

**[High Priority] - H0586 : [COVID-19] Strategies for Addressing Expected Glove Shortages [ECRI Exclusive Hazard Report]
Medical Device Hazard Report**

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UMDNS Terms:

- Gloves [11879]
- Gloves, Examination/Treatment [11882]
- Gloves, Multiuse [11885]
- Gloves, Surgical [11883]

Product Identifier:

[Consumable]

Gloves for Healthcare Personnel Use

Geographic Regions: Worldwide

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

Problem:

1. The coronavirus disease (COVID-19) patient surge is expected to lead to a shortage of gloves used as a method of broad barrier protection for healthcare personnel (HCP).
2. Increased glove use during the COVID-19 patient surge will likely result in demand exceeding the available supply, resulting in shortages in many healthcare facilities.
3. Additionally, there is concern that personal protective equipment (PPE) distributors may allocate PPE to facilities based on purchase history, rather than projected requirements (1), which could exacerbate the potential shortage for certain healthcare systems.
4. When HCP do not have adequate hand protection,
 1. They are at an increased risk for exposure to SARS-CoV-2 virus during the course of COVID-19 patient care.
 2. Patients are at increased risk of exposure to secondary infections.

ECRI Recommendations:

For facilities that have gloves, ECRI recommends the following:

1. Always visually inspect gloves for damage (including discoloration and tears) before use and after donning.
2. Always perform thorough hand hygiene in the following situations:
 1. Before donning gloves.
 2. Before doffing PPE and as necessary during the doffing process; ensure that any alcohol-based handrub has fully dried before proceeding.
 1. During the 2014-2016 Ebola outbreak, a study found that alcohol-based handrubs had more effect on the tensile strength of nitrile gloves, than latex gloves, and that ethanol-based handrubs resulted in fewer changes in glove strength when compared to isopropanol-based rubs. Overall, the study concluded that multiple disinfections with ethanol-based handrubs on latex and some nitrile gloves was safe for PPE doffing procedures (2).
 3. After doffing and disposing gloves.
3. Inventory the available gloves in your facility, keeping a separate inventory for products that have passed their manufacturer's designated shelf life. Applicable gloves include:
 1. Examination gloves
 2. Surgical gloves
 3. Dental gloves
 4. X-ray shielding gloves
 5. Chemotherapy gloves
 6. Nonmedical gloves (e.g., food service, cleaning, embalming)
4. Consider using certain types of PPE only if in direct contact with the patient or their environment (e.g., wearing a mask and face shield but no gown or gloves when entering a patient room for a visual check or to ask questions) (3).
5. Minimize the number of individuals who need to use gloves through the use of engineering and administrative controls, including the following (4):

1. Reduce the number of patients going to healthcare facilities.
2. Exclude HCP not essential to patient care from entering patient care areas (e.g., bundling patient care activities such as having HCP deliver food to patients when entering the room to provide care).
3. Reduce face-to-face encounters between HCP and patients.
4. Maximize the use of telemedicine.
6. Use appropriate precautions when caring for known or suspected COVID-19 patients.
 1. The World Health Organization (WHO) recommends that HCP follow droplet and contact precautions during routine care of COVID-19 patients (5).
 1. HCP should use a facemask, eye protection (i.e., goggles or a face shield), isolation gown, and gloves as PPE (6).
 2. WHO recommends that HCP follow contact and airborne precautions during aerosol-generating procedures (AGPs) (5). CDC adds that respirators should be prioritized for situations in which respiratory protection is most important and the care of patients with pathogens requiring airborne precautions (e.g., tuberculosis, measles, varicella) (6).
 3. HCP should use a respirator, eye protection, isolation gown, and gloves as PPE (6).

For facilities that have gloves, ECRI recommends that infection prevention and control staff do the following:

1. Use the Centers for Disease Control and Prevention (CDC)'s [Personal Protective Equipment \(PPE\) Burn Rate Calculator](#) to determine when your facility's inventory of gloves will be depleted (7).
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 glove resupply via local, state, or federal stockpiles.

For facilities that have gloves, ECRI recommends that procurement staff take the following actions:

1. Continue attempts to source gloves, including exam and surgical gloves.
2. Consult ECRI's Functional Equivalence tool for available glove alternatives that have been purchased by other subscribing facilities.
3. Identify potentially available FDA-cleared medical gloves using the [510\(k\) Database](#) with medical glove product codes (1):
 1. Patient examination gloves (FMC)
 2. Surgeon's gloves (KGO)
 3. Latex patient examination gloves (LYY)
 4. Vinyl patient examination gloves (LYZ)
 5. Polymer patient examination gloves (LZA)
 6. Patient examination gloves, specialty (LZC)
 7. Powder-free guayle rubber examination gloves (OIG)
 8. Powder-free non-natural rubber latex surgeon's gloves (OPA)
 9. Radiographic protective gloves (IWP)

*For facilities that have a **conventional capacity** of gloves and **have not** altered routine care practices, ECRI recommends that frontline HCP take the following actions:*

1. Use FDA-cleared disposable, nonsterile patient exam gloves for routine patient care of suspected or confirmed COVID-19 patients (8).
2. Reserve the use of sterile gloves for sterile procedures (8).
3. Follow the applicable CDC's Conventional Capacity Strategies for optimizing the supply of N95 respirators, which include (4,8):
 1. Where possible, use a physical barrier (e.g., a glass or plastic screen) to separate HCPs from known or suspected COVID-19 patients (e.g., during emergency intake, triage, or pharmacy).
 2. Perform AGPs on known or suspected COVID-19 patients in airborne infection isolation rooms (AIIRs). Exclude visitors to these patients.
 3. Cohort patients—group patients together who are infected with the same organism to confine their care to one area.
 4. Cohort HCPs—designate HCPs to provide care for all patients with suspected or confirmed COVID-19 (e.g., physicians, nurses, Environmental Services staff).
 1. Have only essential HCP enter the patient care area.

2. Bundle care activities and types (e.g., HCP deliver patient food when performing other patient care)

4. In an effort to ensure appropriate use and conservation of PPE, WHO suggests the following situations in which people **would require** gloves as part of their PPE (3):
 1. Inpatient Facilities
 1. HCP providing direct COVID-19 patient care in the absence of AGPs
 2. HCP providing direct COVID-19 patient care in settings where AGPs occur
 3. Cleaners entering COVID-19 patient rooms
 4. Visitors entering COVID-19 patient rooms
 5. Lab technicians handling specimens from known or suspected COVID-19 patients
 2. Outpatient Facilities
 1. HCP in a consultation room performing a physical examination of a known or suspected COVID-19 patient
 2. Cleaners in consultation rooms after and between consultations
 3. Home setting
 1. HCP providing direct care or assistance to a COVID-19 patient at home
 2. Caregivers providing direct care to or handling specimens from a COVID-19 patient
 4. Ambulance
 1. EMT transporting suspected COVID-19 patients to a healthcare facility
 2. Driver assisting with the loading or unloading of a suspected COVID-19
 3. Cleaners in the vehicle after and between transport of suspected COVID-19 patients

*For facilities that have a **contingency (i.e., limited) capacity** of gloves and **have** altered routine care practices, ECRI recommends that frontline HCP:*

Use gloves that are beyond their manufacturer designated shelf life in situations in which broad barrier protection is not required (e.g., training or demonstration purposes) (8).

ECRI suggests that facilities with a conventional capacity of gloves but that are anticipating a shortage may want to perform this contingency measure immediately.

*For facilities that have a **crisis (i.e., low or unavailable) capacity** of gloves, ECRI recommends that frontline HCP:*

1. Use gloves that are beyond their manufacturer designated shelf life in situations where broad barrier protection is not required (e.g., training or demonstration purposes) (8).
2. ECRI suggests that facilities with a conventional capacity of gloves but that are anticipating a shortage may want to perform this contingency measure immediately.

*For facilities that have a **crisis (i.e., low or unavailable) capacity** of gloves, ECRI recommends that frontline HCP:*

1. Use sterile gloves where needed for standard patient care, if your facility has a surplus of surgical gloves as a result of the suspension of elective surgeries.
2. Use medical gloves beyond the designated shelf life in low-transmission-risk settings (e.g., nonsterile, nonsurgical settings) (8).
 1. ECRI would like facilities to be aware that some types of gloves (e.g., polyisoprene) may be more prone to breakdown after exceeding their designated shelf life, so it is imperative that users inspect expired gloves for damage before and after donning; discard any damaged gloves.
3. Consider using alternative glove options.
 1. Prioritize medical gloves such as radiographic protection gloves or radiation attenuating surgeon's gloves (8).
 2. Non-medical gloves that align with ASTM standards for medical gloves per the FDA's Medical Glove Guidance Manual (food service gloves, embalming gloves, cleaning gloves) (8,9).
4. Be alert to counterfeit medical and non-medical gloves (8).
5. As an **absolute last resort**, extend the use of exam and surgical gloves. This effort is recommended by the FDA (8), but not by WHO (3).
 1. FDA recommends:
 1. Do not change gloves between COVID-19 cohort patients in the same cohort with the same disease or exposure type and no other known infections (8).

1. ECRI notes that this effort is essentially treating COVID-19 as if it is superseding any other infections.
 2. ECRI notes that it may be impossible to know whether one patient has an asymptomatic infection or colonization that might be transferred to another patient in their COVID-19 cohort if the HCP has not changed gloves between their care.
 3. ECRI notes that this may be more practical in a setting with a number of patients receiving lower-level treatments, but may become even more dangerous an ICU setting with catheterized and intubated patients.
2. Gloves can be cleaned as hands would when following hand hygiene practices in healthcare settings, but note that vinyl gloves may degrade with use of alcohol-based handrub (8).
 1. ECRI notes that hand hygiene should also be performed when moving from a contaminated body site to another body site on one patient.
 2. A 2017 review concluded that HCP disinfection of gloved hands may substantially reduce the risk of transmission when gloves are indicated for the entire episode of patient care, and when practiced during multiple care activities on the same patient (10).
 3. Replace gloves when they become damaged (e.g., deteriorated, discolored, torn) or contaminated (e.g., with body fluids or chemotherapy drugs) (8).
 - ECRI notes that it may be difficult to detect glove deterioration until the wearer notices a tear or hole.

For facilities that have zero supply of gloves, ECRI recommends that frontline HCP do the following:

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 (4).
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 (4).

For manufacturers of medical gloves that are not currently FDA-cleared, ECRI recommends the following:

1. Work with FDA to expedite the clearance process.
2. Send an e-mail to deviceshortages@fda.hhs.gov with the following designations (1):
 1. Subject field: "Product Codes XXX, Shortage Mitigations Request for FDA Engagement" where XXX represents the applicable product code(s) as outlined in point #3 of "*For facilities that have gloves, ECRI recommends that Procurement staff*" above.
 2. Body of email:
 1. Describe your product, brand name, applicable model/catalog numbers, 510(k) numbers if available, and intended use.
 2. Describe your company's proposed shortage mitigation approach.
 3. Identify what FDA actions you would need in order to implement the proposed shortage mitigation approach (e.g., expedited review of premarket submission).

Background:

1. In March 2020, FDA published an Enforcement Policy for Gowns, Other Apparel, and Gloves during the COVID-19 Public Health Emergency with an aim to clarify the regulatory landscape and help extend the availability of surgical apparel for HCPs, including exam gloves, during the pandemic (11).
2. FDA will not object to the use and distribution of medical gloves that do not have prior submission of premarket notification (11).
3. FDA believes that these gloves should not create undue risk during the public health emergency as long as (11):
 1. The gloves meet ASTM D3577: Standard Specification for Rubber Surgical Gloves (only applicable for surgical gloves).
 2. The gloves are labeled as "unpowdered."
 3. The sterility status of the gloves is accurately labeled when individually packaged (e.g., "nonsterile").
 4. The gloves do not incorrectly claim to be free of a specific material (e.g., "latex-free").
 5. The gloves include a list of the body contacting materials.
 6. The glove labeling includes recommendations and general statements that would reduce the risk of inappropriate use (e.g., "Do not use when FDA-cleared gloves are available).
 7. The gloves are not intended for any use that would create an undue risk (e.g., inappropriately used as chemical-resistant chemotherapy gloves).

4. Gloves are broad-barrier protection used to prevent contamination of HCP when staff (12):
 1. Anticipate direct contact with potentially infectious materials including blood, bodily fluids, mucous membranes, and non-intact skin.
 2. Have direct contact with patients colonized or infected with pathogens that are transmitted via contact.
 3. Handle or touch contaminated patient care equipment and environmental surfaces.
5. During normal public health circumstances (i.e., not during a pandemic), several organizations have a firm stance **against** the extended use and decontamination of medical gloves.
 1. CDC states the following (12) with regard to a non-pandemic situation:
 1. It is necessary to discard gloves between patients.
 2. Gloves must not be washed for subsequent reuse because microorganisms cannot be removed reliably and continued integrity cannot be assured.
 3. Glove reuse has been associated with transmission of MRSA and gram-negative bacilli.
 2. WHO's position has not changed in light of the SARS-CoV-2 public health emergency (3,13), as follows:
 1. Change gloves during patient care if moving from a contaminated body site to another body site.
 2. Remove gloves after caring for a patient; do not wear the same pair of gloves for the care of more than one patient.
 3. Glove decontamination and reprocessing are not recommended and should be avoided, even when glove supply is limited.
 3. In a non-pandemic situation, FDA emphasizes (14) the following:
 1. Never reuse medical gloves.
 2. Never wash or disinfect medical gloves.
6. The successful use or rapid deterioration of medical gloves with the application of alcohol-based handrub can vary depending on the glove and rub type, as well as the duration and intensity of their use.
7. A 2012 study found that disinfection of gloved hands deteriorated glove integrity. In particular, gloves disinfected more than five times were significantly more likely to show damage via leakage than fresh gloves, and disinfected powdered gloves were significantly more likely to show damage after the first disinfection when compared to non-powdered gloves (15).
8. A 2016 study found that disinfection efficacy for different disinfectant/glove combinations was greater than with ungloved hands, though various combinations produced significant difference with regard to disinfection efficacy (16).
9. A 2019 study identified no micro-perforations in 50 gloves after eight applications of alcohol-based handrub disinfection over two hours, though volunteers reported increased stickiness during a tactile competence task (17).
10. A March 27, 2020, survey of U.S. infection preventionists conducted by Association for Professionals in Infection Control and Epidemiology (APIC) revealed the following (18):
 1. 9.48% (108) of respondents' facilities "have plenty" of gloves.
 2. 53.91% (614) of respondents' facilities "have a sufficient amount" of gloves.
 3. 31.78% (362) of respondents' facilities are "running a bit low" on gloves.
 4. 0.26% (3) of respondents' facilities have zero gloves.
11. A recent JAMA article details several approaches for sourcing PPE that may be useful to facilities with dwindling PPE supply (19).

References:

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11. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-gowns-other-apparel-and-gloves-during-coronavirus-disease-covid-19-public-health> [cited 2020 Apr 8].
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Comments:

- ECRI stresses the importance of leaving extended glove use between patients as a last resort for facilities experiencing glove shortages. Gloves are distinguished from other forms of PPE in that they will definitely come into active contact with the COVID-19 patient during the course of routine patient care. Not only could COVID-19 and other pathogens be spread to other patients, but HCP that are unable to monitor the level of deterioration of their gloves are at much greater risk of contamination themselves.
- This alert is a living document and may be updated when ECRI Institute receives additional information.

Source(s):

- 2020 Apr 16. ECRI researched report