ReNews

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A PUBLICATION OF DIALYZER REPROCESSING INFORMATION

Evaluation of the Renatron® II Pre-clean Cycle

By J. Curtis,CHT; C. Imm; R. Inahara,BS,CHT; M. Simon*

Good Samaritan Hospital Nephrology Services (Portland, Oregon) has been reprocessing dialyzers since 1990 using the Renatron® Dialyzer Reprocessing System. We recently evaluated a major change in reprocessing technique at Cherry Park Dialysis Center, our newest satellite.

This change resulted in increasing the average uses per dialyzer of those patients who previously had the lowest overall average, as well as streamlining our process.

Purpose:

The primary reason for changing procedures came at the suggestion of one of the technicians doing the reprocessing, who simply did not like flushing the dialyzers with RO water. He felt that he was exposed to a lot more blood than when they just attached the dialyzers to the Renatron®. Together we developed a plan to evaluate the effectiveness of the Pre-Clean cycle as compared to our then current practice.

Former Procedure:

All dialyzers were brought to the reuse room as soon after dialysis as possible (fifteen to thirty minutes). The dialyzers were attached to an RO water faucet and the blood compartments flushed until the fluid leaving the dialyzer was clear. They were then put on the Renatron® for reprocessing.

Only dialyzers that appeared to be very clotted were Pre-Cleaned with the Renatron®'s Pre-Clean cycle. All others were flushed with RO water, reprocessed, and either passed, or failed the automatic testing.

New Procedure:

Baseline reuse averages were calculated using the Renalog® III data-

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About the Authors

Jim Curtis, CHT was the Technical Specialist at Good Samaritan. (At press time, he has taken a new position as Chief Technician at Oregon Kidney Center) Jim developed the protocol for the evaluation, and wrote the final paper. He is the NW Regional Vice President of NANT, and is a Board Member of the NKF of Oregon.

Craig Imm is the Head Technician at Fort Vancouver Kidney Center, a Good Samaritan satellite. Craig was responsible for analyzing the statistics.

Rob Inahara, BS,CHT is the Head Technician at Cherry Park Dialysis Center. Rob supervised reprocessing during the evaluation.

Mike Simon, BS is a Dialysis Technician at Cherry Park. The concept for this evaluation was his.

These four technologists represent 57 years of combined dialysis experience.

**The procedures for reuse detailed herein reflect the considerations and views of the authors and Good Samaritan Hospital Nephrology Services , which should not necesarily be attributed to Renal Systems or Minntech Corporation.*

In this Issue

TABLE 1
Study Sample Average # Uses ≤ 12; n=30 Group 2

t-Test Paired Two-Sample for Means	Pre-Protocol	Post Protocol
Mean	6.79	9.57
Variance	8.14	26.14
Observations	30	30

df=29
t=-3.93
P=0.002

Continued from page 1

base. Patients were divided into two groups: GROUP 1, those who averaged more than 12 uses per dialyzer; and GROUP 2, those who averaged 12 uses or less per dialyzer.

Dialyzers from patients in GROUP 1 were reprocessed on the Renatron® without any pre-treatment. They were not exposed to either an RO water flush or the Renatron® Pre-Clean Cycle. Our thought was that these dialyzers usually are fairly clean when they come into the reuse room, and flushing was time spent that did not benefit us. Success criteria for this group would be for their reuse average to not decrease significantly.

Dialyzers from patients in GROUP 2 were always run through the Pre-Clean cycle, and allowed to sit in a Renalin® solution for a minimum of two hours before reprocessing. The evening shift dialyzers usually sat overnight.

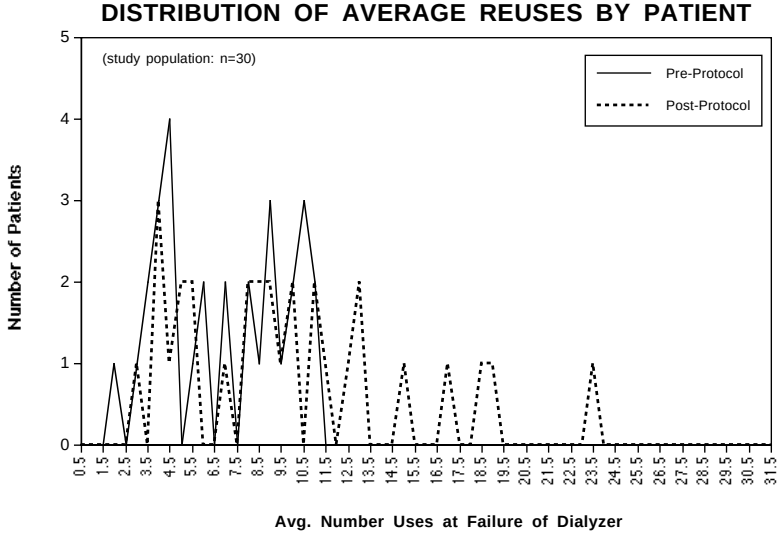
METHOD:

Reuse averages were calculated for all patients at Cherry Park Dialysis Center for the period of 1/1/94 to 4/1/94. These patients were then divided into GROUPS 1 and 2.

Dialyzers from GROUP 2 were identified with a strip of yellow tape to alert the technician to use the Pre-Clean cycle.

There were nine patients who were involved in a study to evaluate the effects of high doses of EPO. These patients were excluded from our reuse evaluation because a high hematocrit would probably affect reuse averages.

Our maximum cut-off of thirty-one uses per dialyzer was not changed.



RESULTS:

The patients (n=39) in GROUP 1 averaged 21.56 (SD=5.86) uses per dialyzer in the three months prior to the evaluation. During the study period, these patients average decreased slightly to 20.63 (SD=6.17) uses.

In the three months prior to this evaluation, the patients (n=30)in GROUP 2 averaged 6.79 (SD=2.8) uses per dialyzer. These same patients averaged 9.57 (SD=5.11) over the next six month period. Based on 'Students' t-Test and Wilcoxon's Signed Ranks Test (tables 1 and 2), a significant improvement was attained in the study population by using the Pre-Clean cycle. Patients' overall reuse average improved (see graph below).

TABLE 2
Wilcoxon's Signed Ranks Test

R=53	n=30
z=3.69	P=0.002

CONCLUSIONS:

The utilization of the Pre-Clean cycle on the Renatron® is effective at improving reuse averages for those patients who tend to run low averages otherwise. The Pre-Clean cycle is more effective than flushing the dialyzer with RO water. There was a net improvement in reuse averages of 40% in GROUP 2.

Those patients who tend to get high reuse averages will do so without using any kind of special treatment. It is a more effective use of resources to focus on the patients who get lower averages.

On average, the thirty nine patients in GROUP 1 used 21 dialyzers per month prior to the study, and 22 per month afterwards. The 30 patients in GROUP 2 used 53 dialyzers per month prior, and 37 dialyzers per month afterwards. The bottom line is that we now use 15 fewer dialyzers per month!

New Primus® Polysulfone Dialyzer Provides High Flux Therapy

Renal Systems is pleased to announce the introduction of the Primus® family of high flux Polyphen™ polysulfone hemodialyzers in the United States. Polyphen™ polysulfone is manufactured in Minneapolis, Minnesota U.S.A. by Renal Systems and offers a high degree of biocompatibility. In addition, the Primus® dialyzers are labelled specifically for multiple use and includes the following statement: "Reuse recommended with the Renatron® System and Renalin® Sterilant."

High Flux Dialyzers

While definitions vary, high flux dialyzers are recognized as having high clearance rates of a broad range of uremic toxins and water. Studies show that patient survival rates increase with the amount of therapy delivered, with urea removal indices often being used as a determinant of the adequacy of dialysis.[1,2] The Primus® high flux dialyzer demonstrates high removal rates of urea and other toxins, thereby enabling physicians to optimize the amount of dialysis therapy delivered during dialysis sessions.

Biocompatibility

Biocompatibility is an increasingly recognized important feature to be considered in dialyzer selection. Cellulosic membranes have been associated with complement activation, as reflected by a rise in circulating anaphylatoxin levels. These reactions are largely eliminated during dialysis with synthetic polysulfone dialyzers[3].

Removal of Beta-2 Microglobulin (β2- M)

Studies show an increase in serum β2- M in long-term hemodialyzed patients. The capacity to remove β2- M is an important characteristic of a dia-

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Extended Service Program

An Extended Service Program will be available soon to add additional years of warranty service to each Renatron® Station. Currently, each Renatron® Station carries a one-year New Equipment Warranty and requests have been made for the option to extend our basic warranty service. You will soon have the option to extend warranty service on a Renatron® Station that is currently covered by the New Equipment Warranty or resume Warranty coverage to a Renatron® Station out of warranty. Our Technical Service Department will then be able to continue to provide the service you expect and refurbish each Renatron® Station to factory specifications. Renal Systems strongly recommends only the use of replacement parts which are manufacturer-approved and which meet Renal Systems' product specifications.

Your sales representative will have all of the information, availability and pricing on this new program.

From the Editor

Renal Systems has reorganized its sales force to offer more complete and in-depth coverage of all its dialysis products. Each sales representative will represent the full line of dialysis products, providing the customer with "one representative—all product service."

Each sales representative has a strong background and years of experience in representing dialysis products. Their collective expertise in the field provides customer credibility and a strong service record.

To obtain the name and number of your Renal Systems sales representative, please call 800-328-3340.

This edition of *ReNews* is the fourth publication in two years. There have been many changes, additions and improvements in the dialysis and reprocessing field since the first edition of *ReNews* in the spring of 1993. These advancements are what make the field of dialysis and dialyzer reprocessing exciting and challenging. I want to thank you for your comments, suggestions and support for *ReNews*.

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

Suzanne Gooselaw, RN.
Reprocessing Product Manager
Renal Systems
Editor

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lyzer. The accumulation of β2- M in patients on long-term hemodialysis using cuprophan membranes is associated with amyloid deposition in joints, bone cysts, carpal tunnel tissue and eventually other organs including the liver, kidneys, bowel and brain. The joints most commonly affected are the shoulders, wrists, hands, knees and ankles, although amyloid may be found in clinically non-affected joints. Amyloid deposited in bone cysts may lead to pathologic fractures and in the spine, to a destructive spondyloarthropathy.[4]

In a study by Carol et al., dialyzers with polysulfone membranes removed 3.5 - 14 times more β2- M than dialyzers with cuprammonium based membranes.[5] Importantly, β2-M removal rates of polysulfone dialyzers are largely unaffected by reuse with peracetic acid.[6]

Backfiltration

A concern among clinicians has been that the potent convective mass transfer of high flux membranes can result in significant backfiltration when low transmembrane pressures are applied to minimize ultrafiltration. Polyphen™ is an advanced form of polysulfone with lower hydraulic (water) permeability than comparable membranes—without sacrificing high clearance rates of uremic toxins.

Reprocessing

With increasingly limited economic resources, reprocessing has permitted the use of more efficient and biocompatible, but also more expensive dialyzers. This was especially evident in the United States during the 1980s when declining reimbursement rates coincided with the introduction of high flux therapies. Elsewhere in the world, economic resources are straining under the pressure of steadily increasing patient populations.

The Primus® dialyzer has been specifically designed for reprocessing with the Renatron® and Renalin® Dialyzer Reprocessing Concentrate. The integration of dialyzer design and materials with state-of-the-art automated reprocessing technology represents a new step in the evolution of dialysis therapy.

Summary

There are presently 130 different models of hemodialyzers sold in the U.S. Many have low clearance rates, some are made of *bio-incompatible* materials and still others are poorly suited for reprocessing. The Primus® Polyphen™ polysulfone membrane is an advanced membrane that provides high clearance rates ranging from relatively small urea to large β2- M molecules, generates low patient immune response and has been specifically designed for multiple use.

Our **Primus**® dialyzer was recently evaluated for safety and efficacy under a clinical trial at two Minneapolis area hospitals, Abbott Northwestern Hospital Dialysis Center and the Artificial Kidney Center at Methodist Hospital. A total of 20 patients participated with each patient being treated twice with a **Primus**® dialyzer. Review of clinical results demonstrates that the **Primus**® dialyzer met expectations for safety, handling and clearance performance characteristics. The **Primus**® dialyzer was found to behave similarly to other dialyzers made of polysulfone fibers during priming, treatment and rinse back. Two other tests — Beta-2 microglobulin and C3, a complement activator — were also evaluated during this clinical trial. These clinical results support our confidence that the **Primus**® dialyzer will make a valuable contribution to the kidney dialysis community.

References

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[3]Bergesio F, Monzani G, Manescalchi F, Boccabianca I, Passaleva A, Frizzi V, "Leukocytes, Eosinophils and Complement Function during Hemodialysis with Polysulphone and Polymethylmetacrylate Membranes: Comparison with Cuprophane and Polyacrylonitrile," *Blood Purification* Volume 6, pp 16-26, 1988.

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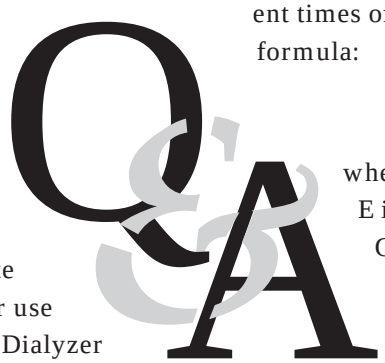
6Kerr P, Argiles A, Canaud B, Flavier JL, Mion C, "The effects of reprocessing high-flux polysulfone dialyzers with peroxyacetic acid on B2-microglobulin removal in hemodiafiltration. *Amer Journ of Kidney Disease*, Vol 19, No. 5 pp. 433-438, 1992.

Q. A 1% Renalin® solution can be used for port cap disinfection. What is the formula for making Renalin® 1% from 21% Renalin® solution ?



A. 21% Renalin® is the concentration of the Renalin® solution in a 2.5 gallon container with two liters of Renalin® concentrate properly diluted for use with the Renatron® Dialyzer Reprocessing System.

A 1% Renalin® solution can be made from the 21% Renalin® solution by using 48 mls of the 21% Renalin® solution and adding 952 mls of AAMI quality water and mixing well. This will deliver one liter of 1% Renalin® solution for port cap disinfection. (Fresh 1% Renalin® solution should be made daily.)

Q. OSHA has 8-hour TWA limits of 1 ppm for hydrogen peroxide and 10 ppm for acetic acid, two of the chemicals included in Renalin®. How are these 8-hour TWA measurements performed and calculated ?

A. A time weighted average (TWA) is an employee's average airborne exposure in any 8-hour work shift of a 40-hour week. In the U.S., the Occupational Safety and Health Administration (OSHA) has established exposure limits for several chemicals used for dialyzer reprocessing including formaldehyde (0.75 ppm TWA), glutaraldehyde (0.2 ppm TWA) and chlorine dioxide (0.1 ppm TWA) as well as the hydrogen peroxide and acetic acid components of Renalin® mentioned above. There are currently no established limits for airborne exposure to peracetic acid, another component of Renalin®.

TWA determinations take into account both the level and duration of exposure to airborne contaminants. Using methods such as the Renatest®, a series of samples are taken to determine airborne levels during different times of the work day. An 8-hour TWA is then calculated using the formula:

$$E = \frac{C1\ T1 + C2\ T2 + \ldots\ldots Cn\ Tn}{8}$$

where

E is the equivalent exposure for the working shift.

C is the occupational exposure.

T is the associated exposure time.

In practice, many facilities collect samples when and where Renalin® vapors are at their highest expected (peak) levels. If these peak hydrogen peroxide and acetic acid levels are below the OSHA TWA limits, the results are considered valid for the purpose of demonstrating regulatory compliance. This is because, while not the same as TWA determinations, measurement of peak levels actually overestimates exposure.

If TWA determinations are desired (or required by a surveyor or inspector), be careful to take into account only the time in which an employee is actually exposed to airborne contaminants. In the case of reuse personnel, there are commonly other routine duties outside of the reprocessing room during which time exposure levels are zero. The following is a sample calculation for hydrogen peroxide which includes 2 hours of the work day outside of the reuse room.

Work Period	Exposure Level (ppm)	Exposure Duration (hr)
8:00-10:00 AM	0.1	2.0
10:00-10:15 AM	0.0 (coffee break)	0.25
10:15-11:45 AM	0.2	1.5
12:15-1:30 PM	0.0 (stocking storeroom)	1.25
1:30-3:00 PM	0.1	1.5
3:00-3:15 PM	0.0 (coffee break)	0.25
3:15-4:30 PM	0.2	1.25

$$TWA = \frac{(0.1 \times 2.0) + (0.2 \times 1.5) + (0.1 \times 1.5) + (0.2 \times 1.25)}{8}$$

$$= \frac{0.2 + 0.3 + 0.25}{8}$$

$$= 0.09375$$

The exposure limits above are those set forth by the Occupation Safety and Health Administration, U.S. Department of Labor and may not be the same in other countries. If outside the U.S., be sure to review local regulations in order to ensure compliance.

Is A Dialyzer Reprocessing Program Beneficial When Low Cost Hemodialyzers Are Available?

Dialyzer Reprocessing Cost Analysis

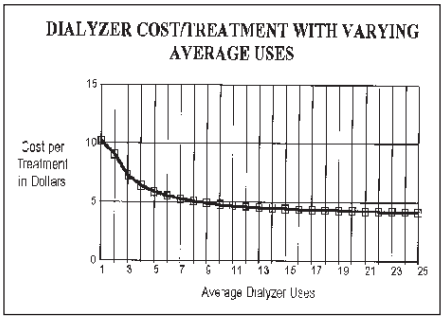
A common question asked by many dialysis centers concerns the benefits of initiating a reprocessing program when hemodialyzers can be purchased for as little as $10.00.

In order to help fully address this and other reprocessing issues, Renal Systems has developed a detailed cost analysis program which takes into account the direct and indirect costs of a reprocessing program (see the following analysis). An example of a small to average size facility with a hemodialyzer purchase price of $10.00 was selected. The program calculated the following results. The graphs shown here are a duplication of actual graphs generated by the cost analysis program (graph size has been reduced for this newsletter).

Input of Variables of the Outcome Analysis Program

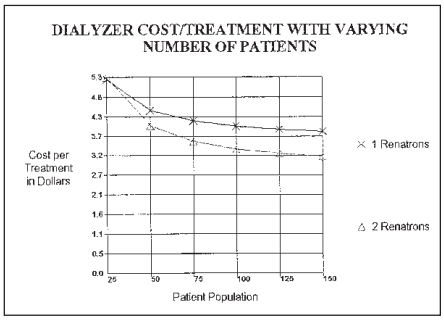
Reprocessing costs include both direct (labor, fringe benefits and supplies) and indirect (equipment depreciation, space used for reprocessing, microbiological monitoring tests, and administrative overhead) factors. An extra field has been included to accommodate any other indirect cost you may incur. The individual costs factors used for this outcome analysis are shown in the table below.

In determining the indirect and direct costs to the facility our list prices have been used for the Renatron® equipment and reprocessing supplies.



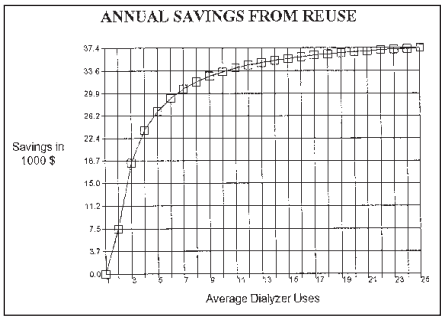
Graph 1
Dialyzer Cost/Treatment With Varying Average Uses

As noted by this graph the cost of a reprocessed dialyzer at 12 reuses is reduced from $10.00 to $4.70. Note that the cost of the dialyzer is not significantly reduced after the 12-14 use level.



Graph 2
Dialyzer Cost/Treatment With Varying Number Of Patients

This graph indicates that at approximately 30 patients the cost of the dialyzer per treatment can be reduced if an additional Renatron® station is added. Many smaller facilities start out with one Renatron® station and add additional as their patient population grows.



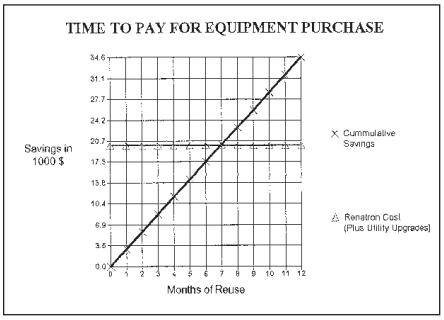
Graph 3
Annual Savings From Reuse

The annual savings from a reuse program, even with a low cost standard dialyzer, is $35,000 plus. If any percent of high flux dialyzers are introduced and reprocessed, the savings increase. Every dialysis unit could benefit from an additional $35,000 a year minimum savings!!

All Variables Used in Cost Analysis:

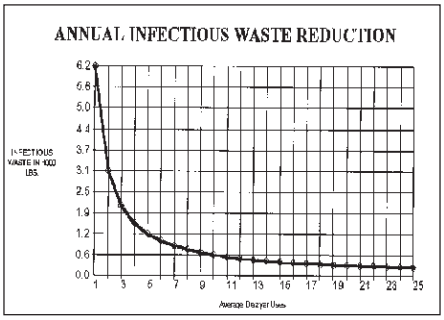
Renatron® Model	RS8330 System	Renatron® Price	$20,170
# of Renatron® Stations	1	Number of Patients Reusing	40
HIgh Flux Dialyzer Price	N/A*	Std. Dialyzer Price	$10
% High Flux Treatments	N/A*	% Standard Treatments	100
Avg. # Dialyzer Uses	12	Treatments/month/patient	13
Reprocessing Tech. Salary	$8/hr.	Fringe Benefits	20%
ISO blood port cap	$19/100	Dialysate port cap	$47.50/500
Renalin®	$108.65/cs	Purified Water	$.01/gal.
Renalin® Residual Test	$20/100	Perassay™ Test	$20/100
Dialyzer Label Cost	$49.50/5000	Infectious Waste Disposal	$.50/lb
Equip. Depreciation Interval	5 yrs.	Utility Upgrade	$0.00
Reprocessing Space	$1,500/yr	Cleaning Solution	$4.49/ 1/2 gal.
Microbiological Monitoring	$30/mo	Other Indirect Costs	$.00
Admin. Overhead Rate	10%		

* N/A = not applicable



Graph 4
Time To Pay For Equipment Purchase

Even with a small program of 40 patients, the cost savings from the reprocessing program pays for the initial equipment outlay within seven months. The reprocessing of more costly hemodialyzers will further accelerate the equipment payoff time frame.



Graph 5
Annual Infectious Waste Reduction

This graph indicates that at a reuse average of 12, this model center can reduce annual infectious waste by as much as 6,000 pounds. The environmental impact of medical waste is already a major issue in Europe and other countries and is becoming an increasing concern in the United States. With the cost of medical waste disposal increasing, reprocessing will continue to provide additional cost savings to dialysis facilities **and** benefit the environment.

Conclusion

A review of this complete analysis demonstrates an economic and environmental benefit for this dialysis facility. The answer to the question, "is a dialyzer reprocessing program beneficial when low cost hemodialyzers are available" is very clearly, YES.

If you would like an initial reprocessing cost analysis for your facility or if you are already reprocessing and would like an update, please contact your Renal Systems sales representative or call 1-800-328-3340.

Report on the 31st Congress of the EDTA/ERA and the 23rd Conference of the EDTNA/ERCA

Vienna, Austria July 1994

By Geraldine Biddle, RN, CNN

The combined annual meetings of the European Dialysis and Transplant Association / European Renal Association (EDTA / ERA) and the European Dialysis and Transplant Nurses Association / European Renal Care Association (EDTNA / ERCA) took place in Vienna, Austria, July 3-6, 1994 and attracted over 6000 health related professionals,

The content of the scientific sessions mirrors that of US programs: adequacy of dialysis, beta 2-microglobulin, advances in multiple organ transplantation, staffing issues and quality assessment. Of particular interest this year, however, was the status of the Annual Report of Renal Failure—the Registry Report.

The data collection in this year's report was marred by what has been a continuous yearly drop in the number of European centers responding to the Registry questionnaires. Only 1,326 centers replied for this year's report, representing less than one half of all the centers receiving the questionnaire (2,887). For the 1992 Combined Reports, 1,553 centers responded to the questionnaire.

In stark contrast to the United States, where data submission is mandatory, data submission to the European Registry is voluntary and lacks accuracy and validity checks similiar to those performed on US data by the United States Renal Data System (USRDS). US mortality is frequently compared to that to the Europeans using the Registry data. Current data problems place those comparisons in a new light and begs the question, "what is the true reflection of mortality in the dialysis community in Europe?"

An audit of the Registry operations is currently taking place and is due in October. The audit will help determine the future direction of the Registry.

The 1995 Annual Congress will take place in Athens, Greece, June 11-14th. Deadlines for submitting abstracts is January 23, 1995. Additional information related to program schedules, fees, and pre- and post-meeting Greek Islands cruises can be obtained by contacting the Organizing Secretariat and Travel Agency at: Triaena Congress,
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