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QUALITY ASSURANCE FOR DIALYZER REPROCESSING

(Abstract)

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Product Quality at Discount Pricing

QUALITY ASSURANCE FOR DIALYZER REPROCESSING

(Abstract)

Dialyzer reprocessing can be a safe and effective practice if performed properly with appropriate quality control measures in place. However, dialyzer reprocessing will not be safe, just as a dialysis treatment will not be safe, if performed improperly or if quality control is not taken seriously. Six primary steps can be taken to implement and maintain a successful quality assurance program for dialyzer reprocessing:

1) understand and comply with the AAMI/HCFA requirements;[1]

2) develop a reuse technique specific policy and procedures;

3) identify "high risk" patient problems for prevention;[2]

4) set a maximum use limit for dialyzers;

5) qualify and select an appropriate test lab for dialysis samples;[2]

6) report death, serious injury or illness, attributable to a medical device, to FDA and/or the device manufacturer.[3]

Compliance with the AAMI/HCFA requirements involves compilation of a Dialyzer Reprocessing Manual (a pre-made checklist is available to facilitate this task[4]), a reprocessing history record, documented process control, a complaint incident file, periodic audit procedures (a schedule of required audit procedures is available to facilitate this task[5]), and adherence to OSHA and state requirements. Development of a reuse technique specific policy and procedures should include, at a minimum, a reference to AAMI/HCFA documents, a policy on informed consent, a policy on dialyzers from positive patients, the title of the person(s) in charge of the reuse program and training, general procedures specific to the reuse technique in use or to be used (e.g., Renatron, DRS-4, Echo, heat, or manual system), location of all detailed reuse procedures, records, documents and the Medical Director's signature of approval on the completed policy. Typical sources of high risk patient problems, requiring QA measures for prevention, include excessive endotoxin/bacteria in the water system and/or inadequate germicide concentration or mixing (pyrogenic reactions and bacteremia), excessive cleaner or germicide concentration in the dialyzer (allergic reactions), physical stress to the dialyzer during the reprocessing procedure (blood leaks, particulate in dialyzers, dialysate channeling), and cumulative clotting of dialyzer fibers during treatment (inadequate dialysis). A maximum dialyzer use limit should be set to minimize the potential for problems due to undetected deterioration of dialyzer materials and dialysate channeling in the dialyzer. Selection of a qualified water/dialysate test lab is essential as the lab reports are a fundamental QC element for determining system safety and documenting overall process control. The lab should use Standard Plate Count Agar for water samples and Tryptic Soy Agar for bicarbonate concentrate or dialysate samples (do not use Blood or Chocolate Agar).

Incubate the sample for 72 hours if the membrane filter technique is used and do not use the calibrated loop technique for water or dialysate/concentrates (not accurate enough). Paddle type sampler results should be compared with more standard testing methods such as pour plate, spread plate, or membrane filtration techniques. Make sure the paddle sampler is properly wetted. Bicarbonate concentrate samples may have to be diluted 1:10 with sterile water to ensure proper wetting of the sampler. Patient death resulting from medical device problems (includes germicides) should be reported to the FDA and to the manufacturer, if known. Serious illness or injury events resulting from medical device problems should be reported to the manufacturer, or if the manufacturer is not known, to the FDA.

REFERENCES

1. Association for the Advancement of Medical Instrumentation/American National Standards Institute. Reuse of Hemodialyzers - American National Standard, RD47 - 1993. Health Care Finance Administration ESRD Facility Survey Report - Addendum, Form 3427A, 10/90.

2. Taaffe, V. Preventing Specific “High Risk” Problems Typically Associated with Dialyzer Reprocessing. RPC/Rabrenco Scientific, September 1996 (3rd release).

3. U.S. Department of Health and Human Services. Highlights of the Safe Medical Devices Act of 1990, Publication FDA 91-4243, August 1991.

4. RPC/Rabrenco Scientific. Dialyzer Reprocessing Manual Checklist, Form 9291B.

5. RPC/Rabrenco Scientific. Dialyzer Reprocessing Quality Assurance & Audit Schedule, Form 92825A.

OBJECTIVES

1) To specify six primary steps for implementing and maintaining a dialyzer reprocessing quality assurance program.

2) To describe a systematic and practical approach for compliance with AAMI/HCFA dialyzer reprocessing requirements.

3) To identify reprocessing associated “high risk” patient problems for prevention; the typical problem sources and solutions.