ic
INFECTION CONTROL

LETTERS TO THE EDITOR

To the Editor:

The recent article, "Excessive Levels of Gram Negative Bacteria in Hemodialysis Machines Because of Inadequate Cleaning Guidelines," Infection Control 2(5):373-376, by Gurevich, Williams and Cunha, contains two major areas of concern to Cobe Laboratories. First, the authors' recommendations for disinfecting the Centry® 2, if followed, will result in damage to the equipment and may present potential hazards to dialysis patients. Secondly, we believe that the authors' conclusions regarding the efficacy of their disinfection procedure cannot be supported by the data they presented. Our position is outlined below:

1. **Potential Damage to Cobe Centry® Dialysis Equipment**
   Users of Centry 2 dialysis equipment should be aware that Cobe cautions operators *NOT* to introduce sodium hypochlorite into the machine via the water intake hose, as damage to machine components may occur. The Centry 2 has been proven to be capable of withstanding sodium hypochlorite concentrations resulting from the introduction of 5.25% sodium hypochlorite solution only through the concentrate line. The high concentrations of sodium hypochlorite the authors recommend to be introduced through the water supply line have not been tested for materials compatibility by Cobe. The corrosive effects to stainless steel from exposure to concentrated sodium hypochlorite have been well documented. The Centry 2 contains many stainless steel components. Damage to such components have already occurred in Centry 2 units at the authors' institution.
2. **Hazard to Patients**
   It is possible that component failure induced by following the authors' procedure could cause patient injury. We are also concerned with the hazard associated with high residual sodium hypochlorite levels. Since the Centry 2 has not been designed for use with the authors' procedure, the precautions necessary for assuring adequate removal of the more concentrated sodium hypochlorite solution have not been included in either machine design or operator's instructions. We note that the authors did not address this matter in their paper.
3. **Efficacy of the Authors' Recommended Procedure**
   As the authors acknowledge, their center was experiencing high levels of microorganisms in their water supply. If so, their ability to assess the efficacy of any disinfection procedure, using the experimental protocols described, must be called into question.
4. **Errors in the Study**
   We believe there are many errors in this study in addition to the above, and wish to point out a few of the more salient ones.
   A. First and foremost, the authors have failed to differentiate between our recommended cleaning and disinfection procedures. Cobe recommends that after each dialysis treatment, the Centry 2 should be cleaned by introducing a 5.25% solution of sodium hypochlorite through the concentrate line. As the authors point out, this procedure does not result in total fluid pathway contact; therefore, Cobe recommends that the Centry 2 should be disinfected by introducing a 1:10 dilution of 37% formaldehyde and water through the water intake hose, resulting in total fluid pathway contact with the disinfectant.

      The authors have confused these two procedures. Their study *never involved* the testing of Cobe's disinfection procedure; consequently, they

https://doi.org/10.1017/S019594170005565X Published online by Cambridge University Press

present no data to support their conclusion that, "increased bacterial counts could not be reduced by using the manufacturer's disinfection guidelines" (page 373).

Furthermore, the authors' statement that, "it is important that anyone using the Cobe Centry 2 Dialysis Machine realize that it cannot be cleaned as recommended by the manufacturer" (page 376) is also in error. The sodium hypochlorite procedure is intended to clean the fluid pathway, especially those components distal to the dialyzer where dialyzable organics may be deposited. The authors present no data to support their statement that sodium hypochlorite will not effectively clean these solutes out of the Centry 2.

B. The authors have erroneously cited a reference in support of their findings. Reference number 4 is cited to support the authors' findings that, "Bacteria growing in several water reservoirs proximal to the uptake point were able to survive and multiply" (page 376). This paper did not mention the Centry 2 and, in fact, was published in April, 1974, one year *prior* to the Centry 2's introduction.

C. Water entering the C-2's, according to the authors, always exceeded the microbiologic standards for water used to prepare dialysate proposed by the Association for the Advancement of Medical Instrumentation (AAMI).

The water used in the authors' clinic never met Cobe's recommendation for water to be used in the Centry 2. We note the authors' report of water entering Centry 2's with greater than 1000 colonies/ml and exiting many machines at ≤10 colonies/ml. We are puzzled that the importance of this observation was not investigated.

At least two possible explanations exist:

i) The authors are measuring effluent dialysate samples when residual sodium hypochlorite remains in the machine. (The authors provide no data to demonstrate they have adequately removed sodium hypochlorite from the Centry 2's.)

ii) The microbiologic quality of the treated water supplied to the Centry 2's varied with time and machine. If this is the case, the authors' conclusions regarding the efficacy of their recommended disinfection protocol must be rejected, as a controlled level of microbiologic contamination into the machines was not achieved prior to trials of their recommended disinfection protocol.

D. The authors have made numerous statements that demonstrate their lack of understanding of dialysis and of operation of the Centry 2.

i) We trust that the authors are in error when they state that, "copper pipes bring the deionized water into the unit ..." (page 373). Hemodialysis literature reports several instances of patient injury and death caused by copper-induced hemolysis resulting from the passage of highly reactive deionized water through copper pipes.

ii) The authors incorrectly state that concentrate and/or Clorox® may be introduced into the Centry 2 (Figure 2). The use of a combination of concentrate *and* Clorox would obviously be hazardous to dialysis patients.

iii) The authors are incorrect in stating that "the machine cleared the disinfectant automatically and signalled when rinsing was complete" (page 374). The Centry 2 does not signal when rinsing of sodium hypochlorite is complete.

iv) The authors are incorrect in stating that, "sodium hypochlorite was being diluted 34:1, the same as the dialysate concentrate ..." (page 375). The Centry 2 will draw sodium hypochlorite in at approximately a 20:1 ratio, not 34:1. Cobe has found that the chlorine content of household bleach varies considerably. If the nominal concentration of household bleach contains 52,500 ppm chlorine, a 20:1 dilution will result in 2500 ppm chlorine in contact with the hydraulic fluid pathway of the Centry 2 distal to the concentrate uptake point. The authors make no mention of measurement of the nominal chlorine content of their bleach solution.

v) The authors incorrectly state that, "the proximal portions of the fluid path ... contained several dead-end water reservoirs" (page 375). There are no dead-end water reservoirs in the proximal portions of the fluid path of the Centry 2.

vi) The authors state that when "... 210 ml of sodium hypochlorite was introduced into the system via the water intake hose...this brought the whole fluid path into contact with the undiluted disinfectant" (page

376). Clearly, 210 ml of undiluted sodium hypochlorite cannot come in contact with the entire fluid path, as it has a volume of 1100 ml.

We conclude the following:

1. The authors' study lacks sufficient control to allow them to conclude that their disinfection procedure was effective.
2. The authors' claim that Cobe's disinfection procedure is unsatisfactory must be rejected, for the authors *never used* Cobe's disinfection procedure.
3. The authors' study has not demonstrated the safety of their recommended procedure, and in fact, they warn of the unsafe aspects of introducing high strength sodium hypochlorite into the Centry 2. They present no guidelines for adequate rinseout, or for testing for residual sodium hypochlorite after using their procedure.

Cobe stands behind the cleaning and disinfecting procedures we have recommended for the Centry 2. We have demonstrated their safety and efficacy for their intended use. Users who elect to employ procedures other than those recommended by Cobe should recognize that they must bear full responsibility for demonstrating the safety and efficacy of those procedures.

Cobe is recognized throughout the hemodialysis community as a company committed to providing a high level of support to our customers. We have offered in the past, and will continue in the future, to offer the authors of this paper, and all Cobe equipment users, technical support to help assure safe, high quality hemodialysis therapy.

Lloyd J. Forrestal, Ph.D.
Director, Hemodialysis Quality Assurance
Cobe Laboratories, Inc.

To The Editor:

We are pleased to have the opportunity to respond to the comments raised by Cobe Laboratories to our article appearing in Volume 2, Number 5 issue of Infection Control, *1981. We believe that the comments by Cobe of our study are the result of a misunderstanding. Initially, it is noted that since the implementation of our suggested disinfectant procedure, we have been using and continue to use Cobe Centry 2 Dialysis machines, and have purchased additional machines during this period. Our article was not intended to be critical of the manufacturer's Centry 2 machine nor of the manufacturer's responsiveness in attempting to resolve possible problems in the utilization of the machine. Rather, our article was intended to demonstrate that our suggested cleaning procedure between patient treatments yields better results than the manufacturer's recommended procedures in terms of bacterial counts.*

Specifically, we have in the past and continue to utilize the manufacturer's suggested 100 hour formaldehyde disinfectant process. Our suggested disinfectant process relates only to "between-patient" procedures and the results of our tests demonstrate that a significantly lower bacteria count is obtained utilizing our "full path" method rather than the manufacturer's suggested "partial path" procedure. Further, our test results included an analysis of water inlet counts. These results show a reduction in colony counts at the predialysis stage to microbiologically acceptable levels if our "full path" method is utilized, regardless of the quality of the inlet water.

The manufacturer asserts that our method may result in additional corrosive effect on parts of the dialysis machine. We have utilized our suggested procedure on a continual basis for the last 18 months and have experienced no adverse consequences vis-a-vis the operation of the machine or patient safety. It is opined that any such possible increased corrosion effect is remedied through the normal machine maintenance program.

Obviously, this is a brief response to comments made about our article. Should someone wish to discuss specific aspects of our study, we would be happy to share them.

Very truly yours,
Burke A. Cunha, M.D.
Inge Gurevich, R.N.
Nassau Hospital
Mineola, New York

https://doi.org/10.1017/S019594170005565X Published online by Cambridge University Press