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The Changing Landscape of Automation in the Practice of Diagnostic Medical Microbiology: But What about Safety?

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Abstract

The clinical microbiology laboratory is undergoing a transformation in diagnostic testing as result of entering the "machine" or "robotic" age with the development and availability of automation, primarily molecular-based multiplex instruments and total laboratory automation. Automation provides substantial benefits to the laboratory, administrators, clinician, and, ultimately, patient. Major benefits include faster and more accurate results, improved workflow efficiency, high-throughput testing, reduction of laboratory costs, reduction of human error, and, for the most part, saving valuable space. Although the benefits are welcome, the issue of safety, especially how to effectively decontaminate (sterilize) the internal compartments and components of these devices, is in need of resolution. An instrument that is contaminated with blood, body fluids, and other liquid specimens that may contain a virulent pathogen, such as Ebola virus or a biothreat agent, represents a safety hazard to personnel and the environment.

Introduction

The practice of diagnostic medical microbiology in today's clinical microbiology laboratory is undergoing significant evolution, driven primarily by advances in automation. Recent changes represent the largest paradigm shift since the introduction of the polymerase chain reaction. Emerging diagnostic technologies highlighted by molecular-based, automated open and closed systems designed to provide rapid detection of infectious agents, including respiratory viruses and gastrointestinal pathogens; direct identification of blood culture isolates; and genes that code for antibiotic resistance and agents of meningitis are reshaping diagnostic microbiology (Fig. 1). These technologies, along with mass spectrometry and the total laboratory automation systems, have significantly improved and streamlined the detection and identification of infectious agents versus conventional methods, and from the administrative perspective, they improve efficiency and productivity, reduce turnaround time, and potentially influence patient management and outcome [1]. Each of these instruments is unique in terms of the nature of assays performed, functionality, and test design, but from a structural perspective, they have much in common with regard to their structural components: metal (stainless steel), plastics (tubing), rubber (sealing purposes), synthetic polyester, glass, lubricants, robotics, and electronics. Despite their advanced technology, there are critical questions related to the safety of their use. For example, in the event of instrument contamination with a virulent pathogen as a result of spillage, breakage, aerosolization, splashing, or spraying, what is the impact on personnel and environmental safety? What specific guidelines and procedures are recommended and available to clean, disinfect, and decontaminate both the exterior and, most importantly, the internal infrastructure of these instruments? These and related challenges are addressed in this discussion. The term decontamination is used interchangeably with sterilization.

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Figure 1. Representative automated instruments susceptible to external and internal contamination. Note that the GeneXpert cartridge is processed under a hood, so it no longer poses a biological threat, and similarly, specimens are also extracted prior to use on the Luminex instrument; however, if a release or malfunction of the instrument occurs prior to extraction, it is possible to contaminate the instrument (externally and internally).

Background

Instrument decontamination was not thought to be anything more than a peripheral issue, and prior to the recent Ebola virus outbreak, it did not receive much attention. It was generally accepted dogma that the manufacturer's recommendations for cleaning, disinfection, and decontamination were acceptable and definitive. However, these recommendations applied to the external rather than the internal portion of the instrument. A major concern of those medical facilities that received and treated patients with active Ebola infection was determining where diagnostic testing would be performed—in the clinical laboratory or an isolated, dedicated space in close proximity to direct patient care using acquired, dedicated point-of-care instruments. Another major concern was how to effectively clean, disinfect, and decontaminate the instruments prior to removal from service while maintaining personnel and environmental safety. During the Ebola scare, the reliability and effectiveness of the cleaning, disinfecting, and decontamination methods to ensure that the instruments were free of the Ebola virus and other pathogens were uncertain—in some cases, they are still uncertain. Total physical destruction, followed by heat sterilization of the instrument components, was contemplated as being the most effective means for assuring and maintaining the safety of personnel and the environment. Instrumentation used in support of biothreat agent research at the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) "will be held in quarantine and destroyed before being removed from the designated containment area" (personal communication). Prions pose the greatest challenge to decontamination due to their high resistance to standard decontamination methods (Table 1). Application and utilization of extreme heat-based and/or chemical treatments is essential for complete inactivation.

Knowing that instruments, including those shown in Fig. 1, are complex, sensitive to environmental conditions, and expensive, the goal should be to retain the instruments for future use, not only in support of Ebola patients, but also for patients infected with other virulent agents. For this concept to become a reality, greater emphasis on and understanding of the importance of cleaning, disinfection, and decontamination of both the external and internal portions of the instrument in question is required.

The Filmarray instrument (Biofire Diagnostics, Salt Lake City, UT) was used extensively for testing blood samples in support of the Ebola outbreak in Liberia, Guinea, and Sierra Leone and for patients transported to the designated treatment centers in the United States. At the end of service, the instruments were cleaned and disinfected by personnel wearing appropriate personal protective equipment and shipped to the manufacturer, who in turn contracted the final decontamination phase using ethylene oxide as the decontaminating agent (personal communication). The effectiveness of this gaseous compound as a decontamination agent

Table 1. Descending order of resistance to decontamination

- Prions
- Bacterial spores (*B. anthracis*, *Clostridium sporogenes*)
- *Mycobacteria tuberculosis* var. *bovis*, NTM
- Nonlipid or small viruses (poliovirus, coxsackievirus, rhinovirus)
- Fungi (*Trichophyton*, *Cryptococcus* spp., *Candida* spp.)
- Vegetative bacteria (*Pseudomonas aeruginosa*, *S. aureus*, *Salmonella choleraesuis*, multiple-drug-resistant organisms)
- Lipid or medium-size viruses (herpes simplex virus, cytomegalovirus, Rous sarcoma virus, hepatitis B virus, hepatitis C virus, HIV, hantavirus, Ebola virus)