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Letter to the Editor

Clinical laboratory equipment manufacturers' lack of guidance for high consequence pathogen response is a critical weakness

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Clinical laboratory equipment (CLE) are invaluable diagnostic tools to support the management of patients suspected or confirmed to be infected with high consequence pathogens (HCP), such as Ebola virus (EBOV) or Nipah virus.[1] CLE need to safely evaluate specimens that may contain a HCP without voiding the manufacturer's warranty or impacting subsequent use for routine clinical care. It is important for CLE manufacturers to provide this guidance because the Centers for Disease Control and Prevention (CDC) defers to the manufacturers in HCP scenarios stating "laboratories should consult the manufacturers' instructions, or the manufacturer directly, on whether there is a need and how to decontaminate the interior surfaces or areas of their specific laboratory instruments".[2] The absence of this information from the manufacturer and uncertainty related to warranty/service implications after potential use for HCP directly impacts patient care and public health response, as some hospital administrators have opted not to use CLE on patients with confirmed or suspected HCP infection to avoid losing CLE use for other patients.[3]

In response to manufacturers' policies during the 2013 EBOV outbreak, a 2019 study contacted manufacturers regarding testing confirmed or suspected HCP specimens and the impact on CLE decontamination and warranty/service contracts.[4] Some manufacturers were uncertain of their policies or would void CLE warranties and/or service contracts; other manufacturers recommended CLE used for HCP specimens be either disposed or quarantined which not only conflicts with scientific evidence and federal/international agencies' guidance but is also cost prohibitive, unsustainable, and could result in lack of life-saving diagnostics for other patients.[4] That study found insufficient availability of EBOV or HCP policies from manufacturers to support clinical laboratories.[4] This lack of guidance remains and is almost completely undocumented; not having such information continues to severely impact clinical care. Given the frequency and burden of HCP outbreaks (eg, Uganda-2022 with *Sudan ebolavirus*,[5] Nigeria-ongoing with Lassa fever virus,[6] Equatorial Guinea with Marburg virus-2023),[7] this study update was conducted to examine current policies from CLE manufacturers on how to handle equipment potentially exposed to a HCP.

Exploring manufacturers' policies

Thirteen major manufacturers of CLE (labeled Company A-M) used for testing suspected or confirmed HCP specimens were contacted. Nine of these companies were contacted previously[4]; four manufacturers were added due to company mergers/acquisitions. In Spring 2023, a standardized email and phone script was used (Supplemental Material, Appendix A) to contact manufactures regarding current HCP policies/guidance on warranties, decontamination, and CLE re-use. Of the current 13 companies, only three responded (23%). Figure 1 summarizes our timeline and challenges contacting CLE manufacturers.

Twenty-six online inquiries were submitted to the companies with online portals. Only Company C responded (response rate [RR] = 7.7%). Despite follow-ups, Company C's initial response was their only contact; no information on policies or recommendations were obtained from any company via online inquiry.

Despite multiple attempts, 40 emails (initial and follow-up) resulted in three responses (RR = 7.5%) (Figure 1). Company F's customer service agent referred us to a sales agent who stated there were no contract restrictions for any type of pathogen but did not provide the requested recommendations or policies. A Company H representative stated that they do not provide regulatory or safety guidance to institutions that purchase their products. A Company K representative stated that they cannot comment on specific microorganisms beyond what was tested and published in their Instructions for Use (IFU) (of 11 tested pathogens included, only one was on our HCP list) and could not provide information regarding extrapolation to other pathogens (Supplemental Material, Appendix B).[8] Only 10 (77%) manufacturers had a functional telephone number; none responded.

The limited engagement that persists five years after our initial study is concerning and affirms clinical laboratories' concerns. Literature on this topic remains scarce with only two additional studies addressing the topic of manufacturers' policies for CLE use for HCP.[9,10] Both studies emphasized the importance of the clinical

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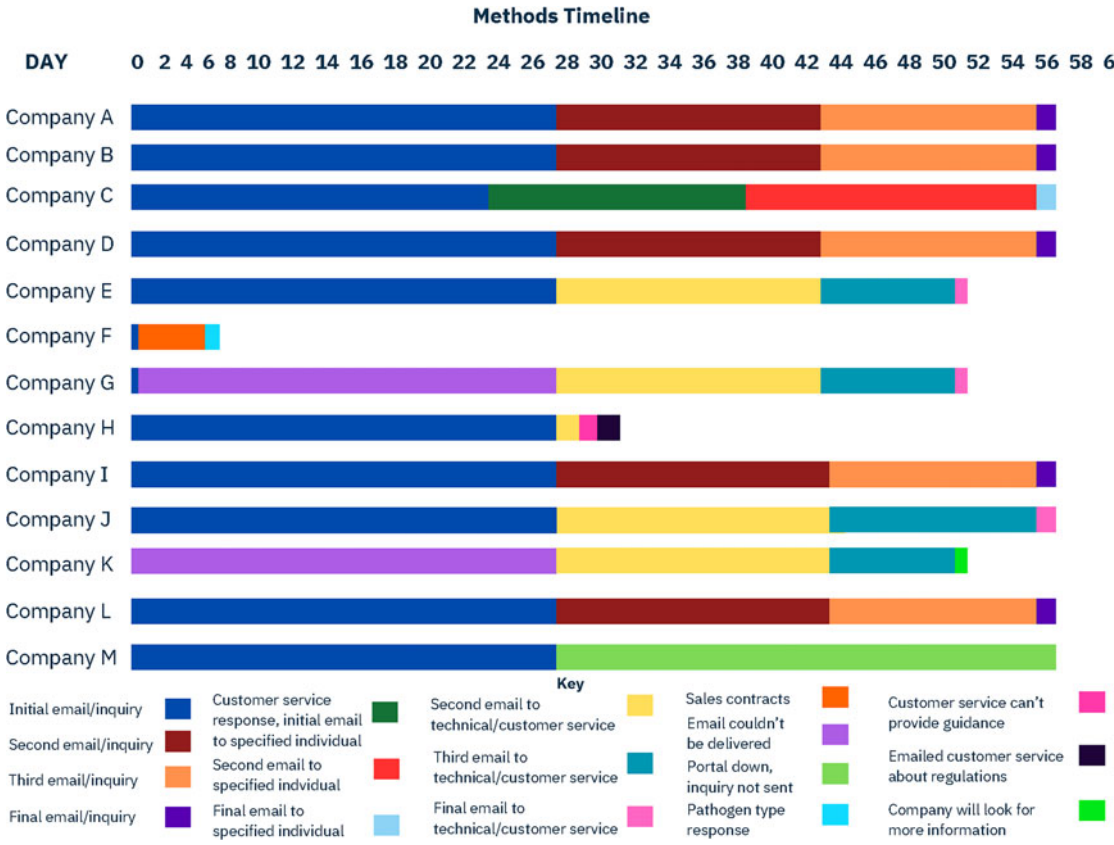

Figure 1. Contact timeline and outcomes for contacting CLE manufacturers.

laboratory's ability to respond to an unknown pathogen quickly, effectively, and safely; however, lack of support from manufacturers could result in poor outcomes that could be avoided with prompt communication and assistance.[9,10]

Given the continued lack of HCP-related guidance from manufacturers post-purchase, we recommend laboratories ask HCP-related questions, document responses, and make response receipt a condition of purchase. Clinical laboratories and healthcare settings must have easy—preferably online—access to manufacturers for prompt responses to questions regarding warranties, contracts, and decontamination policies. Ideally, these would be in the IFU. The challenge of identifying appropriate manufacturer contacts and the absence of response to inquiries have negative implications during outbreaks. Previous manufacturer recommendations to dispose of CLE used for HCP[3] may result in clinical laboratories electing to limit or avoid CLE usage to test patient specimens with potential HCP. Reduction in CLE use can delay or adversely affect the quality of patient care. To optimize patient care, clinical laboratories require support, rapid communication, and clear guidance from CLE manufacturers. It is equally important to ensure manufacturer guidance conforms with scientific evidence and protocols deemed safe and effective by federal and international agencies. We recommend regulatory agencies address these issues, including the timeliness of response to information requests, the availability and monitoring of contact portals, and online availability of existing information. In conclusion, our findings underscore how nonresponse is informative but alarming; this continued dearth of information is detrimental to patient management and public health.

Supplementary material. The supplementary material for this article can be found at https://doi.org/10.1017/ice.2024.39.

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