

Public Health Service

Centers for Disease Control and Prevention (CDC) Atlanta GA 30329-4027

October 19, 2023

The Honorable Greg Landsman U.S. House of Representatives Washington, DC 20515

Dear Representative Landsman:

Thank you for your letter to Health and Human Services (HHS) Secretary Xavier Becerra regarding the feasibility and potential benefits of the increased use of reusable healthcare textiles (HCTs) in healthcare settings to protect healthcare workers, address the rising environmental impact of disposables, prepare for future pandemics, and potentially provide cost savings. I am responding on behalf of Secretary Becerra.

Healthcare facilities must ensure optimal protection of patients and healthcare workers. The Centers for Disease Control and Prevention (CDC) produces recommendations about the types of personal protective equipment (PPE) that should be used by healthcare personnel when caring for patients with infectious diseases. In most instances, CDC guidance currently allows for disposable and reusable PPE. However, recommended PPE, whether it is disposable or is able to be reprocessed and reused, should meet recommended current, minimum standards.^{1,2}

For example, CDC recommends that gowns used to care for patients known or suspected to be infected with certain pathogens meet specific standards for fluid resistance.^{3,4,5,6} In addition, masks that are used to protect healthcare personnel against splashes and sprays to their mucous membranes should also meet standards for fluid resistance.

Reusable medical textiles that are used as PPE should have validated reprocessing instructions to ensure that any risks from residual infectious fluids are eliminated and that the reprocessing does not impact safety parameters (e.g., physical and barrier performance of PPE, respiratory or

¹ U.S. Food and Drug Administration (FDA). Personal Protective Equipment for Infection Control. <u>https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/personal-protective-equipment-infection-control</u>

² U.S. FDA. Personal Protective Equipment for Infection Control: Medical Gowns. <u>https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/medical-gowns</u>

³ CDC's Core Infection Prevention and Control Practices for Safe Healthcare Delivery in All Settings. <u>https://www.cdc.gov/infectioncontrol/guidelines/core-practices/index.html</u>

⁴ 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings (Last update: July 2023). <u>https://www.cdc.gov/infectioncontrol/pdf/guidelines/Isolation-guidelines</u>-H.pdf

⁵ Guidelines for Environmental Infection Control in Health-Care Facilities (2003) (Last Update: July 2019). https://www.cdc.gov/infectioncontrol/pdf/guidelines/environmental-guidelines-P.pdf

⁶ Guidance on Personal Protective Equipment (PPE) To Be Used By Healthcare Workers during Management of Patients with Confirmed Ebola or Persons under Investigation (PUIs) for Ebola who are Clinically Unstable or Have Bleeding, Vomiting, or Diarrhea in U.S. Healthcare Settings, Including Procedures for Donning and Doffing PPE. https://www.cdc.gov/vhf/ebola/healthcare-us/ppe/guidance.html

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dermal reactions due to the residuals from the reprocessing, environmental safety, and processors' health and safety). Outbreaks have occurred related to improperly reprocessed medical textiles (e.g., sheets), including outbreaks of invasive fungal infections among immunocompromised patients related to contamination during the laundry process.^{7,8,9} Additionally, the effectiveness of the laundering process depends on multiple factors that can vary between facilities and even facility types.

The environmental impact of disposable PPE can be considerable, and options that reduce waste but still provide protection for healthcare personnel could be valuable. In addition to CDC recommendations, ^{10,11,12,13} many types of PPE are regulated by other federal agencies (for example, gowns are regulated by the U.S. Food and Drug Administration through a number of pathways), and these agencies would provide regulatory oversight of many of the medical textiles that your letter describes.

As you have noted, an issue of recent concern involves the use of disposable (i.e., single use) versus reusable (i.e., multiple use) surgical attire and fabrics in healthcare settings. Regardless of the material used to manufacture gowns and drapes, these items must be resistant to liquid and microbial penetration. CDC's *Guidelines for Environmental Infection Control in Healthcare Facilities*¹⁴ includes a section on laundry in a healthcare facility.¹⁵ However, this is mainly focused on linens, personal clothing/patient apparel, uniforms, scrub suits, and similar items, and not on reusable PPE beyond surgical gowns.

Within CDC, the National Institute for Occupational Safety and Health (NIOSH) and its National Personal Protective Technology Laboratory are dedicated to addressing all issues concerning PPE, including opportunities for supporting and sustaining the increased use of reusable PPE in healthcare settings.

⁷ Alexander J Sundermann and others, How Clean Is the Linen at My Hospital? The Mucorales on Unclean Linen Discovery Study of Large United States Transplant and Cancer Centers, Clinical Infectious Diseases, Volume 68, Issue 5, 1 March 2019, Pages 850–853, <u>https://doi.org/10.1093/cid/ciy669</u>

⁸ Jordan A, James AE, Gold JAW, Wu K, Glowicz J, Wolfe F, Vyas K, Litvintseva A, Gade L, Liverett H, Alverson M, Burgess M, Wilson A, Li R, Benowitz I, Gulley T, Patil N, Chakravorty R, Chu W, Kothari A, Jackson BR, Garner K, Toda M. Investigation of a Prolonged and Large Outbreak of Healthcare-Associated Mucormycosis Cases in an Acute Care Hospital-Arkansas, June 2019-May 2021. Open Forum Infect Dis. 2022 Oct 17;9(10):ofac510. doi: 10.1093/ofid/ofac510

⁹ Janet Glowicz, Isaac Benowitz, Matthew J. Arduino, Ruoran Li, Karen Wu, Alexander Jordan, Mitsuru Toda, Kelley Garner, Jeremy A.W. Gold, Keeping health care linens clean: Underrecognized hazards and critical control points to avoid contamination of laundered health care textiles, American Journal of Infection Control, Volume 50, Issue 10,2022, Pages 1178-1181, ISSN 0196-6553, <u>https://doi.org/10.1016/j.ajic.2022.06.026</u>

¹⁰ CDC's Core Infection Prevention and Control Practices for Safe Healthcare Delivery in All Settings. <u>https://www.cdc.gov/infectioncontrol/guidelines/core-practices/index.html</u>

¹¹ 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings (Last update: July 2023). <u>https://www.cdc.gov/infectioncontrol/pdf/guidelines/Isolation-guidelines-H.pdf</u>

¹² Guidelines for Environmental Infection Control in Health-Care Facilities (2003) (Last Update: July 2019). https://www.cdc.gov/infectioncontrol/pdf/guidelines/environmental-guidelines-P.pdf

¹³ Guidance on Personal Protective Equipment (PPE) To Be Used By Healthcare Workers during Management of Patients with Confirmed Ebola or Persons under Investigation (PUIs) for Ebola who are Clinically Unstable or Have Bleeding, Vomiting, or Diarrhea in U.S. Healthcare Settings, Including Procedures for Donning and Doffing PPE. https://www.cdc.gov/vhf/ebola/healthcare-us/ppe/guidance.html

¹⁴ https://www.cdc.gov/infectioncontrol/pdf/guidelines/environmental-guidelines-P.pdf

¹⁵ https://www.cdc.gov/infectioncontrol/guidelines/environmental/background/laundry.html

NIOSH previously conducted a study on reusable isolation gowns in which the change in the physical and barrier performance of reusable isolation gowns after multiple processing cycles was studied using standardized laboratory test methods.¹⁶ The findings of this study were reported to the American Society of Testing and Materials (ASTM) International's F23 Committee on Personal Protective Clothing and Equipment and used in the minimum performance requirements of the new isolation gowns standard (ASTM F3352).¹⁷ The study highlighted that multiple reusable isolation gown models on the U.S. market (six of nine models) failed to align with the American National Standards Institute/Association for the Advancement of Medical Instrumentation PB70 requirements for liquid barrier performance at the level specified by the manufacturer after one and multiple laundering cycles.

NIOSH also conducted studies to explore the impact of the decontamination process on multiple PPE items to evaluate the reuse potential of disposable products after decontamination.¹⁸ For example, disposable surgical and isolation gowns, which have been considered for reuse during pandemics and epidemics, and powered air purifying respirator hoods, which are made of disposable materials but generally reused after the decontamination process, were studied in these projects. As a follow-up study, NIOSH started a pilot project that is evaluating the effectiveness of chemical decontamination methods used in healthcare settings for one of the commonly used disposable PPE fabrics, spunbond meltblown spunbond (commonly known as SMS) nonwoven textiles. These fabrics are mostly used in the construction of gowns, head covers, powered air-purifying respirator hood assemblies, and sleeve protectors.

NIOSH will also conduct a study of the potential benefits and feasibility of increasing the usage of reusable HCTs and any potential savings that would be gained through their use. This will include examining ways to encourage healthcare facilities to integrate more reusable HCTs into their activities and commissioning a National Academies Workshop on the topic to be conducted in spring 2024. NIOSH has identified several key issues related to reusable HCTs that will be included in the proposed study. These include the availability of good quality products, the availability of service providers (e.g., cleaning/decontamination services, repairs, quality checks, sizing, stocking), user acceptability, comparative analyses of life cycle costs, thermal comfort, and a rigorous review of studies regarding environmental impact. NIOSH intends to conduct research to further explore each of these issues.

The study's final report describing the feasibility and potential benefits of the increased use of reusable HCTs will consolidate NIOSH research conducted from August 2023-May 2024 to explore the issues described above and report on the pilot research. The report is expected to be completed by August 2024.

¹⁶ Selcen Kilinc-Balci, and Patrick Yorio, Comparison of Physical and Barrier Performance of Reusable Isolation Gowns, 8th European Conference on Protective Clothing, Porto, Portugal, May 7-9, 2018.

¹⁷ ASTM F3352. Standard Specification for Isolation Gowns Intended for Use in Healthcare Facilities; 2023. West Conshohocken, PA: ASTM International.

¹⁸ Selcen Kilinc-Balci, Zafer Kahveci, Christian Coby, Patrick L. Yorio, How do Disinfecting Wipes Impact the Barrier Performance of Protective Clothing?" 10th European Conference on Protective Clothing, Arnhem, Netherlands, May 9-12, 2023.

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I appreciate your letter about this public health issue. If you have further questions, please have your staff contact Jeff Reczek in our CDC Washington Office at (202) 245-0600 or JReczek@cdc.gov.

Sincerely,

Mardy Klahn

Mandy K. Cohen, MD, MPH Director, CDC Administrator, Agency for Toxic Substances and Disease Registry

cc:

The Honorable Mike Carey The Honorable Ann McLane Kuster The Honorable Max Miller The Honorable Glenn "GT" Thompson