The Value of Heat Disinfect in Dialysis

An AmeriWater White Paper Authored By
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INTRODUCTION

The current standards[1] and regulations[2] governing U.S. hemodialysis treatment have seen considerable change with the adoption of the 2011 AAMI/ISO 23500 standard. This standard reduced the endotoxin levels in water used for dilution of hemodialysis concentrates 10 fold (endotoxin limits were reduced from 2EU to 0.25 EU).[10]

Because heat has been used to disinfect dialysis machines for years it seems to follow that heat might be a way to also disinfect water treatment and distribution systems.

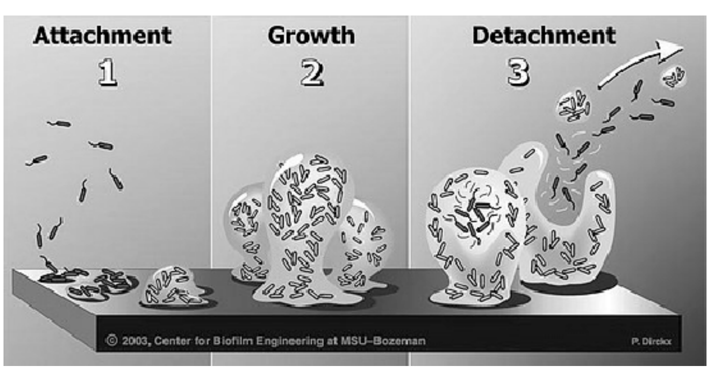
This report outlines the current and future regulatory and clinical environment and how heat disinfection might work and be an answer to these new standards and future regulations.

It also provides information on whether heat is really an adequate disinfectant and appropriate for dialysis.

WHY HAVE THESE STANDARDS BEEN ENACTED

Bacteria is everywhere. Gram negative bacteria builds a shelter in aqueous solutions called biofilm. This biofilm is found on the inside of pipes, tubes and equipment in an aqueous environment.[4, 5]

Biofilm is an extra cellular polymeric substance (EPS) and is a very good shelter for a bacterial community. This community of bacteria within the biofilm excretes waste products by shedding the bacteria's "skin" or endoderma (endotoxin). Also, if bacteria dies or is killed the "body" parts are endotoxin, RNA, DNA, and metabolites.



Biofilm forms fast and will continue to mature as long as there are bacteria to support it. Biofilm is a very good barrier against chemical disinfection. In fact, common chemical disinfectants such as chlorine and peracetic acid (PAA) cannot penetrate the biofilm once it has fully matured.

Bacterial by-products of endotoxin and other cytokines that are present, even at low levels, and in a constant state of contamination in the dilution water for dialysate, cause a chronic state of inflammation in the patient.

If the bacterial by-products and the biofilm that encapsulates them could be eliminated the chronic inflammatory syndrome of the patients could be reduced significantly.[6]

A POSSIBLE APPROACH

Heat disinfection will not remove established biofilms. Because of this our approach must be to prevent biofilm development.[7]

The problem is that bacteria can start to form biofilm within hours. Experimental laboratory studies have shown that planktonic (floating) bacteria can evolve into fully mature biofilm colonies that are extremely resistant to biocides and shed planktonic bacteria within three or four days.

The common practice of monthly disinfection with chemicals is inadequate in preventing the development of a robust biofilm.

The answer to this problem is disinfection on a more frequent basis. Weekly, semi-weekly or even daily disinfection may be required depending on how quickly and how many bacteria enter the dialysis water. Because of this the cost of multiple manual weekly disinfections becomes burdensome. An automated and schedulable disinfection process that is dependable and documented is needed. This need has led us to consider heat disinfection systems.

DOES HEAT DISINFECTION WORK

It is interesting that in research for this report it became clear that there have not been many studies documenting the effectiveness of heat disinfection in high purity water treatment. It seems to be accepted that heating water to 85°C (185°F) for a couple of hours is adequate to kill all bacteria.

In order to receive the FDA approval 510K to market our heat disinfection systems we hired a testing laboratory to validate our heat disinfection systems and determine if heat was an acceptable disinfection process for dialysis water treatment systems.

Laboratory Test Protocol and Results

Dialysate delivery systems and water purification systems for hemodialysis are not considered critical or semi-critical devices by FDA and therefore do not require sterilization or high-level disinfection. The objective of the heat disinfection study was to validate the heat disinfection process following an inoculation procedure. The testing simulated as closely as possible the worst-case conditions under which a heat disinfection system is used. Testing was conducted with clinically relevant waterborne organisms. The organisms used were wild type waterborne microorganisms that have been implicated in disease outbreaks in dialysis clinics. Burkholderia cepacia and Mycobacterium abscessus were the organisms used in the study. A total of three test runs were conducted with each organism. The study was intended to demonstrate that hot water will achieve a minimum of a 6-$\log_{10}$ reduction of Burkholderia cepacia and a minimum of a 3-$\log_{10}$ reduction of Mycobacterium abscessus as required by FDA for intermediate-level disinfection.

A heat disinfection system was connected to a 900' PEX loop with sampling points at 300', 600' and at the loop return (900'). A total of 70 gallons of deionized water was added to the heat disinfection system and distribution loop. For each test run, the heat disinfection system was inoculated by adding a 15.0 mL aliquot test culture directly to the water in the system tank. The water system was allowed to circulate for seven days. On the seventh day, Organism Concentration Population Control samples were obtained. Following the Population Control sampling, the disinfection cycle was initiated per the heat disinfection system instructions for use. The water was heated to a temperature of 185°F and verified at each sampling location. The water was circulated for a two hour disinfection exposure time (at the minimum recommended disinfection temperature of 185°F).

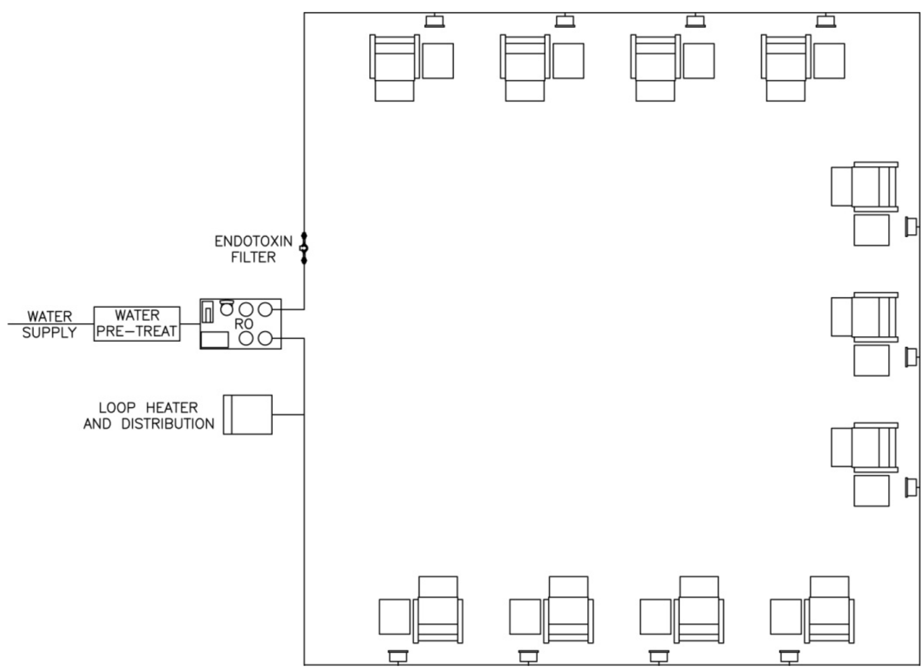
Immediately following disinfection, one water sample of the disinfected water was obtained from each of the three sampling ports (at 300', 600', and loop return). Following disinfected water sampling and cooling, the system was emptied of the remaining water and swab samples were obtained at the designated sample sights.

The heat disinfection system demonstrated a >6-$\log_{10}$ reduction at all sampling locations against Mycobacterium abscessus. The system demonstrated a >7-$\log_{10}$ reduction at all sampling locations against Burkholderia cepacia. Under the conditions of this study, heat disinfection demonstrated intermediate-level disinfection efficacy against Mycobacterium abscessus and Burkholderia cepacia following a two hour exposure time when tested at 185°F.

It is clear from the results of these tests that heat disinfection at 85°C (185°F) for at least two hours will cause at least a 6-$\log_{10}$ reduction of bacteria from the dialysis water system. Because biofilm takes several days to fully mature it seems that weekly disinfection would be a reasonable starting point to control bacteria and it's by-products in the dialysis water system. If however, weekly bacterial cultures and/or endotoxin LAL tests, with samples taken before disinfection, show elevated results it would be necessary to add disinfection one more day per week and continue the process until the number of days per week is determined for the dialysis center, acute treatment or home setting.

It should be noted that local environmental conditions are different and will cause variations in bacterial loading from the water supply, pretreatment equipment and/or reverse osmosis machine which will eventually affect the dialysis water supply.

Typical chronic center water treatment and distribution for dialysis



DIALYSIS WATER TREATMENT

There are three basic venues for hemodialysis treatment: the chronic dialysis center, acute portable treatment and in the home. All three of these settings will benefit from using heat disinfection systems.

It also should be noted that heat disinfection does not eliminate any existing or generated endotoxin in the water treatment system. Because of this it is prudent to always include an endotoxin final filter in the water treatment system. This filter should be an absolute filter validated for endotoxin removal, have a 510K[9] and be able to handle 185°F hot water.

Other features that a heat disinfection dialysis water treatment system should have are the ability to program when disinfection takes place, to alarm if the disinfection did not fully complete, to record the temperature of the disinfection and the length of time of the disinfection. The ability to download these records and keep them electronically or print them is also an important function.

CONCLUSION

It is very clear that central chronic, acute treatment and home care dialysis will benefit from heat disinfection if the AAMI/ISO 23500 standard is to be met and maintained. Heat disinfection is a very safe and effective method of maintaining hemodialysis water treatment systems. In addition it is also a very cost effective process for the dialysis function.

References:

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