ReNews

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A PUBLICATION OF DIALYZER REPROCESSING INFORMATION

Highlights of the New AAMI Reuse Guidelines

Last spring AAMI completed its long-awaited revision of the 1986 Recommended Practice for Reuse of Hemodialyzers and the new edition has since been approved by the American National Standards Institute(ANSI). The new guideline, ANSI / AAMI RD47-1993, is extensively changed from the original 1986 document. Overall, the 1993 version is more "user-friendly" than the original guideline, with requirements being more readily understood, realistic and achievable. While it is not possible in this space to describe all of the changes, some of the more significant differences are listed below:

- Formal validation protocols are no longer required. In fact, in the main body of the guideline, the term "validation" appears only in the section of definitions.
- Requirements for environmental safety and monitoring refer to Occupational Safety and Health Administration (OSHA) regulations. Confusing references to the National Environmental Balancing Bureau are eliminated. Also eliminated is the separate AAMI monitoring schedule for formaldehyde vapors.
- Centers for Disease Control and Prevention (CDCP) "Universal Precautions" and OSHA regulations regarding prevention of bloodborne diseases have been incorporated into the revised guidelines. These were not available during the development of the 1986 version.
- Simpler, patient outcome-oriented requirements for verifying adequate dialyzer clearance performance have been incorporated, replacing the unrealistic and difficult-to-understand clearance validation requirements of the 1986 guidelines.
- Membrane integrity (leak) testing is required for all reprocessed dialyzers. The 1986 guidelines required such testing only when the leak rate of reprocessed dialyzers was higher than that of new dialyzers.
- The new guidelines have deleted the 1986 requirement that facilities maintain logs of incoming materials or, when appropriate, results of quality control tests of incoming materials.
- The microbiological requirements for water (maximum 200 cfu / ml of bacteria and / or 1 ng / ml of endotoxin) have been extended to include water used to dilute germicides. The 1986 version included only water used for dialyzer rinsing and cleaning.

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EDTA/ERA & EDTNA/ERCA 1993 Annual Meetings Report

By Geraldine Biddle, R.N., C.N.N.

Glasgow, Scotland was the venue for the concurrent sessions of the 30th Congress of the European Dialysis and Transplant Association—European Renal Association (EDTA / ERA) and the 22nd Annual Conference of the European Dialysis and Transplant Nurses' Association—European Renal Care Association (EDTNA / ERCA).

The combined meetings attracted a record number of over 7,000 attendees, industry representatives and guests who were housed in hotels and guest houses from Glasgow to Edinburgh!

The Congress was officially opened by Her Royal Highness, Princess Anne. The Official Opening Ceremony included a musical interlude performed by the Strathclyde Police Pipe Band and the Scottish Fiddle Orchestra followed by a Welcome Reception hosted by the City of Glasgow District Council.

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The Foundation of Quality Assessment and Improvement

by Sally Burrows-Hudson

The art and science of quality assessment and improvement continues to evolve. The entire health care arena is in a state of change with respect to the quality assessment and improvement process. Our search for the "right" methods to use is driving the evolution.

The nephrology community is quite familiar with the need for and the various means of monitoring structure, process, and outcome aspects of patient care. The community has acknowledged, however, that there is a need for reliable and valid methodologies for quality assessment and analysis. This may include instrument design, reliability and validity testing, analysis methodology developments, and guidelines for intervention strategies. To this end, nephrology professionals and patients as well as experts in the field of quality assessment and improvement are working in a very positive and cohesive manner to secure research or scientific based quality assessment instruments. Certainly the Institute of Medicine ESRD Report and follow-up IOM Conference on Measuring, Managing and Improving Quality in the ESRD Setting (Sept. 1993) provides the necessary impetus for this effort.

Defining Quality of Care

It is essential that the monitoring and improvement process be based upon a foundation that supports and upholds all elements involved. The basic underpinnings of quality monitoring and improvement processes are twofold. First, there must be an agreed upon definition of quality of care. Definitions may vary greatly from one professional to another, from one patient to another, or from one facility to another. This variation creates conflict and fragments the assessment focus and subsequent actions. To alleviate this fragmentation, the Institute of Medicine has recommended the adoption of the following definition:

"Quality of care is the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge" (Lohr, 1990).

This definition provides the nephrology community with a clear picture of the overall goal of the quality monitoring and improvement process. The definition tells us that a measurable scale will be used; the entire scope of care provided to the ESRD patient will be considered; both individual patients and populations of patients will be acknowledged and evaluated; health outcomes desired by both the patient and the professional will be taken into account and improved; and that all efforts will be based upon current scientific knowledge as well as technology assessment.

Standards

Standards also serve as an underpinning of the foundation for quality assessment and improvement. A standard is an authoritative statement by which responsibility and accountability is described. Standards are generally based upon several guiding principles: society's values and priorities and professional values and priorities. A standard defines accountability and desired outcomes to the public. At the same time, a standard provides direction for a specific practice and a framework for the evaluation of that practice (ANA, 1991).

Used as guides for quality assessment and improvement, standards focus on structure, process, and outcome aspects of care. For example, professional performance standards are typical of **structure standards**. These describe a level of behavior in the professional role. Professional performance standards may include education and other qualifications, collegiality and collaboration, and professional behavior and development.

Structure standards for a facility are exemplified by the Joint Com-

About the Author

Sally Burrows Hudson, MSN, RN, CNN is a past president of the American Nephrology Nurses' Associations (ANNA), and the National Federation for Specialty Nursing Organizations (1990-1991). Ms. Burrows-Hudson is the Clinical Support Administrator for Spectra Laboratories Inc.

She is also a member of the National Kidney and Urological Diseases Advisory Board of the National Institutes of Health.

Together with Douglas L. Vlchek and Nancy Pressly, Ms. Burrows-Hudson authored "Quality Assurance Guidelines for Hemodialysis Devices", a publication of the U.S. Department of Health and Human Services Center for Devices and Radiological Health. Ms. Burrows-Hudson has published several papers and articles on quality assurance issues.

mission for the Accreditation of Healthcare Organizations. The standards address specific program elements, policies and procedures, and documentation (JCAHO, 1993).

Structure standards may also address medical devices. For example, standards clearly define the nature of information that must be provided with or included on the medical device.

Process standards may define a level of care as demonstrated by a specific process. For example, standards of clinical nursing practice define the level of nursing care as demonstrated by the process of assessment, diagnosis, planning, implementation, and evaluation (ANA, 1991).

Process standards do not always focus on the care-giver. In fact, process standards may be applied to medical devices. For example, a medical device standard may define the techniques that are used to assure conformity to safety maintenance and performance criteria.

Outcome standards tend to focus on patient outcome. Ideally, valid and reliable patient outcome standards are based on sound scientific research as well as expert clinical opinion. While patient complexity, professional education and experience and / or lack of appropriate or adequate resources may pose barriers to the specific desired outcome, the overall standard provides a guide by which a target may be set and continuously advanced.

Outcome standards are also applied to medical devices. For example, medical device standards articulate the basic safety and performance characteristics of specific and / or categories of devices (AAMI, 1990). These standards provide the guidelines for medical device safety and reliability monitoring.

Standards may seem to be static statements in an extremely dynamic environment. Standards, however, are used to guide the dynamics. As an example, a specific component of dialysis technology may change, but the patient outcome standard may remain quite stable. While standards remain as the solid foundation, indicators or criteria used for the quality assessment process are significantly more dynamic. Guidelines, policies, procedures, and protocols are also dynamic, yet guided by standards.

Structure, process, and outcome standards must be addressed as a whole. Current interest lies in understanding and articulating the relationship between process and outcome. This presumes, however, that the structure is in place to assure an adequate and appropriate environment for the practitioner, patient, and even the medical device. Quality assessment and improvement efforts must be comprehensive in addressing the full scope of standards.

Quality assessment and improvement are based upon a foundation that includes an agreed upon definition of quality of care and standards that clearly articulate accountability, responsibility, and expectations.

References

American Nurses Association (1991) *Standards of Clinical Nursing Practice.* American Nurses Association: Kansas City.

Joint Commission on Accreditation of Healthcare Organizations (1993). *Accreditation Manual for Hospitals.* JCAHO: Chicago.

Association for the Advancement of Medical Instrumentation (1990). *AAMI Standards and Recommended Practices. Volume 3: Dialysis.* AAMI: Arlington, VA.

Lohr, R.N. (Ed) (1990). *Medicare: A Strategy for Quality Assurance.* National Academy Press: Washington, D.C.

From the Editor

Renal Systems would like to extend a tremendous "Thank You" to its customers for their continued support and loyalty.

The updated HCFA dialysis facility survey protocol began this year and included a new feature, the "Flash" survey. This new survey protocol presented challenges to all of those involved. Together with the dialysis facilities and HCFA surveyors, Renal Systems worked to resolve concerns and misunderstandings of the new interpretive guidelines. Customers are encouraged to continue contacting their Renal Systems representatives for assistance. Again, thanks to all of our customers for their patience and support.

If you plan to attend the ASN meeting November 14-17 in Boston, a calendar of events is included in this newsletter. Stop by the Renal Systems booth for extra copies of this edition of ReNews.

Please contact me if you have ideas for future issues of ReNews. Your comments and suggestions are always welcome.

Suzanne Gooselaw

Suzanne Gooselaw, R.N.
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Renal Systems
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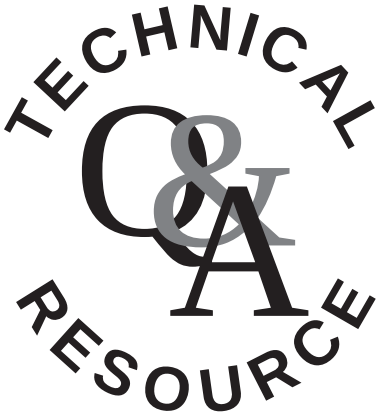

Q. What happens when the dialyzer reprocessing water temperature exceeds the recommended 75° F?

A. When water temperature exceeds 75°F (24°C), secondary gas pressure inside the dialyzer may increase. The increase of secondary gas pressure could dislodge the dialyzer port caps or cause displacement of Renalin®.

The publication "Renalin® Dialyzer Reprocessing Concentrate Research Data" cites acceptable dialyzer storage temperatures with limits as high as 86° F (30°C). The water used to reprocess dialyzers and dilute Renalin® if ≤ 86° F, is analogous to a short term elevation of dialyzer storage temperature. This short-term temperature elevation will not reduce the efficacy of Renalin® as a sterilant. Therefore, if a facility is not experiencing dialyzer port cap dislodgment and the dialyzer headers remain at least 2/3 full of Renalin®, water temperatures up to 86°F are acceptable.

Note: Care should be exercised when removing dialyzer port caps (prior to preparation for patient use) to prevent accidental spraying of Renalin® solution onto the operator. Appropriate precautions against accidental spraying include the use of protective eyewear.

Q. Is it necessary to calculate the "F" Factor when using the Renatest® Vapor Detector to monitor hydrogen peroxide and acetic acid levels in the air?

A. Results obtained from the Renatest® Vapor Detection tubes are based on an atmospheric (barometric) pressure of 29.88 inches of mercury (inHg). Differences between this "standard" pressure and actual barometric pressure at the time of sampling will have an effect on vapor detection test reults. While not ordinarily done, (barometric pressure effects on test accuracy are minimal) vapor detection test results can be corrected for barometric pressure effects. This is done by determining the ratio between standard barometric pressure and actual barometric pressure at the time of vapor sampling. The resulting ratio is referred to as an F factor. Vapor detection tube test results are then multiplied by the F factor to obtain a corrected result.

When correcting vapor detection test results for barometric pressure effects, proceed as follows:

1. Obtain barometric pressure from a barometer or by phoning a local weather station.
2. Determine the F factor.
3. Perform the vapor test.
4. Multiply the vapor test results by the F factor.

For example:

1. Barometric pressure is 29.90.
2. F factor is 29.88 / 29.90 = 0.999.
3. Acetic acid vapor test result (measured) is 5 ppm.
4. Corrected test result is 5 x 0.999 = 4.995 ppm of acetic acid vapor.

Q. What are the recommended storage conditions of preprocessed or reprocessed dialyzers filled with Renalin® cold sterilant? Specifically, what light exposure conditions are acceptable?

A. To avoid deterioration of Renalin® solution, preprocessed or reprocessed dialyzers should be stored out of **direct** sunlight. A storage area lit by sunlight is acceptable, provided that the dialyzers filled with Renalin® solution are kept out of the direct rays of the sun. Preprocessed or reprocessed dialyzers filled with Renalin® Sterilant do not need to be shielded from fluorescent light.

Reuse in the Nineties - Are We Better Off?

By Timothy E. Moone

Historically, reuse has been in practice since the beginning of dialysis. I can remember in 1970 building mini klungs with reused parts. The used blood ports, wafers and mats were rinsed with tap water, dried and then reused in the building of a new dialyzer.

The rebuilt dialyzer was then pressure tested and flushed with a hydrochloric acid solution to disinfect and "etch" the membranes. Normal saline was then used to partially flush the hydrochloric acid from the dialyzer. The remaining acid was "dialyzed" out when the dialyzer was initially attached to the dialysis machine. The definitive test

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AAMI Reuse Guideline Highlights

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- The 1993 guidelines have extensively modified the quality assurance / quality control requirements from those of the 1986 version. A partial listing of these revisions include:
  - eliminating the need for designated quality assurance and quality control personnel
  - replacing these with "designated" personnel
  - a new schedule for quality assurance activities
  - emphasizing that clinical outcomes and patient outcomes are the most important indicator of quality of all reuse processes
  - establishing that the medical director is responsible for the schedule of review, endorsement of findings, and, where appropriate, implementation of changes.

Although the revised, 1993 reprocessing guidelines are most welcome and will greatly aid reuse facilities, it is pointed out that the Health Care Financing Administration (HCFA) is still utilizing the 1986 version as the basis for facility audits. HCFA cannot, by law, simply announce the adoption of the new reuse guidelines as a regulation. It is first necessary for HCFA to announce their intentions in this regard by publishing a "notice of proposed rulemaking" (NPRM). Following the publication of the NPRM, a period of time is allowed for public comment, after which the agency adopts its final rule. HCFA has taken the first step in this process, by publishing an NPRM in the Federal Register on April 26, 1993 and indicating that the proposed rule will be made public around the first of the year. In the meantime, dialysis facilities are confronted with a dilemma—whether to use the old or new AAMI guidelines. Using the new guidelines will ensure that reuse is done according to the latest available information but risks failing a HCFA audit based on the now-outdated guidelines. It is unlikely, however, that HCFA will be able to adopt the new AAMI guidelines sooner than next spring. In the meantime, reuse facilities have the time to plan an orderly transition from the old to the new AAMI reuse guidelines.

Copies of the new AAMI guidelines can be obtained by contacting:

Association for the Advancement of Medical Instrumentation
3330 Washington Blvd., Suite 400
Arlington, VA 22201-4598

EDTA/ERA & EDTNA/ERCA

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The EDTA / ERA scientific program consisted of six simultaneous oral sessions and more than 350 posters. Highlights from the annual presentation of the EDTA Registry data revealed that a majority of hemodialysis patients still receive more than 12 hours of treatment per week. However, there is a shift towards shorter hours exchanging the 15 hours per week for nine hours per week. Overall, survival for patients with "standard primary renal disease" is decreasing due to the impact of the admission of older patients to the end stage renal disease programs. The 1992 report showed a decrease in the number of reporting centers to 58 percent.

The EDTNA / ERCA scientific program also contained a wide range of topics with guest speakers from as far afield as the USA and Singapore as well as Europe. Simultaneous interpretation was provided in French, German, Spanish, Italian and Greek in two main halls. Nurses, technicians, social workers, and dietitians from all over the Continent shared information on the growth and development of their disciplines within their own countries.

Presentations from international representatives from South Africa, Australia, the United States, and Singapore rounded out the depth of world wide scope of the EDTNA.

Plans are underway for the 1994 meetings that will be held in Vienna, Austria, July 3-6. Information can be obtained by writing to EDTA-ERA Congress, EDTNA / ERCA Conference, c / o Wiener Medizinische Akademie, Alser Straße 4, A-1090 Wien, Austria.

Resources

A workshop titled "Reuse of Hemodialyzers" was sponsored by Renal Systems at the 1993 EDTNA/ERCA conference. Presenting at the workshop were:

Dominick E. Gentile, M.D.
University of California at Irvine
St. Joseph Hospital, Irvine, CA
"Twenty Years of Hemodialysis with Dialyzer Reprocessing and Reuse"

Pintos Dos Santos, M.D.
Centro De Hemodialise Do Lumiar
Lisbon, Portugal
"Survival Analysis of a Sample of 429 Hemodialysed Patients"

Brian J. Schniepp
Div.of Nephrology and Internal Medicine, Mayo Clinic and Mayo Foundation
Rochester, MN
"Dialyzer Reuse at the Mayo Clinic"

Copies of the workshop proceedings are available upon request.

Reuse in the Nineties

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for acid elution was the blood remaining red and the patient not experiencing pain or burning on "hook-up."

In 1971, parallel plate dialyzers encased in an opaque material became commercially available. Reuse of these parallel plate dialyzers involved flushing the dialyzer with tap water until the effluent cleared and then filling the dialyzer prior to storage with a solution of formaldehyde. The strength of the formaldehyde used was around 2% but this often varied depending on the technician performing the dilution. At this time there were no regulations governing the reuse of dialyzers.

In contrast, today the entire procedure can be performed with computer-based equipment that allows for excellent record keeping and dialyzer traceability. Errors of the past involving dilution and dispensing of the sanitizing agent have all but been eliminated with the automatic reprocessing equipment available.

The automatic reprocessing equipment performs testing to ensure the reprocessed dialyzer membrane is intact and the dialyzer volume is adequate. It also will track the maximum allowable uses as determined by the dialysis facility. Improvement of dialyzer design allows for partial viewing of the inside of the dialyzer, so that the reprocessor can determine the reusability of the dialyzer from an aesthetic standpoint.

In the nineties, automated reprocessing should be encouraged for all facilities that practice reuse. Automated reprocessing equipment has features that help eliminate guesswork and add safety to the process.

REUSE IN THE NINETIES - ARE WE BETTER OFF?...The answer to the question is a resounding YES. Reprocessing in the nineties has improved from all standpoints - better for the patients and better for the reprocessor.

About the Author

Timothy E. Moone has been involved with dialysis since 1970, holding positions which include Assistant Chief Technician, Chief Technician and Home Training Coordinator at Grady Hospital and Dialysis Clinic, Incorporated in Atlanta, Georgia. Currently, he is the Technical Manager at Dialysis Clinic, Incorporated in Atlanta. He holds a B.S. in pre-med zoology from Southern University, Baton Rouge, Louisiana and has pursued studies at the masters level at Atlanta University, Atlanta, Georgia. Tim is also a member of the National Association of Nephrology Technologists.

Technical Service Department

Renal Systems announced several staff changes this fall in the Technical Service Department.

Vince Bazanni is the new Manager of Technical Services for the European Operations in Ober-Mörlen, Germany. He will provide technical support and training to the growing number of dialyzer reprocessing customers in Europe.

Mike Neary has been promoted to Technical Service Manager, and remains in the U.S. office along with Technical Representatives Tony Houle and Shawn Grady. In addition, a new Technical Representative, Greg Pielow, has joined the staff.

The main focus of the Technical Service Department is to provide quality service and support to customers. A large number of service calls are handled directly on the telephone. Most calls involve explanations of equipment functions or troubleshooting problems. Any mechanical repairs that are required are handled in-house by the Technical Service staff.

Technical Service Staff (from left to right): Greg Pielow, Tony Houle, Shawn Grady and Mike Neary.

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