem is HCP exposure to SARS-CoV-2 virus during the COVID-19 pandemic.

## ECRI Recommendations:

*ECRI recommends that facilities immediately:*

1. Inventory the following products if available in your facility:
  1. Surgical masks
  2. Procedure masks
  3. Other medical masks
  4. Non-medical masks, including homemade masks
2. Place all facemasks in a secure, monitored site that is accessible in case of emergent clinician need (e.g., room with keypad or badge entry).
3. Minimize the number of individuals who need to use facemasks through the use of engineering and administrative controls, including (3,4):
  1. Reducing the number of patients going to healthcare facilities
  2. Excluding HCP not essential for patient care from entering patient care areas
  3. Reducing face-to-face HCP encounters with patients
  4. Maximizing the use of telemedicine
4. As needed, provide HCP with education, hands-on training, and competency assessment of:
  1. Isolation precautions and personal protective equipment (PPE) requirements for their job responsibilities
  2. PPE donning and doffing

*For facilities that have facemasks, ECRI recommends to:*

1. Use appropriate precautions when caring for known or suspected COVID-19 patients.
  1. WHO recommends that HCP follow droplet and contact precautions during routine care of COVID-19 patients (1).
    1. HCP should use a facemask, eye protection (i.e., goggles or a face shield), isolation gown, and gloves as personal protective equipment (PPE) (2).
  2. WHO recommends that HCP follow contact and airborne precautions during aerosol-generating procedures (AGPs) (1).
    1. HCP should use a respirator, eye protection, isolation gown, and gloves as PPE (2).

*For facilities that have facemasks, ECRI recommends that Infection Prevention and Control staff:*

1. Use the CDC's [Personal Protective Equipment \(PPE\) Burn Rate Calculator](#) to determine when your facility's inventory of facemasks will be depleted (5).
2. Share the calculator findings with local, state, or federal public health officials, appropriate state agencies that are managing the overall COVID-19 emergency response, state crisis standards of care committees, or other relevant public health organizations.
3. Inquire about facemask resupply via local or state stockpiles.

*For facilities that have facemasks, ECRI recommends that Procurement staff:*

1. Continue attempts to source facemasks, including surgical masks, procedure masks, and other medical masks.
2. Check the FDA's Establishment Registration & Device Listing to verify that a vendor is registered with the FDA as a facemask manufacturer (6).

*For facilities that have facemasks and have not altered routine care practices, ECRI recommends that frontline HCP:*

1. Follow the CDC's Conventional Capacity Strategies for optimizing the supply of facemasks, which include (3):

1. Perform AGPs on known or suspected COVID-19 patients in airborne infection isolation rooms (AIIRs). Exclude visitors to these patients (4).
2. Cohort patients—group patients together who are infected with the same organism to confine their care to one area.
3. Cohort HCPs—designate HCPs to provide care for all patients with suspected or confirmed COVID-19 (e.g., physicians, nurses, Environmental Services staff).
4. Use facemasks according to product labeling and local, state, and federal requirements:
  1. Surgical masks generally provide Level 2 or 3 fluid resistance per ASTM standard F2100 (7). Surgical masks are FDA-regulated and designed to protect against fluid splashes and sprays. Surgical masks should be used when fluid exposures are anticipated, such as during surgical procedures.
  2. Procedure masks generally provide no level or Level 1 fluid resistance per ASTM standard F2100 (7) and are typically used for patients under contact or droplet isolation precautions. Procedure masks that do not protect against splashes/sprays are not regulated by FDA.

*For facilities that have facemasks and have changed routine care practices, ECRI recommends that frontline HCP:*

1. Cancel all elective, non-urgent procedures and appointments for which facemasks are typically used by HCP.
2. Wear facemasks under disposable or reusable faceshields that cover the entire front (that extends to the chin or below) and sides of the face to the ear.
3. Refer to the CDC's Conventional and Contingency Capacity Strategies for optimizing the supply of facemasks. Contingency capacity strategies include (3):

1. Remove facemasks for visitors in public areas.
  1. Healthcare facilities can consider removing all facemasks from public areas.
  2. Facemasks can be available for symptomatic patients upon check in at entry points.
2. Restrict facemasks to use by HCP, rather than patients for source control.
  1. Have patients with symptoms of respiratory infection use homemade masks or other barriers (e.g., tissues) to cover their mouth and nose.
3. Extended use of facemasks
  1. Extended use is the practice of wearing the same facemask for repeated close contact encounters with several cohorted patients, without removing the facemask between patient encounters.
  2. Facemasks should be removed and discarded if soiled, damaged, or become difficult to breathe through.
  3. HCP should take care not to touch their facemask. If HCP touch or adjust their facemask, they should immediately perform hand hygiene with soap and water or an alcohol-based hand sanitizer.
  4. HCP should leave the patient care area if they need to remove their facemask for any reason.

*For facilities that have a low supply of facemasks, ECRI recommends that frontline HCP:*

1. Refer to the CDC's Conventional, Contingency, and Crisis Capacity Strategies for optimizing the supply of facemasks. Crisis capacity strategies include (3):
  1. Use facemasks that exceed the manufacturer-designated shelf life during patient care activities.
  2. Reuse facemasks.
    1. Facemask reuse is the practice of one HCP using the same facemask for multiple encounters with different patients, but removing it after each encounter.
    2. Not all facemasks can be reused.
      1. Facemasks that fasten to the provider via ties may not be able to be undone without tearing and should be considered only for extended use, rather than reuse.
      2. Facemasks with elastic ear hooks may be more suitable for reuse.
    3. Follow previous recommendations for extended use of facemasks.
    4. If possible, issue HCP a minimum of five facemasks that will be used over a time period specified by facility policy (8).
    5. Follow the employer's maximum number of donnings and recommended inspection procedures.
    6. Avoid touching the inside of the facemask. If inadvertent contact is made with the inside of the facemask, discard the facemask and perform hand hygiene.
    7. For facemask storage:
      1. Place in a clean, breathable paper bag between uses so that facemasks do not become damaged or deformed. The paper bag should be an appropriate size for the facemask to reduce cross-contamination during storage.
      2. Carefully fold the facemask so that the outer surface is held inward and against itself to reduce contact with the inner surface during storage.
      3. To further minimize cross-contamination, store facemasks so that they do not touch each other, with the name of the person using the facemask and the date of last use clearly written on the paper bag.
      4. The amount of time in between uses should exceed the 72 hour expected survival time of the SARS-CoV2 virus (4).
      5. Paper bag storage containers should be disposed of after use.
  3. Prioritize facemask use for patient care activities, such as:
    1. Essential surgeries
    2. Procedures where body fluid splashes or sprays are anticipated
    3. Prolonged face-to-face or close contact with a potentially infectious patient
    4. Performing AGPs if there are no respirators. Eye protection should be a faceshield that covers the entire front and sides of the face.

*For facilities that have zero facemasks, ECRI recommends that frontline HCP:*

1. Exclude HCP at higher risk for severe illness (i.e., those of older age, those with chronic medical conditions, or those who may be pregnant) from contact with known or suspected COVID-19 patients (3).
2. Designate convalescent HCP (i.e., those who have clinically recovered from COVID-19 and may have some protective immunity) to preferentially provide care to known or suspected COVID-19 patients (3).
3. Use an expedient patient isolation room for risk-reduction (3). For additional information, see NIOSH's report "Expedient Methods for Surge Airborne Isolation within Healthcare Settings during Response to a Natural or Manmade Epidemic" (9).
4. Use a ventilated headboard to decrease risk of HCP exposure to patient-generated aerosols (3).
5. Use a faceshield that covers the entire front and sides of the face with no facemask (3).
6. As a last resort, use homemade masks (3).
  1. Homemade masks (e.g., bandanas, scarves) should be used with a faceshield that covers the entire front and sides of the face.
  2. Homemade masks are not considered PPE because their ability to protect HCP is unknown.

## **Background:**

1. For guidance on addressing respirator shortages, please refer to ECRI's free resource: [Strategies for Addressing Expected or Known N95 Respirator Shortages](#).
1. FDA is aware of challenges throughout the supply chain that are presently impacting the availability of PPE products and is taking steps to mitigate shortages that health care facilities are already experiencing (10).
2. WHO reports that SARS-CoV-2 virus is primarily transmitted between people through respiratory droplets (1):

- Respiratory infections can be transmitted through droplets of different sizes: when the droplet particles are >5-10 µm in diameter, they are referred to as respiratory droplets, and when they are <5µm in diameter, they are referred to as droplet nuclei. According to current evidence, COVID-19 virus is primarily transmitted between people through respiratory droplets and contact routes (1).
- WHO and CDC guidance details possible airborne transmission of SARS-CoV-2 virus:
  - WHO guidance states: airborne transmission [of SARS-CoV-2] may be possible in specific circumstances and settings in which procedures that generate aerosols are performed (e.g., endotracheal intubation, bronchoscopy, open suctioning, administration of nebulized treatment, manual ventilation before intubation, turning the patient to the prone position, disconnecting the patient from the ventilator, non-invasive positive-pressure ventilation, tracheostomy, and cardiopulmonary resuscitation) (1).
  - CDC's guidance states: Some procedures performed on known or suspected COVID-19 patients could generate infectious aerosols. In particular, procedures that are likely to induce coughing (e.g., sputum induction, open suctioning of airways) should be performed cautiously and avoided if possible (2).
    - If performed, the following should occur (2):
      - HCP in the room should wear an N95 or higher-level respirator, eye protection, gloves, and a gown.
      - The number of HCP present during the procedure should be limited to only those essential for patient care and procedure support.
      - AGPs should ideally take place in an AIIR.
      - Clean and disinfect procedure room surfaces promptly.
- A March 27th survey of US infection preventionists conducted by APIC revealed that (11):
  - 31.7% of respondent's facilities are almost out of or have zero facemasks.
  - 48.3% of respondent's facilities are almost out of or have zero respirators.
  - 49.2% of respondent's facilities are almost out of or have zero faceshields.
  - 24.5% of respondent's facilities are almost out of or have zero isolation gowns.
- A recent JAMA article details several approaches for sourcing PPE that may be useful to facilities with dwindling PPE supply (12).

## References & Source Documents:

- World Health Organization. Modes of transmission of virus causing COVID-19: implications for IPC precaution recommendations [online]. 2020 Mar 29 [cited 2020 Apr 14]. Available from: <https://www.who.int/publications-detail/modes-of-transmission-of-virus-causing-covid-19-implications-for-ipc-precaution-recommendations>.
- Centers for Disease Control and Prevention, U.S. Interim Infection Prevention and Control Recommendations for Patients with Suspected or Confirmed Coronavirus Disease 2019 (COVID-19) in Healthcare Settings [online]. 2020 Apr 13 [cited 2020 Apr 15]. Available from: <https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html>.
- Centers for Disease Control and Prevention, U.S. Strategies for Optimizing the Supply of Facemasks [online]. 2020 Mar 17 [cited 2020 Apr 16]. Available from: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/face-masks.html>
- Centers for Disease Control and Prevention, U.S. Strategies for Optimizing the Supply of N95 Respirators [online]. 2020 Apr 2 [cited 2020 Apr 16]. Available from: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/index.html>.
- Centers for Disease Control and Prevention, U.S. Personal Protective Equipment (PPE) Burn Rate Calculator [online]. 2020 Mar 25 [cited 2020 Apr 14]. Available from: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/burn-calculator.html>.
- Food & Drug Administration, U.S. Establishment Registration & Device Listing [online]. 2020 Apr 13 [cited 2020 Apr 16]. Available from: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/r1.cfm>.
- ASTM International. ASTM F2100-19, Standard Specification for Performance of Materials Used in Medical Face Masks. West Conshohocken, PA, 2019, <https://www.astm.org/Standards/F2100.htm>.
- Centers for Disease Control and Prevention, U.S. Decontamination and Reuse of Filtering Facepiece Respirators [online]. 2020 Apr 9 [cited 2020 Apr 16]. Available from: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/decontamination-reuse-respirators.html>.
- The National Institute for Occupational Safety and Health (NIOSH). Expedient Methods for Surge Airborne Isolation within Healthcare Settings during Response to a Natural or Manmade Epidemic [online]. 2012 Apr [cited 2020 Apr 16]. Available from: <https://www.cdc.gov/niosh/surveymethods/pdfs/301-05f.pdf>.

10. Food & Drug Administration, U.S. Coronavirus Disease 2019 (COVID-19) Frequently Asked Questions [online]. 2020 Apr 7 [cited 2020 Apr 16]. Available from: <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/coronavirus-disease-2019-covid-19-frequently-asked-questions>.
11. Association for Professionals in Infection Control and Epidemiology (APIC). Protecting Healthcare Workers During the COVID-19 Pandemic: A Survey of Infection Preventionists [online]. 2020 Mar 27 [cited 2020 Mar 31]. Available from: [https://apic.org/wp-content/uploads/2020/03/Protecting-Healthcare-Workers-Survey\\_Report\\_3\\_26\\_20\\_Final.pdf](https://apic.org/wp-content/uploads/2020/03/Protecting-Healthcare-Workers-Survey_Report_3_26_20_Final.pdf).
12. Livingston, Desai, and Berkwits. Sourcing Personal Protective Equipment During the COVID-19 Pandemic. JAMA Editorial 2020 Mar 28. Available from: <https://jamanetwork.com/journals/jama/fullarticle/2764031>.

## Geographic Region(s)

Worldwide

## Suggested Distribution

Anesthesia, Cardiology/Cardiac Catheterization Laboratory, Clinical/Biomedical Engineering, Critical Care, Dialysis/Nephrology, Emergency/Outpatient Services, Infection Control, Nursery, Nursing, Obstetrics/Gynecology/Labor and Delivery, Oncology, OR/Surgery, Orthopedics, Pediatrics, Pulmonology/Respiratory Therapy, Diagnostic Imaging, Risk Management/Continuous Quality Improvement, Facilities/Building Management, Diabetes Education/Coordination, Home Care, Gastroenterology, Dentistry/Oral Surgery, Ophthalmology, Phlebotomy, Physical Therapy/Rehabilitation, Internal Medicine, Dermatology, Otolaryngology, Point-of-Care Coordination, Sleep Laboratory, Vascular Laboratory, Pain Clinic, Staff Education, NICU, Behavioral Health/Psychiatry, EMS/Transport, Perfusion, Pharmacy, IV Therapy, Central Sterilization Reprocessing, Materials Management

## Comment

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