Medical Glove Conservation Strategies: Letter to Health Care Providers

The U.S. Food and Drug Administration (FDA) recognizes the need for personal protective equipment (PPE), such as medical gloves, may outpace the supply available to health care organizations during the Coronavirus Disease 2019 (COVID-19) outbreak.

This Letter to Health Care Providers refers specifically to potential shortages relating to surgeons' gloves and patient examination gloves. The following conservation strategies for use by health care organizations and personnel are categorized for a range of needs and supply levels and are intended to assist health care organizations as they determine procedures during the COVID-19 pandemic.

The conservation strategies described below are intended to augment, and not intended to replace, specific controls and procedures developed by health care organizations, the Centers for Disease Control and Prevention (https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html) (CDC), or the CDC's Healthcare Infection Control Practices Advisory Committee (https://www.cdc.gov/hicpac/index.html) (HICPAC) to aid in infection prevention and control. These strategies are not limited to use in the care of patients infected with COVID-19.

Conservation Strategies

For **medical gloves**, i.e., patient examination gloves and surgeon's health care providers may wish to consider these strategies and risk mitigations based on the supply levels of their health care organization.

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

- Use FDA-cleared medical gloves according to labeling and federal, state, and local requirements.
- Nonsterile disposable patient examination gloves, which are used for routine patient care in health care settings, are appropriate for the care of patients with suspected or confirmed COVID-19.
- Employ engineering and administrative controls (https://www.cdc.gov/niosh/topics/hierarchy/default.html) following the CDC and HICPAC guidelines to reduce the need for medical gloves while minimizing risks to health care providers and patients. Some of the CDC's Strategies for Optimizing the Supply of N95 Respirators (https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/index.html) may also be useful for gloves conservation.
- Reserve use of sterile gloves for procedures in which sterility is required.

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

- For training or demonstration in which broad barrier protection is not needed, use medical gloves that are beyond the manufacturer-designated shelf life, if available.

Crisis or Alternate Strategies if Medical Gloves are Running Low or Not Available (may need to be considered if medical glove supplies are critically low and demand is high)

- Refer to the CDC's **Hand Hygiene in Healthcare Settings** (https://www.cdc.gov/handhygiene/providers/index.html)
- Use medical gloves beyond the manufacturer-designated shelf life in a setting where there is a lower risk of transmission if feasible (for example, non-surgical, non-sterile, patients with no known COVID 19 diagnosis). The user should visibly inspect the gloves prior to use and, if there are concerns (for example, discolored or visible tears, holes), discard the gloves.
- Extend the use of medical gloves without changing the gloves between patients with no known infectious diseases. Gloved hands should be cleaned between patients and at other times when hand hygiene would normally be performed during routine patient care. Alcohol-based hand sanitizers may degrade vinyl gloves. If a glove becomes damaged (for example, discolored, deteriorated, visible tears, holes), contaminated (for example, body fluids, chemotherapy drugs) or no longer provides a liquid barrier, replace it.
- Consider using radiographic protective gloves or radiation attenuating surgeon's gloves that are clean and offer fluid barrier protection. These gloves cannot be sterilized but can be cleaned following the manufacturer's labeling.
- Consider using non-medical gloves such as those used for food service, embalming, cleaning, or other industrial-grade gloves that most closely align with the ASTM standards for medical gloves as outlined in the FDA's Medical Glove Guidance Manual (/regulatory-information/search-fda-guidance-documents/medical-glove-guidance-manual).
- **Be aware that counterfeit medical and non-medical gloves may be on the market, especially during this time of increased demand**.

FDA Actions

The FDA is collaborating with manufacturers of medical gloves to better understand the current supply chain issues related to the COVID-19 pandemic and to help mitigate any widespread shortages of these products.

On March 25, 2020, the FDA issued the guidance, Enforcement Policy for Gowns, Other Apparel, and Gloves During the Coronavirus Disease (COVID-19) Public Health Emergency (/regulatory-information/search-fda-guidance-documents/enforcement-policy-gowns-other-apparel-and-gloves-during-coronavirus-disease-covid-19-public-health). This guidance provides a policy to help expand the availability of surgical apparel for health care professionals during the COVID-19 public health emergency.

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

Reporting Problems to the FDA

The FDA encourages users and facilities who are concerned about distribution of a medical product, or anticipates a potential or actual shortage, to notify the FDA. For potential or actual supply issues, email information to the FDA at deviceshortages@fda.hhs.gov (mailto:deviceshortages@fda.hhs.gov).

The FDA also encourages health care providers to report any adverse events or suspected adverse events experienced with medical gloves.

- 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).
- Health care 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, 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)