LETTER TO THE EDITOR

Decontamination of Extracorporeal Membrane Oxygenator Devices With an Intensified Disinfection Protocol: How Strict Is Too Strict?

To the Editor—In a recently published article, Garvey et al[1] describe the successful water decontamination from mycobacteria in an extracorporeal membrane oxygenator device (ECMO) when applying an intensified weekly disinfection protocol.

The study refers to the intensified disinfection protocol for the Maquet ECMO Heater Unit 35 device (HU35, Rastatt, Germany), released in September 2016.[2] This new maintenance guideline requires HU35s to be disinfected after each patient and at least every 7 days, compared to a monthly disinfection cycle recommended previously. Also, the intensification of the protocol depends on whether atypical mycobacteria were previously detected in a given device.[2] These measures were put in place following reports of invasive and fatal infections with atypical mycobacteria transmitted by heater-cooler devices (HCDs) in cardiac surgery.[3,4]

We call the proportionality of these measures into question. First, there is currently no conclusive link between HU35 colonization and human disease.[1,5] Moreover, we do not know whether the intensified protocol completely eliminates mycobacteria or just suppresses them below the detection limit. Finally, the manual states that the HU35 must be disinfected every 7 days, even if the ECMO device is in use.[2] Because the oxygenator is part of the heater-cooler water circuit, it is not sufficient to disinfect only the HU35 device. Consequently, the complete ECMO system would have to be separated from the patient and exchanged after 7 days of treatment. In addition to causing substantial costs for disposable materials, this is a risky maneuver for patients who depend on ECMO-assisted oxygenation and/or circulation.

While applying the previous monthly disinfection regimen in our institution, *Mycobacterium chimaera* was isolated in some but not all of the HU35 water circuits. This finding may suggest an overall low mycobacterial concentration in the HU35 water. Also, total microorganism counts in the HU35 water were mostly in the range of drinking-water quality (Table 1).

Notably, the HU35 works differently than the incriminated HCDs used for cardiac surgery. The latter involve open water tanks and a fan for cooling, due to which infectious aerosols may be propelled from the device to the patient environment.[3,4] HU35s, in contrast, are closed air tight and have no ventilation to the outside. It would, therefore, require a breach in the ECMO exchange membrane for a transmission to the patient to occur. In HCDs, this is an extraordinarily rare event.[6] Even if it occurred, the higher pressure in the patient circuit would likely cause a blood spillover into the ECMO circuit but not the other way around. In the very unlikely case of a massive water/blood exchange, mycobacterial contamination would presumably be the least problem for the patient.

The time needed to clean a single HU35 device in our institution is approximately 2–2.5 hours or at least 10 hours per week for our 5 devices. This total time does not include additional intermediate cleaning procedures for short-term ECMO use. Furthermore, costs for mycobacterial cultures and disposable materials are substantial.

We consulted with the Swiss Federal Office of Public Health, and they recognized that the updated measures are quite strict and not evidence based. In cases like this, a healthcare institution may therefore decide to deviate from the procedure suggested by the manufacturer. According to Swiss Medical Devices Ordinance articles 19 and 20, legal responsibility for a device is transferred from the manufacturer to the user in case of deviation from a maintenance protocol.[7] However, according to Swiss law, the user is only liable if damage can causally be attributed to noncompliance with the manufacturer's protocol. The Swiss Agency for Therapeutic Products can examine the conformity of disinfection procedures of medical devices through on-site inspections. According to Swiss legislation, if an institution choses to deviate from a maintenance protocol, this has to be substantiated scientifically, documented, and kept on file to accommodate inspections.

To the best of our knowledge, we do not endanger our patients by continuing to adhere to the established monthly

TABLE 1. Settings and Results of the HU35 Sampling

HU35 Serial No.	Sampling Date	Last Disinfection and Water Change	Total Microorganisms Per mL Water[a]	*Mycobacteria*[b]
90004272	3 Aug 2017	14 Jul 17	30	*M. chimaera*
90004206	3 Aug 2017	4 Jul 17	65	No growth
90004385	3 Aug 2017	26 Jul 17	540	*M. chimaera*
90004559	3 Aug 2017	2 Aug 17	5	No growth

NOTE. HU35, heater unit 35 device.

[a]A 200 µL volume was plated on blood agar supplemented with 2% sheep blood and incubated for 4 days at 36°C.

[b]50 mL water samples, processed as described previously.[3]

disinfection protocol. Therefore, the infection control unit and the department of intensive care medicine of our institution decided to assume joint responsibility for the protocol deviation. A corresponding document was created, signed, and filed by the parties involved. The document will be scrutinized as new evidence becomes available.

In conclusion, it may be possible to deviate from a disinfection protocol that is perceived as too strict, provided that the deviation is well justified and does not jeopardize patient safety. Should other institutions decide to take a similar approach, local legislation and other particularities need to be taken into consideration.

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