ReNews

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A PUBLICATION OF DIALYZER REPROCESSING INFORMATION

Current Issues in Dialyzer Reuse

One of the most-talked about issues in recent years has been the statistical studies undertaken by the Urban Institute of Baltimore, Maryland, and made public at a meeting held by the U.S. Food and Drug Administration on October 8, 1992. According to the authors, these studies, which focused on free-standing facilities employing low-flux dialyzers, showed a statistically significant increased risk of death associated with dialyzer reuse employing Renalin® or glutaraldehyde as the germicide.

While a complete analysis of the study findings and enumeration of superior survival results reported by other researchers using Renalin® for dialyzer reuse is beyond the scope of this newsletter, we would like to update readers on aspects of the study which are not disputed as well as ensuing developments which will affect all facilities reusing dialyzers.

FACT

Worldwide, 200,000 dialyzers are reprocessed with Renalin® every week.

(That's 1 dialyzer every 3 seconds).

- **Data presented in summary form by the Urban Institute at the October 8, 1992 meeting was intended to demonstrate a statistical association only-not cause and effect. In their summary, the authors noted that their findings should be interpreted with caution.**

- **Similar relationships were not found for facilities employing reused high flux dialyzers. [This important finding, that the statistical association of increased mortality is evident only with low-flux dialyzers, suggests that the underlying cause is not related to germicide usage *per se*, but some other factor(s), such as underdialysis.-Editor]**

Subsequent to the meeting of October 8, Renal Systems undertook at the direction of the FDA, several actions intended to ensure proper use of Renalin®. These actions (since completed) were of a largely educational nature and included developing manual reprocessing instructions and conducting regional training seminars for both Renalin® users and Health Care Financing Administration (HCFA) personnel. However, in addition to these educational activities, FDA has also required Renal Systems to obtain certification from Renalin® users that the product will be used according to Renal Systems instructions and the reprocessing guidelines developed by the Association for the Advancement for Medical Instrumentation (AAMI). This requirement, which appears to be unprecedented, will continue into the indefinite future.

FACT

$276 million dollars is saved annually in the U.S. because of dialyzer reuse.

In addition to the FDA-mandated actions taken by Renal Systems as a result of the mortality studies, HCFA will be conducting surveys of facilities reusing with Renalin® or glutaraldehyde. These surveys will utilize a newly developed set of interpretive guidelines and be initially "focused" on facilities reusing with either Renalin® or glutaraldehyde. Currently, HCFA intends to complete their focused surveys by September, 1993. While Renalin® and glutaraldehyde users will be the first facilities surveyed under the new interpretive guidelines, HCFA will in the future be using them for all reuse facilities.

Key aspects of the new HCFA guidelines

- The new survey procedures are effective May 24, 1993.

- The survey protocol calls for a "flash" survey of the actual reprocessing activity as quickly as possible after the surveyor enters the facility, with a more detailed "sequenced" survey routine to follow. The purpose of the "flash" survey of the reuse process is to determine the actual state of the reprocessing area and the behavior of the facility personnel before the facility adjusts to the surveyor's presence.

- During the flash survey, surveyors will:
  - Observe the area for clean and sanitary conditions;
  - Evaluate the area for adequacy of ventilation;
  - Evaluate for visible, tangible separation between storage for new dialyzers, reprocessed dialyzers, and used dialyzers awaiting reprocessing;
  - Observe that durable gloves, eye protection (goggles, eye wash station), and protective clothing (impervious apron) are available and used during reprocessing;
  - Inspect the reprocessed and stored dialyzers;
  - Interview the technician(s) responsible for reuse.

- During reuse technician interviews surveyors have been instructed to:
  - Ask the technician to describe the reprocessing procedures for dialyzers;
  - Ask the technician some questions regarding reuse;
  - Ask the technician to describe his/her behavior if it is apparent that he/she cannot perform tasks or procedures properly;
  - Ask the technician about records;
  - Ask the technician to describe the risks and actions associated with the toxic substances used in reprocessing;
  - Ask the technician to describe the storage and handling of reprocessing chemicals;
  - Ask the technician about environmental safety;
  - Ask the technician about quality controls ("What happens when a patient has an adverse reaction? How is the reused dialyzer investigated? If a dialyzer is investigated, where is the investigation documented?");
  - Ask the technician to describe the training and certification necessary for working with reprocessing.

- During the sequenced portion of the survey attention will be directed not only to records demonstrating compliance with AAMI guidelines for water quality, but the methods used to ensure that they are consistently achieved.

- During the sequenced portion of the survey, a conference will be scheduled with the Medical Director or his/her designee to review the reuse procedures in the facility. Surveyors have been instructed to:
  - Ask about the reuse procedures in the facility;
  - Ask who reviews the policies and procedures regarding reuse;
  - Ask what policies and procedures are available to train, assess, and certify staff performance;
  - Ask what procedures are followed for staff who do not meet performance standards;
  - Ask what systems are in place to provide for review of incident reports and trends or patterns of problems by the Medical Director;
  - Ask how problems potentially related to reuse are identified and handled during reuse, during dialysis treatments, and during laboratory and chemical data review.

There are certain to be misunderstandings or difficulties as the new interpretive guidelines are imple-

FACT

14.4 million dialyzers are saved every year in the U.S. compared with those used by the same number of patients in Europe.

FACT

120,00 dialysis patients in the U.S. participate in a dialyzer reuse program.

From the Editor

I hope that you will find this first edition of ReNews, to be an informative and helpful resource. The aim of this newsletter is to provide dialysis professionals, like yourself, with timely insights into the practice of dialysis in areas where Renal Systems has been most active and has considerable expertise, namely dialyzer reuse and hemodialyzers. Also, this is an opportunity to be in touch with you, the nurses, and technicians who are in close contact with patients and their needs.

I look forward to your comments about this newsletter and welcome any suggestions you have to improve its content or format.

For those of you attending the ANNA / NANT meetings in Orlando, June 5-8, stop by the Renal Systems' booth to pick up extra copies of this newsletter.

Suzanne Gooselaw, R.N.
Editor

FACT

34.4 million reuse procedures have been performed with Renalin® since its introduction in 1983.

Safety Alert Terminated

Renal Systems, division of Minntech Corporation, was notified by the FDA on April 30, 1993 that the October 8, 1992 safety alert for Renalin® cold sterilant and Renalin® dialyzer reprocessing concentrate has been completed and "the FDA considers the safety alert terminated." The FDA added, however, that "we continue to expect that Minntech will follow the provisions...to ship the product only to consignees who sign certifications that they will use the product according to AAMI guidelines and your (Minntech's) recommended practices."

Studies on the Association of Dialyzer Reuse and Patient Mortality

On October 8, 1992, two Studies on the Association of Dialyzer Reuse and Patient Mortality were presented to the FDA. There has been confusion in the ESRD community related to the origin of these studies. Information on the two studies is presented here.

Most recent presentations related to patient mortality and dialyzer reuse sterilant have been of Study # 2 only. Study #1, with analysis of the USRDS Case Mix data for the years 1986 and 1987, found an association with increased patient mortality when Renalin® concentrate was used in facilities with manual reuse procedures. Renal Systems has noted that data utilized for study #1 was not a cross-section of multiple dialysis facilities using Renalin® for manual reprocessing. This is a potential "confounding" effect (which has been called "The Center Effect") that could prevent reaching statistically valid conclusions. We are unaware of any efforts underway to publish Study #1.

	Study #1	Study #2
Description	United State Renal Data System Case Mix Study	"A Brief Overview of Current Analyses of the Association of Dialyzer Reuse and Patient Mortality"
Investigators	Held, Wolfe, Gaylin, Port	Held, Wolfe, Gaylin, Port, Levin, Turenne
Presenters at FDA meeting	Striker, Agodoa	Held
Data Source	USRDS	HCFA, CDC
Funding Source	NIH/NIDDK	HCFA
Study has been referred to as	"The Striker Study"	"The HCFA Study"

FACT

The first Renatron® built for commercial use purchased in February 1982 is still functioning today in a center that operates 3 shifts/day six days a week.

Questions from our Customers

"What is the status of the FDA safety alert?"

The FDA safety alert was mailed to all dialysis facilities to advise them of the statistical studies reported by the Urban Institute. Renalin® was never recalled and continues to be available for dialyzer reuse. All actions required of Renal Systems by the FDA have been completed.

"Must a Renalin® Indicator Test be performed on every dialyzer? How often and when do dialyzers need to be tested with the Renalin® Indicator test strips?"

Our instructions for use require that each preprocessed or reprocessed dialyzer be tested for the presence of Renalin® with the Indicator Test after storage and before rinsing for patient use.

"Vapor detection-what has to be checked and how often?"

The two components of Renalin® which are subject to OSHA regulation for maximum airborne levels are hydrogen peroxide and acetic acid. OSHA specifies that their maximum levels, measured as 8 hour time-weighted averages are, 1 and 10 ppm, respectively. OSHA has not established a frequency for monitoring, only that these limits be met. We recommend that initial testing be done when exposure appears greatest, such as when diluting Renalin®, to establish the maximum expected levels. If these are found to be below the OSHA limits, routine testing can be infrequent. Testing should always be repeated if processes are changed or if personnel experience discomfort.

"What is a Renalin® Certification Agreement?"

As directed by the US Food and Drug Administration (FDA) in their 518(a) order, Renal Systems is required to obtain a signed agreement by all dialysis facilities reusing dialyzers with Renalin, to ensure that they conform with the 1986 Association for the Advancement of Medical Instrumentation Recommended Practice for Reuse of Hemodialyzers (AAMI ROH-1986) and Renal System's guidelines. The FDA prohibits the sale of Renalin® to dialysis facilities which have not returned a signed copy of this agreement. The agreement has five different categories of Renalin® usage. The customer needs to determine which category or categories accurately describe their Renalin® usage.

Almost all centers that are Renalin customers prior to April 1, 1993 have a signed Certification Agreement on file. New customers are requested to send a Certification Agreement, signed by their Medical Director or Administrator.

FACT

New Dialyzer Syndrome was reported by 28% of U.S. dialysis facilities in 1991.

FACT

In 1990, 7,566,000 pounds or 4,000 tons of medical waste was saved because of dialyzer reuse.

NANT Core Curriculum for the Reprocessing of Dialyzers

The National Association of Nephrology Technologists is pleased to announce the release of the Core Curriculum for the Reprocessing of Dialyzers. This document is a compilation of knowledge directed at the training of reuse personnel.

The idea behind this document was to provide facilities with a basis for a comprehensive training manual. After more than a year, with input from nephrology professionals around the country and financial support from Renal Systems, this project is now complete.

The Core Curriculum for the Reprocessing of Dialyzers will be available during the Orlando ANNA meeting. Copies are also available through the NANT national office by calling 708-480-7675. Thank you to everyone who made this project possible.

RS AD

ANNA at a Glance

Reprocessing Events at ANNA

Other events at ANNA which will focus on reprocessing include the following:

Renalin® Reuse Training Seminar
Free and open to HCFA inspectors, Renal Systems' customers, FDA personnel and ESRD network personnel. Friday June 4 8:30 a.m. to noon Asia Room IV

Clinical Aspects of Dialyzer Reprocessing Seminar
This session will be awarded 1.5 contact hours of continuing education approval by the American Nephrology Nurses' Association (ANNA) which is an accredited provider of continuing education credit in nursing by the American Nurses Credentialing Center Commission on Accreditation (ANCC COA). ANNA is an approved provider of continuing education in nursing by the following states: California BRN 00910, Florida BRN 27F0441 and Alabama BRN P034.
Tuesday June 8 6:30 - 7:00 a.m, breakfast 7:00 - 8:15 a.m. seminar

Understanding ESRD Mortality Data
Presented by Karen Ilstrup, BS JD during the Exhibitor Continuing Education Program (ECEP) at the ANNA Symposium. Tuesday June 8 12:00 noon to 12:15 p.m.

Safe Reuse Practices
Presented by Doug Luehmann during the Exhibitor Continuing Education Program (ECEP) at the ANNA Symposium. Tuesday June 8 12:00 noon to 12:15 p.m

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Saturday June 5, 1993	Program Event	Location
12:00 - 4:00 p.m.	NNCB Examination	S. Hemisphere II-V
1:30 - 7:00 p.m	Registration Opens	Convention Foyer
4:30 - 5:00 p.m.	Award Winners/Corp. Sponsors Gathering	Oceanic 3
5:15 - 7:00 p.m.	Opening Ceremonies	N. Hemisphere Ballroom
7:00 - 8:30 p.m.	Opening of Exhibit Hall (Reception)	
8:30 - 12:30 a.m.	Opening Reception (Sponsored by AMGEN)	S. Hemisphere Ballroom

Sunday June 6, 1993	Program Event	Location
7:00 - 7:30 a.m.	Continental Breakfast	
7:00 - 5:30 p.m.	Registration Opens	Convention Foyer
7:30 - 9:00 a.m.	Roundtable Clinical SIG's	
Session 1	Hemodialysis	S. Hem. I-V/ N. Hem. E
2	Pediatric Nephrology	Asia 3
3	Peritoneal Dialysis	Asia 4/5
4	Transplantation	Asia 1
9:00 - 10:30 a.m	Break - Exhibits/Poster Presentations (Sponsored by ORTHO BIOTECH, INC.)	
10:30 -11:30 a.m.	KEYNOTE ADDRESS (Sponsored by Spectra Laboratories)	S. Hemisphere Ballroom
11:30 - 1:00 p.m.	Lunch - Exhibits/Poster Presentations	
1:00 - 2:30 p.m.	CONCURRENT SESSIONS	
5	Resources	S. Hemisphere I
6	Ethics	S. Hemisphere II
7	Communication	S. Hemisphere III
8	Regulation Environment	N. Hemisphere E
9	Special Populations	S. Hemisphere IV/V
2:30 - 3:30 p.m.	Break- Exhibits/Poster Presentations	
3:30 - 5:00 p.m.	CONCURRENT SESSIONS (Sessions 5-9 con't)	
5:00 - 8:00 p.m.	Regional Receptions	The Swan Hotel
7:30 - 8:30 p.m.	Pre-Concert Refreshments (Sponsored by Fresenius)	N. Hemisphere Foyer
8:30 -10:30 p.m.	Concert with Franki Valli and The Four Seasons and Danny Gans (Sponsored by ANNA and Exhibitors)	N. Hemisphere Ballroom

Monday June 7, 1993	Program Event	Location
7:15-9:30 a.m.	AMGEN Breakfast Symposium	N. Hemisphere Ballroom
8:30 - 5:30 p.m.	Registration Open	Convention Foyer
9:30 - 11:00 a.m	Break - Exhibits/Poster Presentations	
11:00 - 12:00 noon	Plenary Session	N. Hemisphere Ballroom
12:00 - 1:30 p.m.	Lunch - Exhibits/Poster Presentations	
1:30 - 3:00 p.m.	CONCURRENT SESSIONS - CLINICAL PRACTICE	
Session 10	Hemodialysis	S. Hemisphere I & II
11	Peritoneal Dialysis	S. Hemisphere III
12	Transplant	America's Seminar Room
13	Pediatric Nephrology	Asia 5
14	Professional Models	S. Hemisphere IV & V
3:00 - 4:00 p.m.	Break - Exhibits/Poster Presentations	
4:00 - 5:00 p.m.	NETWORKING -FUNCTIONAL SIGs	
Session 15	Administration	N. Hemisphere E
16	Corporate/Government	S. Hemisphere IV
17	Clinical Practice	S. Hem. I & II/America's Seminar Rm.
18	Education	S. Hemisphere III
19	Research	S. Hemisphere V
6:30 - 8:00 p.m.	CNN Reception (sponsored by ANNA and NNCB)	S. Hemisphere Ballroom
8:00 - Midnight	Baxter's Party	N. Hemisphere Ballroom

Renal Systems at ANNA

Keep up with changes in the reprocessing industry. Renal Systems will be featuring its full line of quality reprocessing supplies (booths 701-707) including the Renatron® II Dialyzer Reprocessing System with Renalog III™ Data Management software.

An outcome analysis of dialyzer reprocessing, using specific data from your facility, will demostrate annual savings and dialyzer cost per treatment. This comprehensive analysis is available free of charge at the Renal Systems' booth.

How much do you really know about dialyzer reprocessing? Test your knowledge and at the same time your name will be entered into the DAILY drawing for a Sony Car Discman.

Tuesday June 8, 1993	Program Event	Location
5:30 - 7:00 a.m.	Continental Breakfast (Sponsored by Renal Systems/ Sandoz/Schein)	
7:00 - 8:15 a.m.	CONCURRENT PROGRAMS	
	Renal Systems	N. Hemisphere B, C, D
	Sandoz	N. Hemisphere A
	Schein	N. Hemisphere E
8:00 - 3:30 p.m.	Registration Open	
8:30 - 9:30 a.m.	CONCURRENT SESSIONS - VERBAL ABSTRACTS	
Session A1	Hemodialysis	S. Hemisphere I & II
A2	Peritoneal Dialysis	S. Hemisphere III
A3	Transplantation	S. Hemisphere IV & V
A4	Pediatric Nephrology	Asia 5
A5	Education	America's Seminar Rm.
9:30 - 10:00 a.m	Break	
10:00 - 11:30 a.m.	CONCURRENT SESSIONS - CLINICAL PRACTICE	
Session 20	Resources (Research Abstracts)	Asia 5
21	Ethics	S. Hemisphere III
22	Communication	America's Seminar Rm.
23	Regulations	S. Hemisphere I & II
24	Special Populations	S. Hemisphere IV & V
11:45 - 12:45 p.m.	CONCURRENT SESSIONS - EXHIBITOR CONTINUING EDUCATION PROGRAM (ECEP)	
Session E1	Product Evaluation	S. Hemisphere I
E2	Peritoneal Dialysis	S. Hemisphere III
E3	Quality Improvement	America's Seminar Room
E4	Hemodialysis	S. Hemisphere II
E5	Hemodialysis	S. Hemisphere IV & V
1:00 - 3:00 p.m.	Nephrology Nurse Day Recognition Lunch & Closing	N Hemisphere Ballroom

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