ReNews

A PUBLICATION ON DIALYZER REPROCESSING

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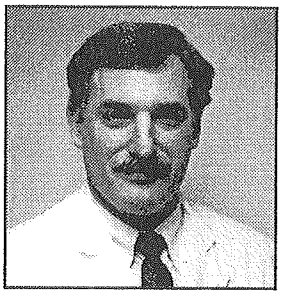
A Conversation with Dr. Allan Collins

*Dr. Allan Collins will be presenting his study "Reuse-Associated Mortality: 1989-90 vs. 1991-93" at a poster session at the 29th Annual Meeting of the American Society of Nephrology (Tuesday, November 5th - abstract A0974). We recently spoke with him to discuss his findings. **



What is your background and experience with dialyzer reuse?

"My experience with reuse has spanned 18 years. I was involved with a number of colleagues in the evaluation of peracetic acid as it was introduced as a reuse agent in 1983, with the original clinical testing, microbiology testing, its integrity in the dialyzers, and all the premarket evaluations of the product. I was also involved with formaldehyde reuse prior to coming to the kidney program in 1978.

I've been at the Regional Kidney Disease Program in nephrology since 1978. I was the director of the inpatient acute critical care unit and then, subsequently, the outpatient units. I took over operation of the entire kidney program in 1984. I'm also the person that does all the quality assurance and the outcome analysis of survival, and morbidity, and mortality of all the patients.

Why did you embark on the Reuse-Associated Mortality study?

There were questions about the original 1989-1990 data analysis relative to the methods that were used and the selection of particular dialy-

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New Analysis of Mortality Data and Reuse Presented at EDTNA/ ERCA Conference

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

In a presentation entitled "Reuse Analysis of Freestanding and Hospital-Based Units in the U.S.A.: 1989-1993," Dr. Allan Collins discussed findings from a recently completed analysis of survival data among U.S. patients from 1989 through 1993. Briefly, Dr. Collins' data shows that overall, the germicide-associated mortality risk identified in the USRDS 1989-1990 data analysis is not borne out in 1991-1993. The latest analysis shows a higher mortality risk for the no reuse group. Furthermore, Dr. Collins discovered that "for profit" status of dialysis units had a significant impact on re-examination of the results of associated germicide mortality. According to Dr. Collins, "The interactions of unit status and profit status provide a clearer view of the specific associations with germicide and reuse technique. The variability in our

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sis units and particular membranes. I proposed to the Health Care Finance Administration to develop a working set of data from the existing federal data that would include not only germicides into the analysis and the individual patient characteristics that had already been developed, but to add several other pieces. One was to add a comorbidity profiling system for the diseases patients had, which had not been done, and then to look at other unit characteristics to test whether or not the assumptions that were made in the original analysis would hold up. In addition, we've looked at more recent intervals than the 1989-1990 interval. And they granted that request. So I acquired the national data and essentially duplicated the analysis the USRDS did, but looked at it in more detail and looked at a more recent interval.

"It has to do with other things—whether it is practices within the units, or techniques, or ownership of the units, or therapy, or erythropoietin use - it could be a whole host of things. But there isn't anything that would explain this change that would be specific to the germicide itself."

Could you give our readers a brief overview of the study and your findings?

The study involves patients who were in hemodialysis units from 1989 to 1993. Some 34,000 patients were analyzed in this study, with about 12,000 patients in hospital-based units and about 19,000 patients in freestanding units. The patients were selected as a 10% random sample throughout the entire country. We utilized the facility survey data from the Health Care Finance Administration which classifies dialysis units into size, number of patients, for-profit and non-profit status, and whether or not they are freestanding or hospital-based. We also acquired the facility survey data from the CDC for its surveillance of diseases categorized by facility number. That data was also used and merged together with the patient's specific information. Then a sample of patients was taken for each year. To duplicate the USRDS data we took 1989 and 1990 together, and then looked at a newer interval of patients from 1991 through 1993. We compared associations with the germicide, dialysis unit type, and profit status in 1989 and 1990 and then looked at the same kind of analysis in 1991 through 1993 to see if there were similar or different results.

The findings were that in the 1989 and 1990 data, there is in fact an association between peracetic acid manual reuse in freestanding dialysis units that had a higher association with mortality. When you look at it on a basis of for-profit and non-profit status, some of it is explained by the fact that the freestanding for-profit dialysis units had a higher mortality rate then non-profit units. Manual peracetic acid reuse and for-profit freestanding units came up as a very high significant relative risk. That association was present only in 1989 and 1990. When you repeat the exact same analysis from 1991 to 1993, it's all gone. You cannot find that association between peracetic acid or any of the other germicides compared to no reuse.

There is a persistent effect, however, of for-profit status. For-profit, freestanding units have a higher risk of mortality than non-profit units. The exact opposite is true in the hospital-based units. That finding is as strong, if not stronger, than anything that was ever found relative to peracetic acid's association in 1989 and 1990. So the conclusion to all of that is, yes, there really was an association in 1989 and 1990. It is isolated to a very specific kind of unit and technique. And if you look at that in 1991 and 1993, you can't find it anymore. In fact, it looks like most of the reuse has a lower risk of mortality than no reuse.

I would conclude from that that it has nothing to do with the germicide itself. It has to do with other things - whether it is practices within the units, or techniques, or ownership of the units, or therapy, or erythropoietin use - it could be a whole host of things. But there isn't anything that would explain this change that would be specific to the germicide itself.

How do your findings impact renal nurses and reuse technicians that are practicing reuse now?

There are areas relative to technical use of any of these products that are of importance. There are practices that go on within dialysis units that are trouble because they do not

necessarily meet the guidelinesthat manufacturers recommend. Several of those things are to make sure that the concentration of germicides are appropriately used, that the techniques to clean and sterilize dialyzers are monitored, and that the quality of the water is appropriate.

** The opinions expressed herein are those of the author and do not necessarily reflect the views or opinions of Renal Systems or Minntech Corporation*

Renal Systems Conducts 5th Educational Session at EDTNA/ERCA's Silver Anniversary Conference

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

The 25th Annual Conference of the European Dialysis and Transplant Nurses Association / European Renal Care Association (EDTNA/ERCA) was held in Amsterdam, The Netherlands, June 15 - 18, 1996. Approximately 3500 nurses, technicians, social workers, nutritionists, and industry representatives attended the anniversary meeting which was held in the RAI Convention Center.

The conference program for this year's meeting contained a variety of topics presented in workshops, plenary sessions, and special industry sponsored educational symposia, all related to the care of patients receiving renal replacement therapies. Dr. Wilhem Kolff was the Patron of the Silver Jubilee Conference during which new topics such as "Collaborative Research" and a "Debate on Euthanasia" were introduced into the curriculum.

Each year, renal-related corporations are invited to organize and present educational sessions on topics of their choosing. The corporate sponsored sessions offer a selection of excellent speakers to discuss current topics in a particular area of interest. Unlike U.S. conferences, industry sponsored sessions account for about half of the educational programming at the EDTNA/ERCA. The corporate sessions are translated both from and into English, French, German, Italian, Spanish, and Greek.

The 1996 Renal Systems Program consisted of presentations by Dr. K. Ya. Gurevich (Russia), Dr. Allan Collins (U.S.A.), and Dr. Colin B. Brown, Alison Smith, R.N., and Paul McNestry (UK). Their topics included "First Experience of Renatron Dialyzer Reprocessing in Russia," "Reuse Analysis of Freestanding and Hospital-Based Units in the U.S.A.," and, "Introducing a Program of Reuse to an Established Hemodialysis Unit." Reuse of dialyzers in Europe has been limited until recent years primarily because the availability of significantly higher reimbursement rates for dialysis treatments (no economic pressure to reuse), and legal controversies surrounding the labeling of dialyzers "for single use only." However, each year interest in reuse has been increasing as resources become scarcer. The European community is aware of dialyzer labeling changes that are taking place in the United States and are evaluating their current positions in light of these changes. Europeans also voice a strong concern for environmental issues and see reuse as a part of the environmental solution.

The 26th Annual Conference will be held in Prague, July 5-8, 1997. For further information, contact:

EDTNA/ERCA Conference Department, Mayfair House, 4 Christ Church Way, Woking, Surrey GU21 1BP, United Kingdom. Tel: +44 1483 764114 Fax: +44 1483 727816

Question:
What are the appropriate storage conditions for a Renalin®-reprocessed dialyzer?

Answer:
Renalin®-filled, reprocessed dialyzers should be stored in a designated storage area. According to the 1993 edition of the AAMI Guidelines for Reuse of Hemodialyzers, "Segregation of new, used and reprocessed dialyzers should be maintained to make clear the status of each group of dialyzers." Ideally, each patient should have a clearly marked space for storage of their respective reprocessed dialyzer(s).

Because internal pressure may build in the dialyzer and cause the dialysate port caps to dislodge, Renalin®-filled dialyzers should be stored with both dialysate port caps resting against a shelf or other hard surface. If shelves are not available, dialyzers should be kept in a polyethylene plastic bag to protect personnel and equipment from Renalin® exposure should the dialysate port caps dislodge under pressure.

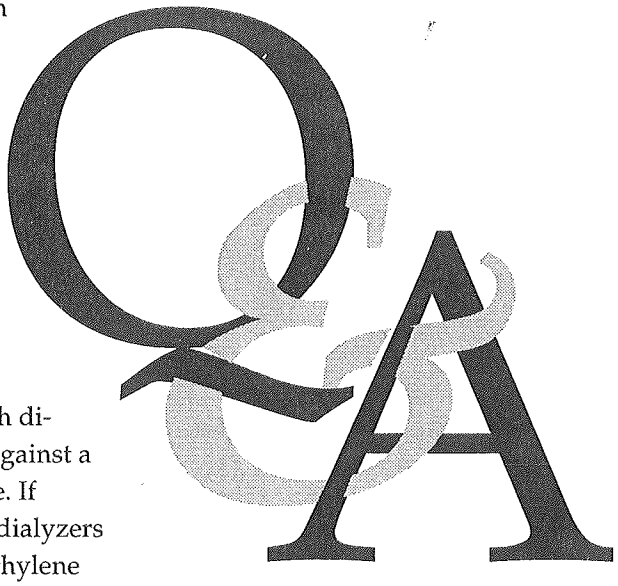
If port cap dislodgment occurs frequently, storage conditions could be the cause. Renalin®-reprocessed dialyzers should be stored in a well-ventilated, cool area and should be kept out of direct sunlight. The recommended temperature of the storage room is 65°F (18°C) to 75°F (24°C).

High residual blood volume may also contribute to pressure buildup. Dialyzers with residual organic load might benefit from a pre-clean cycle prior to reprocessing.

If pressure buildup in your dialyzers continues to be a problem, contact technical service or your Renal Systems representative for help in determining the possible cause of the problem.

Question:
If a dialysate port cap does dislodge from a Renalin®-reprocessed dialyzer during storage, what should be done with that dialyzer?

Answer:
The disposition of a Renalin®-reprocessed dialyzer with a dislodged port cap is ultimately the decision of the medical director. Renal Systems recommends discarding the dialyzer if the dialysate compartment is completely empty of Renalin® solution. If Renalin® solution remains in the dialyzer, a Renalin® presence test should be performed with a Renalin® Indicator test strip or a Perassay 500 Peracetic Acid Test strip. If the result of this presence test is positive, the dialyzer should be reprocessed and stored for a minimum of eleven hours prior to testing and rinsing for patient use.



Question:
Can dialyzers from patients testing positive with hepatitis B surface antigens be reprocessed?

Answer:
The 1993 edition of the AAMI guidelines on "Reuse of Hemodialyzers" (which was adopted by HCFA as Final Rule in October of 1995) states in Section 6, "[d]ialyzers should not be reprocessed from patients who have tested positive with hepatitis B surface antigens." According to the Federal Register Vol. 60, No. 180, this decision to prohibit the reuse of dialyzers was developed by the medical community and reflects the general concern of most professionals that extreme caution is necessary in treating patients with the disease.

We Appreciate Your Patience

Renal Systems would like to thank all of our customers for their patience and support during our recent computer system changeover. Some of you may have experienced an increased lead time for product shipments to your facility. Please be assured that we are working diligently to eliminate these problems and expedite all orders. Our most important goal is your satisfaction.

The Mark of Quality

Communaute Europeene mark

Over the past year, you may have noticed a new symbol on several Renal Systems products. The Communaute Europeene (or CE) mark was created by the European Commission to indicate that a product has been certified for sale throughout the European Union. It also indicates that a manufacturer complies with stringent safety and quality standards outlined in the European Medical Device Directive. Simply put, the CE mark signifies that a sound quality assurance system is behind a product - and that's important to customers around the globe.

ISO 9001 - What does it mean?

Before a manufacturer can sell goods in the European marketplace, it must demonstrate strict adherence to safety and quality standards from product development through distribution. These standards are governed by the International Organization for Standardization (ISO), a federation of standards organizations from 100 member countries, including the U.S. Since 1947, ISO has defined over 9000 global specifications for everything from credit cards to catheters.

ISO has developed a series of standards known as the ISO 9000 family that deal specifically with quality systems. Before a manufacturer can put the CE mark on a product, it must be registered in one of the ISO 9000 quality standards. ISO 9001, *Quality Systems - Models for Quality Assurance in Design, Development, Production, Installation and Servicing*, is the most comprehensive and far–reaching of these to date.

Making the grade

Before earning ISO 9001 registration, a company must develop a quality manual and documented quality system procedures. ISO 9001 also requires specific plans of action for important quality issues, such as identifying training needs within an organization and correcting quality problems. Once all requirements are met, a company must successfully complete a series of assessments by a third party registration agency. When a medical device manufacturer achieves ISO 9001 registration, it can self-certify products that meet European standards with the CE mark.

An ongoing process

As an ISO 9001 registered company, Renal Systems, division of Minntech Corporation, conducts regular internal audits of our quality systems across the company. In addition, a third-party registration agency, TÜV Product Service of Munich, Germany, performs annual surveillance audits to ensure that the integrity of our quality system is upheld. In Europe and around the globe, a CE mark on a Renal Systems product represents our ongoing commitment to superior product and service quality.

International Symbols

As the international medical community attempts to standardize care and products, the use of symbols on medical devices is becoming more prevalent. The following symbols are commonly found on dialyzers and other medical devices:

LOT	Indicates manufacturer's product lot number	STERILE EO	Product sterilized with ethylene oxide		Refer to the instructions for use
SN	Indicates manufacturer's product serial number	STERILE R	Product sterilized with irradiation		Use product by a specific date (accompanied by date)
REF	Indicates manufacturer's part or catalogue number	STERILE	Product sterilized with steam or dry heat		Date of manufacture (accompanied by date)
		2	Product made for single use only		

Back Issues

To receive a personal copy of future issues, or any of our back issues, call Renal Systems customer service at 1-800-328-3340.

The following back issues of *ReNews* are available free-of-charge. Please limit your order to one per issue.

Vol 1, #1, 1993
"Current Issues in Dialyzer Reuse"
"Key Aspects of the New HCFA Guidelines"

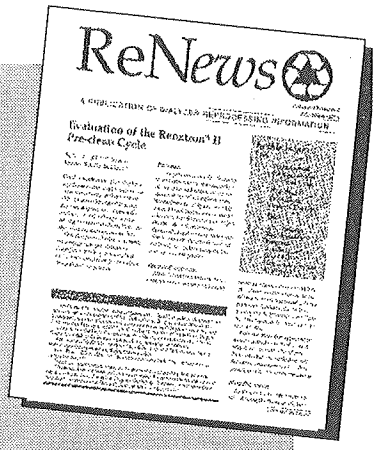
Vol 1, #2, 1993
"Highlights of the New AAMI Reuse Guidelines"
"Reuse in the Nineties - Are We Better Off?"

Vol 2, #1,1994
"Achieving Maximum Use - One Unit's Perspective"
"Endotoxins, Dialysis, and Pyrogen Reactions"

Vol 2, #2,1994
"Evaluation of the Renatron II® Pre-Clean Cycle"
"Is a Dialyzer Reprocessing Program Beneficial When Low Cost Hemodialyzers are Available?"

Vol 3, #1, 1995
"The Impact of Anticoagulation Techniques on Dialyzer Reuse"
"What IS a Sterilant, Anyway?"

Vol 3 #2, 1995
"FDA Prepares to Regulate Dialyzer Reuse Labeling"
"HCFA Adopts 1993 ANSI/AAMI Guidelines"



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analysis would suggest that other factors beside the germicide itself are contributing to these results."

Ironically, Dr. Collins' data demonstrates that the mortality trend had already reversed in favor of reuse at the time of the 1992 controversy surrounding reuse with Renalin® and higher mortality rates. The important finding of a strong association with facility profit status supports a commonly held theory that poor technique was a root cause of the 1992 findings. Dr. Collins concludes that "Major changes in dialysis therapy had been initiated in the U.S. after the first USRDS report in 1989, and after the Dallas Morbidity and Mortality Conference, published July 1990. The improved survival rate in the U.S. since 1990, in conjunction with increased reuse, is more consistent with the mortality reduction from improved therapy (the 8% lower mortality risk for each 0.1 Kt/V increase) than with reuse or specific germicides."

Dr. Collins is the Director of Nephrology Analytical Services (NAS), Hennepin County Medical Center, The Fred Shapiro Center for Evidence-Based Medicine. The new analysis represents about 10% of the U.S. hemodialysis patient population and was derived from expanded data sets including, among others, HCFA Data (PMMIS, Outpatient Claims, Inpatient Claims, and Facility Survey from 1978-1994; CDC National Surveillance of Dialysis-Associated Diseases 1987-1994).

FDA Sets Deadline For Dialyzer Reuse Labeling

As previously reported here (see "FDA Prepares to Regulate Dialyzer Reuse Labeling," *ReNews* Vol. 3 No. 2, Fall/Winter 1995), the FDA has established new labeling guidelines that will require manufacturers who market dialyzers intended for reuse to label them as such.

The FDA has now set a deadline of February 24, 1997 for compliance with the new guidelines. By that time, manufacturers marketing multiple-use dialyzers must either 1) submit a 510(k) and the required reuse labeling information for each multiple-use dialyzer model or 2) discontinue the marketing and sale of dialyzers labeled "single use" to reuse facilities.

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