Open Letter to the Centers of Disease and Prevention (CDC)

Dr. Rochelle P. Walensky, MD, MPH May 5, 2023

Director, Centers for Disease Control and Prevention

1600 Clifton Road, Atlanta, GA 30329

Dear Dr. Walensky,

We honor Dr. Rutala's lifetime contribution to science, public health, and the Sterile Processing industry, and it is through this spirit of scientific advancement that we strive to continue his work. This letter is an effort to support areas that may already have been underway within the wider community of infection prevention and Sterile Processing while also seeking to raise awareness of the need for future development. It is with this aim that updating the CDC's guidelines would strengthen and improve international adherence to the most current evidence of best practice.

Purpose

A taskforce was developed from the Beyond Clean Advisory Committee specifically designated to target the review of the *Guidelines for Disinfection and Sterilization in Healthcare Facilities, 2008 Centers for Disease Control and Prevention* (CDC, 2019). The purpose of this committee was to identify high priority, critical areas within the document (or absent from it) that we would advocate for updating on behalf of our Sterile Processing industry.

Objective

Propose a revision to the CDC guidance by providing recommendations, in alignment with national HAI prevention goals, that improve patient outcomes related to medical device reprocessing.

Background

As the CDC makes deliberate efforts to "reset" their organizational approach for improved responsiveness to public health interests, a window of opportunity has opened to take a closer look at the 2008 sterilization and disinfection guidelines document and request consideration for revisions that address the changing landscape of medical device reprocessing, particularly in relation to the cascading effect on healthcare systems from emerging threats such as growing antimicrobial resistance, and novel pathogens (NPR, 2022). Beyond Clean has supported this effort to improve patient safety protocols related to medical device reprocessing by coordinating a workgroup specifically tasked with reviewing the current language of the CDC's sterilization and disinfection guidelines document and provide recommendations that are centered on critical areas to improve patient outcomes (CDC, 2019).

Justification and Implementation Context

- *High Impact Finding 1:* Fragmented Guidance within CDC website imposes risks to end users of missing content. Multiple pages within the CDC website are not linked to the CDC 2008 Disinfection and Sterilization Guidance page creating gaps in adherence to standards for clinical practice.

Recommendation: An update to the CDC 2008 Disinfection and Sterilization Guidance webpage would increase the probability of adherence to standards by reducing gaps in access to content by creating one central medical device reprocessing hub for all healthcare settings.

Rationale: Exhibit A provides examples of two pages which are located outside of the CDC 2008 Disinfection and Sterilization Guidance page.

Exhibit A:

1. Oral Health: https://www.cdc.gov/oralhealth/infectioncontrol/index.html
2. Creutzfeldt-Jakob Disease, Classic (CJD): https://www.cdc.gov/prions/cjd/index.html

- *High Impact Finding 2:* Currently, the CDC 2008 Disinfection and Sterilization Guidance contains outdated terminology that does not align with other standards documents and increase opportunities for confusion amongst industry professionals.

Recommendation: Align terminology with industry best practice.

Rationale: Globally unified language reduces the probability of misinterpretation and sets the guardrails in error proofing and risk mitigation. It is highly encouraged to conform to ISO standards for harmonized terminology.

Appendix A sufficiently validates the significance of each outdated section in Table 1: *Evidence to Support High Impact Findings*

- *High Impact Finding 3:* Multiple sections within the CDC 2008 Disinfection and Sterilization Guidance contains outdated content related to recommendations and supporting evidence.

Recommendation: The CDC 2008 Disinfection and Sterilization Guidance must be updated to reduce the risk of healthcare associated infections globally. Current state leads to a non-standard approach of care between healthcare institutions resulting in increased risk of harm.

Rationale: Due to the international scope of reach and the limitations of some healthcare settings to access other industry standards publications (i.e., ANSI/AAMI), the CDC guidelines for sterilization and disinfection are relied upon for reduction of risk and cross-contamination for zero preventable harm. Conformance to standards of care improves high reliability creating quality assurance in scientific evidence-based practice.

Appendix A sufficiently validates the significance of each outdated section in Table 1: *Evidence to Support High Impact Findings*

- *High Impact Finding 4:* Recent adverse health events and FDA recalls have highlighted the need for modification of the Spaulding Classification scheme. Internationally, devices that are classified as semi-critical, per the current Spaulding Classification, may be used to access critical tissue. The practitioner determines if disinfection or sterilization is required based on the language of the CDC 2008 Disinfection and Sterilization Guidance.

Recommendation: Dr. Rutala's recent work to modify the Spaulding scheme must be incorporated in the CDC 2008 Disinfection and Sterilization Guidance.

Rationale: According to Dr. William Rutala, in an article recently published by Susan Klasik, "the Spaulding classification for critical items should be modified from 'direct contact with sterile tissue'

to ‘direct or secondary/indirect contact with sterile tissue.’ He further noted that when the Spaulding system was designed 50 years ago, semicritical items rarely, if ever, penetrated sterile tissue and healthcare did not have an adequate appreciation for the infection risk associated with endoscope reprocessing, with endoscopes used primarily for diagnostic purposes” (Klasik, 2019; Rutala, 2022).

Internationally, medical devices (bronchoscopes, ureteroscopes, cystoscopes, cystoureteroscopes, ureterorenoscopes, duodenoscopes, etc.) that are categorized as semi-critical, according to the current Spaulding scheme, are used to access critical tissue. As described in the 2008 CDC Sterilization and Disinfection Guide, these devices can be disinfected.

In a study published in 2011, researchers challenged the current phrasing of the Spaulding scheme stating that “the understanding of microbiology and micro-organisms has changed” since it’s inception and “the expectations for the efficacy of various levels of disinfectants, and even sterilants, and how they are determined may need to be reconsidered” (McDonnell & Burke, 2011). The following is Dr. Rutala’s modified phrasing of the Spaulding scheme for critical devices:

“CRITICAL - objects which directly or secondarily (i.e., via a mucous membrane such as duodenoscope, cystoscope, bronchoscope) enter normally sterile tissue or the vascular system or through which blood flows should be sterile” (Rutala, 2022).

Appendix A sufficiently validates the significance of each outdated section in Table 1: *Evidence to Support High Impact Findings*

- *High Impact Finding 5:* Lack of clearly defined expectations for standardization of education and documentation criteria. Accreditation organizations, state health agencies, and healthcare organizations are left to interpret these guidelines on their own terms.

Recommendation: Clearly defined expectations for standardization of education and documentation criteria for medical device reprocessing.

Rationale: Through the U.S. Department of Health & Human Services (HHS) Health Care-Associated Infections Steering Committee, the National Action Plan to Prevent Health Care-Associated Infections: Road Map to Elimination “provides a strategic framework for a national HAI prevention agenda that communicates a vision for improving health” (HHS, 2013; & ODPHP, 2020). Interventional strategies listed for “implementing state activities to build capacity for HAI prevention” within the Healthcare-Associated Infections: Prevention Status Reports (PSR) National Summary include “optimizing infection control practices within healthcare facilities” and includes “conducting or supporting HAI training” (CDC, 2019). This national HAI program points to state strategies for education initiative however most states do not clarify requirements for education (APIC, 2017; CDC, 2019; & ODPHP, 2020). Furthermore, the CDC/FDA advisory statement, *Immediate Need for Healthcare Facilities to Review Procedures for Cleaning, Disinfecting, and Sterilizing Reusable Medical Devices*, doesn’t provide detailed criteria expectations for implementation of competence-based education approaches or its documentation (CDC/FDA, 2015). Without clearly defined expectations for standardization of education and documentation criteria, accreditation organizations, state health agencies, and healthcare organizations are left to interpret these guidelines on their own terms. Since every essential job function of Sterile Processing is designed to eliminate the risk of HAIs, a revision of the regulations by providing explicit definition and expectations of HAI prevention competence for Sterile Processing personnel is vital to adherence of industry standards for scientific evidence of best practice.

Appendix A sufficiently validates the significance of each outdated section in Table 1: *Evidence to Support High Impact Findings*

Limitations

Considering the scope of this workgroup, and the intent to provide a letter to the CDC which will invoke a response to compelling, evidence-based recommendations, we understand the need to focus on a few high priority findings, which may not address all areas identified. With this in mind, we can begin the process of open dialogue which can spark movement for additional improvements through future work. We anticipate that this project will produce a working document that will serve to initiate necessary changes to the language of the CDC's 2008 sterilization and disinfection guidance document to builds capacity for better adherence to the most current scientific evidence of best practice (CDC, 2019).

Conclusion

The CDC is uniquely positioned, as a global health actor, to influence the adherence of best practice by advocating for the most current scientific evidence. From the perspective of both the CDC's mission as well as the scope of its reach, there is a tremendous opportunity to improve patient outcomes, related to medical device reprocessing. We appreciate the careful attention that you will provide for each of the recommendations we have made. Aligning the CDC's resources and guidance with the broader community of infection prevention and Sterile Processing can promote one cohesive message that strengthens the link between evidence and practice.

Sincerely,

Beyond Clean Advisory Committee:

2008 CDC Disinfection and Sterilization Guidelines Taskforce

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Appendix A

See the appendix here

Table 1: Evidence to Support High Impact Findings