

Problem

1. Personal protective equipment (PPE), including isolation gowns, are a primary strategy to protect healthcare personnel (HCP) from infectious diseases.
2. Increased gown utilization to treat patients with suspected and confirmed coronavirus disease (COVID-19) may exceed the available supply of isolation gowns, resulting in shortages at some healthcare organizations.
3. Multiple organizations and governing bodies have recommended strategies to conserve and optimize supplies for isolation gowns for healthcare organizations and personnel.
4. Lack of isolation gowns may result in HCP exposure to SARS-CoV-2 virus during the COVID-19 pandemic.

ECRI Recommendations:

1. To minimize the need for gowns:
 1. Understand your facility's current gown inventory, (including isolation, surgical, and non-surgical gowns), supply chain, and utilization rate.
 2. Consider use of telemedicine to evaluate suspected cases of COVID-19, minimizing the need for these individuals to go to healthcare facilities. [1,2]
 3. Use physical barriers, such as glass or plastic windows, to reduce exposure to SARS-CoV-2 virus. This can be implemented in areas of the healthcare setting where patients will first present, such as triage, registration, or pharmacy window. [1]
 4. Restrict healthcare workers from entering the rooms of COVID-19 patients if they are not involved in direct care. Consider bundling activities to minimize the number of times a room is entered.
 5. Restrict visitors from hospital areas that require gowns to be worn.
2. Contingency capacity strategies: For situations in which limited supply levels may change patient care strategies, but will not have a significant impact on patient care and healthcare worker safety:
 1. Postpone, reschedule, or cancel all scheduled elective and non-urgent procedures and appointments for which a gown is typically needed. [3]
 2. Shift to use of reusable (cloth) isolation and surgical gowns.
 1. Although disposable isolation gowns are generally used in the U.S., reusable isolation and surgical gowns are also available. These can help alleviate the shortage of gowns because they can be used multiple times.
 1. Laundry operations and personnel may need to be augmented to facilitate additional washing loads and cycles. [4]
 2. Establish systems to routinely inspect, maintain (e.g., mend a small hole in a gown, replace missing fastening ties), and replace reusable gowns when needed (e.g., when they are thin or ripped). [4]
 3. Extended use of disposable and reusable isolation gowns:
 1. The same gown can be worn by the same healthcare worker when interacting with patients with the same infectious disease when these patients are housed in the same location (e.g., COVID-19 patients in an isolation cohort). [4]
 1. Clinicians must be careful of patients who may have additional communicable diseases.
 4. Implement the use of coveralls [4,5], which may be more readily available because they are not used as commonly as gowns.
 5. Use expired gowns beyond the manufacturer-designated shelf life.
 1. Use in instances with lower risk of transmission (e.g., non-surgical) or for training purposes. The user should visibly inspect the product before use and, if there are notable defects (e.g., degraded materials, visible tears), discard the product. [6,7]
 6. Use of gowns or coveralls conforming to international standards:
 1. In times of shortages, facilities can consider using international gowns and coveralls. These products, including EN13795 and EN14126, could be reserved for activities that may involve contact with moderate to high amounts of body fluids. [8]

3. Crisis capacity strategies: Considered when the demand of gowns exceeds the supply, not commensurate with the standard of care in the U.S.
 1. Continue the use of contingency capacity strategies.
 2. Extended use of surgical gowns [4]:
 1. Surgical gowns may be worn for multiple surgeries in which the surgical procedure has a low risk of contamination.
 3. Re-use of cloth isolation gowns without laundering [4]:
 1. Cloth isolation gowns can be untied and retied and could be considered for re-use without laundering in between. These gowns should be used only when the gown was used as part of a standard precaution to protect healthcare workers from a splash. The goal of this strategy is to minimize exposures to healthcare workers and not necessarily prevent transmission between patients.
 2. Any gown that becomes visibly soiled during patient care should be removed and sent for laundering.
 4. Prioritize gowns for the following uses:
 1. Aerosol-generating procedures (such as suctioning, nebulizer treatments, and other respiratory treatments or procedures), care activities where splashes and sprays are anticipated, and high-contact patient care activities that provide opportunities for transfer of pathogens to the hands and clothing of healthcare providers [7]
 2. Surgical and sterile procedures [8]
 5. Purchasing non-surgical gowns, low-to-minimal barrier protection (ANSI/AAMI PB70 Level 1 and 2) surgical apparel, and ANSI/AAMI PB70 Level 3 moderate- to high-barrier protection surgical gowns that do not comply with regulatory requirements:
 1. FDA does not intend to object to the distribution and use of gowns not intended for use as "surgical gowns," other low-to-minimal barrier protection surgical apparel, and ANSI/AAMI PB70 Level 3 moderate-to-high barrier protection surgical gowns that do not comply with regulatory requirements and would not create undue risk. [9]
 2. Refer to the background section below for more information regarding gown requirements that would not create undue risk.
4. When no gowns are available:
 1. Consider using gown alternatives that have not been evaluated as effective. [4]
 1. Preferable features include long sleeves and closures (snaps, buttons) that can be fastened and secured.
 1. Disposable laboratory coats
 2. Reusable (washable) patient gowns
 3. Reusable (washable) laboratory coats
 4. Disposable aprons
 2. Combinations of clothing: Combinations of pieces of clothing can be considered for activities that may involve body fluids and when there are no gowns available:
 1. Long sleeve aprons in combination with long sleeve patient gowns or laboratory coats
 2. Open back gowns with long sleeve patient gowns or laboratory coats
 3. Sleeve covers in combination with aprons and long sleeve patient gowns or laboratory coats

Background:

1. FDA recognizes that the need for PPE, such as surgical and isolation gowns, may outpace the supply available to healthcare organization during the COVID-19 outbreak.
2. The current global stockpile of PPE is insufficient, particularly for medical masks and respirators; the supply of gowns and goggles is also soon expected to be insufficient. Surging global demand, driven not only by the number of COVID-19 cases but also by misinformation, panic buying, and stockpiling, will result in further shortages of PPE globally. [10]
3. Most of the manufacturing for personal protective equipment is done in China, and those factories were previously shut down because they have had to respond to original source of the outbreak, which has since gone global. A "worldwide demand" on supplies, in conjunction with China's decreased production, has fueled shortage concerns. [11]
4. Additional information for facilities looking to purchase gowns and protective apparel that do not conform to FDA regulation:

1. FDA currently believes non-surgical gowns and low-to-minimal barrier protection surgical apparel would not create undue risk where
 1. The product includes labeling that accurately describes the product as a "gown," "toga," or other apparel (as opposed to a "surgical gown" or "surgical toga") and includes a list of the body-contacting materials (which does not include any drugs or biologics).
 2. The product includes labeling that makes recommendations that would sufficiently reduce the risk of use, for example, recommendations against use in a surgical setting or where significant exposure to bodily liquid or other hazardous fluids may be expected, use in a clinical setting where Level 3 or 4 protection is warranted, and use in the presence of high-intensity heat source or flammable gas; and
 3. The product is not intended for any use that would create an undue risk in light of the public health emergency (e.g., the labeling does not include uses for antimicrobial or antiviral protection or related uses or uses for infection prevention or reduction or related uses).
2. FDA currently believes ANSI/AAMI PB70 Level 3 moderate-to-high barrier protection surgical gowns would not create undue risk where:
 1. The product meets liquid barrier protection at Level 3 or higher, consistent with ANSI/AAMI PB70 for the critical zone areas.
 2. The product meets the Class I or Class II flammability standard per 16 CFR Part 1610.
 3. The product has been demonstrated to be sterile if intended for use in surgical settings.
 4. The product includes labeling that accurately describes the product's sterility status (sterile or non-sterile), including any sterilization method used, barrier protection as Level 3, flammability classification (Class I or Class II), and a list of the body-contacting materials
 5. The product includes labeling with general statements and makes recommendations that would sufficiently reduce the risk of use, for example, a general statement about devices that have not been cleared by FDA, recommendations against use when FDA-cleared surgical gowns are available, and recommendations against use of non-sterile product settings.
 6. The product is not intended for any use that would create an undue risk in light of the public health emergency (e.g., the labeling does not include uses for antimicrobial or antiviral protection, uses for infection prevention or reduction, or is labeled as having ANSI/AAMI PB70 Level 4 liquid barrier protection).

References & Source Documents:

1. https://apps.who.int/iris/bitstream/handle/10665/331215/WHO-2019-nCov-IPCPPE_use-2020.1-eng.pdf
2. <https://www.cdc.gov/coronavirus/2019-ncov/healthcare-facilities/guidance-hcf.html>
3. <https://www.facs.org/covid-19/clinical-guidance/elective-surgery>
4. <https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/isolation-gowns.html>
5. <https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirator-use-faq.html>
6. <https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/faqs-shortages-surgical-masks-and-gowns>
7. <https://www.fda.gov/medical-devices/letters-health-care-providers/surgical-mask-and-gown-conservation-strategies-letter-healthcare-providers>
8. http://www.kdheks.gov/coronavirus/toolkit/Strategies_for_Optimizing_Isolation_Gowns.pdf
9. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-gowns-other-apparel-and-gloves-during-coronavirus-disease-covid-19-public-health>
10. https://apps.who.int/iris/bitstream/handle/10665/331215/WHO-2019-nCov-IPCPPE_use-2020.1-eng.pdf
11. <https://www.mcknights.com/news/this-is-the-perfect-storm-cdc-releases-new-guidance-as-providers-face-mask-gown-shortages-as-covid-19-spreads/>

UMDNS Term(s)

Gowns [11897]
 Gowns, Isolation [15037]
 Gowns, Medical [11898]
 Gowns, Medical, Disposable [11901]
 Gowns, Medical, Reusable [11902]

Geographic Region(s)

Worldwide

Suggested Distribution

Anesthesia, Critical Care, Emergency/Outpatient Services, Infection Control, Nursing, OR/Surgery, Pulmonology/Respiratory Therapy, Diagnostic Imaging, Risk Management/Continuous Quality Improvement, Staff Education, Materials Management

Comment

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