Surgical Mask and Gown Conservation Strategies - Letter to Healthcare Providers

The U.S. Food and Drug Administration (FDA) recognizes that the need for personal protective equipment (PPE), such as surgical masks, surgical and isolation gowns, and surgical suits, may outpace the supply available to healthcare organization during the Coronavirus Disease 2019 (COVID-19) outbreak.

The following conservation strategies for use by healthcare organizations and personnel are categorized for a range of needs and supply levels and are intended to assist healthcare organizations as they determine operating procedures during the COVID-19 outbreak. These strategies do not cover N95 respirators (https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/index.html) and are not limited to use in the care of patients infected with COVID-19. The FDA's recommendations are intended to augment, and not intended to replace, specific controls and procedures developed by healthcare organizations, the Centers for Disease Control and Prevention (CDC (https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html)), or CDC's Healthcare Infection Control Practices Advisory Committee (HICPAC (https://www.cdc.gov/hicpac/index.html)) to aid in infection prevention and control.

Recommendations

For **surgical masks and gowns**, the FDA recommends that healthcare providers follow these strategies based on the supply needs of their healthcare organization.

Gowns that are ANSI/AAMI PB70 Level 1 and 2 barrier protection are considered non-surgical isolation gowns. Gowns that have ANSI/AAMI PB70 Level 3 and 4 barrier protection and/or can be used for a sterile procedure are considered surgical gowns or surgical isolation gowns.

Conventional Capacity Strategies (supply levels are adequate to provide patient care without any change in routine practice)

- Use FDA-cleared surgical masks and gowns according to labeling and local, state, and federal requirements.
- Employ engineering and administrative controls (https://www.cdc.gov/niosh/topics/hierarchy/default.html) following CDC and HICPAC guidelines to reduce the need for surgical masks while minimizing risks to healthcare providers and patients.
- Specifically, for gowns, consider:
    - Implementing the use of reusable gowns (https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html) instead of disposable single use gowns.
    - Using ANSI/AAMI PB70 standard Level 3 or 4 gown (that is, sterile surgical isolation gowns) for surgery/invasive procedures with a medium to high risk of contamination.
    - Using ANSI/AAMI PB70 standard Level 1 or 2 gown (that is, sterile non-surgical isolation gowns) for surgery/invasive procedures with a low risk of contamination.

- Using non-surgical isolation gowns for routine care of patients that are suspected to be infected with COVID-19.

Contingency Capacity Strategies (limited supply levels may change patient care, but may not have a significant impact on patient care and healthcare provider safety)

- During times of limited access to surgical masks, facilities could consider having healthcare providers continue to wear the same surgical mask (i.e., extended use), remove only used gloves and gowns , and perform hand hygiene between treating patients with the same infectious disease diagnosis or exposure who are maintained in a confined area. If the mask, gloves, or gowns become contaminated, replace them.
- For training, use gowns that are beyond the manufacturer-designated shelf life, if available.
- Prioritize the use of gowns and surgical masks by the type of activities required for patients. If there are shortages of gowns, they should be prioritized for 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. Examples of high-contact patient care activities requiring gown use include: dressing, bathing/showering, transferring, providing hygiene, changing linens, changing briefs or assisting with toileting, device care or use, or wound care.

Crisis or Alternate Strategies (may need to be considered if surgical mask or gown demand exceeds the supply)

- **If Surgical Masks and/or Gowns Are Running Low**
  - Extend the use of single use gowns for healthcare providers without changing the gown between patients with the same infectious disease diagnosis or exposure who are maintained in a confined area. If the gown becomes contaminated, replace it.
  - Use surgical masks and/or gowns that meet CDC recommendations and/or ANSI standards for fluid resistance and bacterial filtration efficiency.
  - Prioritize the use of unexpired FDA-cleared surgical masks for healthcare providers in procedures where it is important to protect the healthcare provider and/or the patient from risk of exposure to blood and body fluids.
  - Use surgical masks beyond the manufacturer-designated shelf life in a setting where there is a lower risk of transmission(e.g., non-surgical). The user should visibly inspect the product prior to use and, if there are concerns (such as degraded materials or visible tears), discard the product.
  - Re-use surgical masks during care for multiple patients where they are used to protect the healthcare provider from an activity with low transmission risk (such as dispensing medications) and thus do not create a risk to the healthcare provider or patient. If the mask becomes contaminated, replace it.
  - Be aware that counterfeit masks and gowns may be on the market, especially during this time of reduced supply.
- **If No Surgical Masks and/or Gowns Are Available, see CDC's Considerations for Selecting Protective Clothing used in Healthcare for Protection against Microorganisms in Blood**

and Body Fluids (https://www.cdc.gov/niosh/npptl/topics/protectiveclothing/)

- NIOSH (https://www.cdc.gov/niosh/emres/2019_ncov.html) and OSHA (https://www.osha.gov/SLTC/covid-19/) have issued standards and recommendations for protective clothing based on fluid barrier properties.

Background

Personal protective equipment (PPE) includes protective clothing, gowns, gloves, face shields, goggles, face masks and respirators or other equipment designed to protect the wearer from injury or the spread of infection or illness. This communication refers specifically to certain types of surgical masks and gowns.

Surgical masks are fluid-resistant, disposable, and loose-fitting protection devices that create a physical barrier between the mouth and nose of the wearer and the immediate environment. Unlike respirators, surgical masks do not seal tightly to the wearer's face, and therefore do not provide a reliable level of protection from inhaling infectious aerosols. FDA reviews and clears surgical masks under 21 CFR 878.4040 as Class II medical devices, which may be labeled as surgical masks, surgical masks with an antimicrobial/antiviral agent, or pediatric/child face mask. For information and specific regulations associated with surgical masks, see N95 Respirators and Surgical Masks (Face Masks) (/medical-devices/personal-protective-equipment-infection-control/n95-respirators-and-surgical-masks-face-masks).

Gowns (/regulatory-information/search-fda-guidance-documents/premarket-notification-requirements-concerning-gowns-intended-use-health-care-settings) are PPE regulated by FDA under 21 CFR 878.4040 for use in healthcare settings. They may be marketed as surgical gowns, surgical isolation gowns, isolation gowns, or surgical suits, commonly known as scrub suits. Isolation gowns and surgical gowns are Class II medical devices. Surgical suits are Class I Exempt devices and are not reviewed by the FDA, but are required to be registered and listed with the FDA. Though the configuration of these products may vary, their primary purpose with regard to barrier protection is the same. Protective clothing may have various critical fabric and/or clothing properties. Thus, in this communication, the use of the word "gowns" includes all types of protective clothing including gowns and surgical suits. For more information and specific regulations associated with medical gowns, see Personal Protective Equipment for Infection Control > Medical Gowns (/medical-devices/personal-protective-equipment-infection-control/medical-gowns) and FDA's guidance, *Premarket Notification Requirements Concerning Gowns Intended for Use in Health Care Settings* (/regulatory-information/search-fda-guidance-documents/premarket-notification-requirements-concerning-gowns-intended-use-health-care-settings).

FDA Actions

The FDA is collaborating with manufacturers of surgical masks and gowns to better understand the current supply chain issues related to the COVID-19 outbreak, and to avoid any widespread shortages of these products.

The FDA will continue to keep healthcare providers, manufacturers, and the public informed if new or additional information becomes available.

Reporting Problems to the FDA

For potential or actual supply issues, email information to the FDA at deviceshortages@fda.hhs.gov (mailto:deviceshortages@fda.hhs.gov). Any one-- user, patient, manufacturer, or organization within the supply chain – who is aware of a delay in distribution of a product, and/or anticipates a potential or actual shortage, can notify us.

The FDA encourages healthcare providers to report any adverse events or suspected adverse events experienced with gowns or surgical masks.

- Voluntary reports can be submitted through MedWatch, the FDA Safety Information and Adverse Event Reporting program (/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda).
- Device manufacturers and user organizations must comply with the applicable Medical Device Reporting (MDR) regulations (/medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities).
- Healthcare personnel employed by organizations that are subject to the FDA's user facility reporting requirements (/medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities) should follow the reporting procedures established by their organizations.

Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with medical devices.

Contact Information

If you have questions about this letter, please see FAQs on Shortages of Surgical Masks and Gowns (/medical-devices/personal-protective-equipment-infection-control/faqs-shortages-surgical-masks-and-gowns), contact deviceshortages@fda.hhs.gov (mailto:deviceshortages@fda.hhs.gov) or, for general questions, the Division of Industry and Consumer Education (DICE) (/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice).