

Joined: 14 Feb 2003  
Posts: 2

PostPosted: Tue Feb 18, 2003 6:07 am Post subject: REUSE

Effect of dialyzer reuse on survival of patients treated with hemodialysis. <  
>Feldman HI, Kinosian M, Bilker WB, Simmons C, Holmes JH, Pauly MV, Escarce JJ. <  
>Center for Clinical Epidemiology and Biostatistics, University of Pennsylvania Medical Center, Philadelphia 19104-6021, USA. <  
>OBJECTIVE: To evaluate the impact of dialyzer reuse on the survival of US hemodialysis patients. <  
>STUDY DESIGN AND PARTICIPANTS: Nonconcurrent cohort study of 27938 patients beginning hemodialysis in the United States in 1986 and 1987. <  
>MAIN OUTCOME MEASURE: Patient survival. <  
>RESULTS: Dialysis in freestanding facilities reprocessing dialyzers with the combination of peracetic and acetic acids was associated with greater mortality than treatment in facilities not reprocessing dialyzers (rate ratio [RR],1.10, 95% confidence interval [CI], 1.02-1.18; P=.02) In contrast, there was no significant difference between survival in freestanding facilities reprocessing dialyzers with either formaldehyde (RR,1.03, 95% CI, 0.96-1.10; P=.45) or glutaraldehyde (RR, 1.13, 95% CI, 0.95-1.35, P=.1 and survival in freestanding facilities not reprocessing dialyzers. Among freestanding facilities reprocessing dialyzers, use of peracetic/acetic acid was associated with a higher rate of death than use of formaldehyde (RR = 1.08, 95% CI, 1.01-1.14; P=.02). There was no statistical difference between survival in hospital-based facilities reprocessing dialyzers with either peracetic/acetic acid (RR=0.95, 95% CI, 0.85-1.06; P=.40), formaldehyde (RR=1.06, 95% CI, 0.98-1.15; P=.12), or glutaraldehyde (RR=1.09, 95% CI, 0.71-1.67; P=.70) and survival in hospital-based facilities not reprocessing dialyzers. In addition, choice of sterilant was not associated with a statistically significant difference in survival among hospital-based facilities reprocessing dialyzers.<  
> <  
>CONCLUSIONS: **Dialysis in freestanding facilities reprocessing dialyzers with peracetic/acetic acid may be associated with worse survival than dialysis in free-standing facilities not reprocessing dialyzers or in those reprocessing with formaldehyde.** We were unable to determine whether these relationships arose from greater comorbidity among patients treated in facilities using peracetic/acetic acid, poor quality of dialysis procedures in these facilities, or direct toxicity of peracetic/acetic acid. These findings raise important concerns about potentially avoidable mortality among US hemodialysis patients treated in dialysis facilities reprocessing hemodialyzers.<  
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starting

Joined: 18 Feb 2003  
Posts: 1

PostPosted: Tue Feb 18, 2003 6:09 am Post subject: REUSE

Septicemia in dialysis patients: incidence, risk factors, and prognosis. <

>Powe NR, Jaar B, Furth SL, Hermann J, Briggs W. <

>Department of Medicine, John Hopkins University School of Medicine, Baltimore, Maryland, USA.  
[npowe@jhmi.edu](mailto:npowe@jhmi.edu)<

> <

>BACKGROUND: Infection is second to cardiovascular disease as a cause of death in patients with end-stage renal disease (ESRD), and septicemia causes a majority of these infectious deaths. To identify patients at high risk and to characterize modifiable risk factors for septicemia, we examined the incidence, risk factors, and prognosis for septicemia in a large, representative group of U.S. dialysis patients. METHODS: We conducted a longitudinal cohort study of incident ESRD patients in the case-mix study of the U.S. Renal Data System with seven years of follow-up from hospitalization and death records. Poisson regression was used to examine independent risk factors for hospital-managed septicemia. Cox proportional hazards analysis was used to assess the independent effect of septicemia on all-cause mortality and on death from septicemia. Separate analyses were performed for patients on peritoneal dialysis (PD) and hemodialysis (HD). RESULTS: Over seven years of follow-up, 11.7% of 4005 HD patients and 9.4% of 913 PD patients had at least one episode of septicemia. **Older age and diabetes were independent risk factors for septicemia in all patients. Among HD patients, low serum albumin, temporary vascular access, and dialyzer reuse were also associated with increased risk.** Among PD patients, white race and having no health insurance at dialysis initiation were also risk factors. Patients with septicemia had twice the risk of death from any cause and a fivefold to ninefold increased risk of death from septicemia. CONCLUSIONS: Septicemia, which carries a marked increased risk of death, occurs frequently in patients on PD as well as HD. Early referral to a nephrologist, improving nutrition, and avoiding temporary vascular access may decrease the incidence of septicemia. Further study of how race, insurance status, and dialyzer reuse can contribute to the risk of septicemia among ESRD patients is indicated.<

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Joined: 18 Feb 2003

Posts: 3

PostPosted: Tue Feb 18, 2003 6:11 am Post subject: REUSE

Association of dialyzer reuse and hospitalization rates among hemodialysis patients in the US. <

>Feldman HI, Bilker WB, Hackett M, Simmons CW, Holmes JH, Pauly MV, Escarce JJ.<

> <

>Center for Clinical Epidemiology and Biostatistics and Department of Biostatistics and Epidemiology, University of Pennsylvania Medical Center, Philadelphia, PA, USA. <

>OBJECTIVES: To determine if reuse of hemodialyzers is associated with higher rates of hospitalization and their resulting costs among end-stage renal disease (ESRD) patients. METHODS: Noncurrent cohort study of hospitalization rates among 27,264 ESRD patients beginning hemodialysis

in the United States in 1986 and 1987. RESULTS: Dialysis in free-standing facilities reprocessing dialyzers was associated with a greater rate of hospitalization than in facilities not reprocessing (relative rate (RR) = 1.08, 95% confidence interval (CI), 1.02-1.14). **This higher rate of hospitalization was observed with dialyzer reuse using peracetic/acetic acids (RR = 1.11, CI 1.04-1.1 and formaldehyde (RR = 1.07, CI 1.00-1.14), but not glutaraldehyde (p = 0.97).** There was no difference among hospitalization rates in hospital-based facilities reprocessing dialyzers with any sterilant and those not reprocessing. Hospitalization for causes other than vascular access morbidity in free-standing facilities reusing dialyzers with formaldehyde was not different from hospitalization in facilities not reusing. However, reuse with peracetic/acetic acids was associated with higher rates of hospitalization than formaldehyde (RR = 1.08, CI 1.03-1.15). CONCLUSIONS: Dialysis in free-standing facilities reprocessing dialyzers with peracetic/acetic acids or formaldehyde was associated with greater hospitalization than dialysis without dialyzer reprocessing. This greater hospitalization accounts for a large increment in inpatient stays in the USA. These findings raise important concerns about potentially avoidable morbidity among hemodialysis patients.<

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miss

Joined: 18 Feb 2003

Posts: 1

PostPosted: Tue Feb 18, 2003 6:13 am Post subject: REUSE

Dialyzer reuse: what we know and what we don't know. <

>Despite extensive clinical experience, the effects of different reuse procedures have not been fully evaluated. The available data suggest that the effect of reuse on dialyzer performance depends upon the type of chemicals employed, the mem

ane type, and the size of the solute whose removal is being assessed. The effect of reuse on urea clearance is essentially defined by the residual cell volume with a total cell volume of > 80% associated with a dialyzer clearance that is within 10% of its original value. **The effect of reuse on large solute clearance can be dramatic, with the procedure resulting in substantial changes in the beta2-microglobulin clearance of different dialyzers.** Of note is the limited data available regarding the effect of reuse procedures on dialyzers processed more than 20 times.<

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Joined: 18 Feb 2003

Posts: 1

PostPosted: Tue Feb 18, 2003 6:15 am Post subject: REUSE

**An outbreak of pyrogenic reactions in chronic hemodialysis patients associated with hemodialyzer reuse.**

Rudnick JR, Arduino MJ, Bland LA, Cusick L, McAllister SK, Aguero SM, Jarvis WR.

Investigation and Prevention Branch, U.S. Department of Health and Human Services, Atlanta, Georgia 30333, USA.

In February 1992, 22 patients undergoing chronic hemodialysis at an outpatient dialysis center experienced pyrogenic reactions (PR). The PR rate was significantly greater ( $p < 0.001$ ) during the epidemic (February 3-5) than the pre-epidemic period (November 1, 1992-February 1, 1992). All patients with PR used dialyzers that had been manually reprocessed either on February 1 or 3. These dialyzers contained up to 120.8 EU/ml of endotoxin in the blood compartment. The only dialyzer reprocessed before February 1 that was available for analysis was found to contain no detectable endotoxin, while dialyzers reprocessed during the epidemic period contained a median endotoxin concentration of 52.8 EU/ml. The bioburden of water used to prepare dialysate was in excess of the Association for the Advancement of Medical Instrumentation (AAMI) standard for water,  $\leq 200$  colony forming units (CFU)/ml. Samples of treated water collected in the reuse area were within AAMI standards at the time of the investigation (February 11 and February 26), but before the investigation, water samples were assayed with a culture method that could not detect microbial concentrations below  $10(3)$  CFU/ml. In addition, the treated water feed line to the disinfectant container may never have been disinfected. However, no samples were collected from this line during the investigation. This outbreak emphasizes the need to use water that meets the AAMI bacteriologic and endotoxin standards of  $\leq 200$  CFU/ml and/or 5 EU/ml, respectively, for reprocessing hemodialyzers and to ensure that appropriate culture techniques are used for treated water dialysate.

<http://www.ncbi.nlm.nih.gov/pubmed/7598647>

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articles

Joined: 18 Feb 2003

Posts: 1

PostPosted: Tue Feb 18, 2003 6:19 am Post subject: REUSE

Dilemma of mem

ane biocompatibility and reuse. <

>Klinkmann H, Grassmann A, Vienken J <

>International Faculty for Artificial Organs, University of Strathclyde, Glasgow, U.K.<

> <

>Numerous articles have been published on the multiple use of dialyzers and on the effect of different reprocessing chemicals and techniques on the dialyzer biocompatibility and performance. The results often appear contradictory, especially those comparing standard biocompatibility parameters. Despite this confusion, a discerning review of the published works allows certain limited conclusions to be drawn. Reprocessing of used hemodialyzers changes the biocompatibility profile of a dialyzer as defined by the parameters complement activation, leukopenia, and cytokine release. The effect of reprocessing depends on the chemicals and reprocessing technique applied and also on the type of membrane polymer being subjected to the reprocessing procedure. Reports of pyrogenic reactions indicate that the flux of the membrane

also influences how suitable it is for safe reuse. **An increased risk of allergic and pyrogenic reactions appears to be associated with dialyzer reuse.** Furthermore, there has been a lack of investigations into the immunologic effect of the layer of adsorbed and chemically altered proteins that remains on the inner surface of reprocessed dialyzers. We conclude that the clinical benefit of dialyzer reuse cannot be generally accepted from a biocompatibility point of view.<

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Joined: 18 Feb 2003

Posts: 1

PostPosted: Tue Feb 18, 2003 6:22 am Post subject: here you go!

The effect of dialyzer reuse on dialysis delivery <

>RA Sherman, RP Cody, ME Rogers and JC Solanchick <

>Department of Medicine, UMDNJ-Robert Wood Johnson Medical School, New Brunswick 08903.<

> <

>It is well documented that the reprocessing of dialyzers may reduce their solute clearance capabilities. However, the effect of dialyzer reuse has never been assessed in an uncontrolled clinical practice setting. We addressed this issue in a prospective 436-patient, 34-center study. All patients underwent formal urea kinetic modeling monthly, usually for 3 sequential months. Dialyzers were reprocessed and reused in the usual manner for each unit. As a result, urea kinetic modeling was performed in individual patients using dialyzers with differing numbers of prior uses. For each patient, Kt/V urea for the treatment using the dialyzer with the most reuses (mean, 13. was compared with that with the treatment using the dialyzer with the fewest reuses (mean, 3. . The mean Kt/V delivered for high reuse treatments was significantly lower than that for low reuse treatments (1.05 v 1.10, P = 0.002). Prescribed Kt/V in high and low reuse treatments was identical. Individual centers appeared to differ substantially (P = 0.06) in the effect of reuse on delivered Kt/V. Of the 23 centers using formalin-based reprocessing, an average difference of > or = 0.12 (mean, 0.17) in Kt/V between high and low reuse treatments was seen in 10 centers. **Dialyzer reprocessing significantly impairs dialysis delivery, an effect that may be related to the methods and procedures in individual dialysis centers.** <

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REUSE

Joined: 22 Feb 2003

Posts: 5

PostPosted: Sat Feb 22, 2003 6:44 am Post subject: Reuse is bad Reply with quote  
Read the FYI it contains clinical studies and not those that are industry driven for profit. <

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REUSE

Joined: 22 Feb 2003

Posts: 5

PostPosted: Fri Feb 28, 2003 1:33 pm Post subject: more information

1980's Renalin reactions<

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>Roxy<

>Unregistered User<

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>Reply 1990 Renalin Reactions<

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>Unregistered User<  
>(10/3/02 8:35:12 pm)<  
>Reply Dializer reuse article<  
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Joined: 11 Jan 2003  
Posts: 226

PostPosted: Wed Aug 09, 2006 4:54 am Post subject: 2004 study

**All analyses suggested favourable survival advantage among patients treated with single use dialysers.**

The reprocessing of disposable dialysers was first proposed for economic reasons [1]. Early studies suggested that the reprocessing and reuse of dialysers manufactured using cellulosic membranes conferred medical benefits to patients, apparently rendering the membrane more biocompatible with blood?

Dialysers using synthetic membranes have largely replaced those using cellulosic membranes in recent years. More than 80% of dialysis units used cellulosic dialysers in 1990 while <25% used any dialysers with a synthetic membrane. Those statistics were reversed by 2000 such that <25% of facilities used any cellulosic dialysers while >80% used synthetic membrane dialysers [4]. The synthetic membranes are more biocompatible than their cellulosic predecessors so the reuse-associated medical benefit probably disappeared. The rationale for reusing synthetic membrane dialysers thus became purely financial.?

Reprocessing dialysers is essentially limited remanufacturing that involves the cleaning and disinfection of a medical device. The practice is subject to few controls in the USA. Manufacturers could not follow such an uncontrolled practice for first use dialysers under current regulations in the USA (United States Code of Federal Regulations, Title 21, Parts 1, 26, 110, 211, 860, 876. April 1, 2003). The exposure of membranes to different disinfection chemicals and processes may

alter those membranes in unpredictable ways [14]. Hence, the membrane used may not be functionally equivalent to the membrane purchased if it has been reprocessed. **Simply said, dialysis facilities and regulatory agencies that oversee their operation in the USA do not require the levels of process control or quality surveillance that are required of manufacturers before a product is used to treat patients.**

<http://ndt.oxfordjournals.org/cgi/content/full/19/11/2823>

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## **Abandoning Peracetic Acid-Based Dialyzer Reuse Is Associated with Improved Survival**

1. Eduardo Lacson Jr,
2. Weiling Wang,
3. Ann Mooney,
4. Norma Ofsthun,
5. J. Michael Lazarus,
6. Raymond M. Hakim

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### Summary

**Background and objectives** Higher mortality risk reported with reuse versus single use of dialyzers is potentially related to reuse reagents that modify membrane surface characteristics and the blood-membrane interface. A key mechanism may involve stimulation of an inflammatory response.

**Design, setting, participants, & measurements** In a prospective crossover design, laboratory markers and mortality from 23 hemodialysis facilities abandoning reuse with peracetic acid mixture were tracked. C-reactive protein (CRP), white blood cell (WBC) count, albumin, and prealbumin were measured for 2 consecutive months before abandoning reuse and subsequently within 3 and 6 months on single use. Survival models were utilized to compare the 6-month period before abandoning reuse (baseline) and the 6-month period on single use of dialyzers after a 3-month ♦ washout period. ♦

**Results** Patients from baseline and single-use periods had a mean age of approximately 63 years; 44% were female, 54% were diabetic, 60% were white, and the mean vintage was approximately 3.2 years. The unadjusted hazard ratio for death was 0.70 and after case-mix adjustment was 0.74 for single use compared with reuse. Patients with CRP  $\geq$  5 mg/L during reuse (mean CRP = 26.6 mg/ml in April)



declined on single use to 20.2 mg/L by August and 20.4 mg/L by November. WBC count declined slightly during single use, but nutritional markers were unchanged.

**Conclusions Abandonment of peracetic-acid-based reuse was associated with improved survival and lower levels of inflammatory but not nutritional markers. Further study is needed to evaluate a potential link between dialyzer reuse, inflammation, and mortality.**

\* Received April 9, 2010.

\* Accepted September 8, 2010.

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<http://cjasn.asnjournals.org/content/6/2/297.abstract>

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Beta(2)-microglobulin clearance decreases with Renalin reuse.  
**(increased risk of Amyloidosis)**

Castro R, Morgado T.

Unidade de Hemodiálise, Serviço de Nefrologia-Hospital S. Pedro, Vila Real, Portugal.  
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Abstract

The HEMO study revealed that beta(2)-microglobulin clearance decreases over time with Renalin reuse in the high-flux group. It was suggested that the reuse of polysulfone or cellulose triacetate high-flux dialyzers with Renalin (without bleach) results in degradation of the high-flux capacity. At our haemodialysis unit (Vila Real, Portugal) we reused dialyzers until January 2000 (limited to 10 reuses), with an automatic machine Renatron (Renal Systems, Minntech. All of our 31 patients who started with postdilution haemodiafiltration on-line (HDFol) were always dialyzed with F-80 polysulfone (Fresenius). The reposition rate was 10 litres/session until 1998 and 20 litres/session thereafter. Reuse techniques were abandoned in our country in January 2000 following an EEC directive. Thereafter, we have decided to maintain HDFol with the same dialyzers without reuse. The mean beta(2)-microglobulin predialysis values did not decrease over time until reuse was terminated (1995 with low-flux haemodialysis: 25.4 +/- 6.4 microg/l; 1997: 24.7 +/- 6.6 microg/l; 1998: 29.2 +/- 8.9 microg/l; 1999: 33.7 +/- 4.7 microg/l) whereas beta(2)-microglobulin clearances were reasonable with HDFol (1998: 56.4 +/- 25.9 ml/min; 1999: 47.9 +/- 16.4 ml/min). After stopping reuse we have noticed that predialysis beta(2)-microglobulin values decreased (2000: 23.0 +/- 3.9 microg/l) in accordance with beta(2)-microglobulin clearance duplication (2000: 84.1 +/- 25.0 ml/min;  $p < 0.01$ ). **It is our opinion that the reuse of polysulfone dialyzers with Renalin should be abandoned in the field of high-flux haemodialysis. It causes deterioration in the beta(2)-microglobulin clearance and probably interferes with the high-flux haemodialysis benefits, namely the reduction of dialysis-related amyloidosis.**



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PMID: 11867958 [PubMed - indexed for MEDLINE]  
<http://www.ncbi.nlm.nih.gov/pubmed/11867958>

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Medline  Abstract for Reference 4

of 'Reuse of dialyzers'

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Single-use versus reusable dialyzers: the known unknowns.

AU

Upadhyay A, Sosa MA, Jaber BL

SO

Clin J Am Soc Nephrol. 2007;2(5):1079-86.

The practice of reusing dialyzers has been widespread in the United States for decades, with single use showing signs of resurgence in recent years. Reprocessing of dialyzers has traditionally been acknowledged to improve blood-membrane biocompatibility and prevent first-use syndromes. These proposed advantages of reuse have been offset by the introduction of more biocompatible membranes and favorable sterilization techniques. **Moreover, reuse is associated with increased health hazard from germicide exposure and disposal. Some observational studies have also pointed to an increased mortality risk with dialyzer reuse, and the potential for legal liability is another concern.** The desire to save cost is the major driving force behind the continued practice of dialyzer reuse in the United States. It is imperative that future research focus on the environmental consequences of dialysis, including the need for more optimal management of disinfectant-related waste with reuse, and solid waste with single use. The dialysis community has a responsibility to explore ways to mitigate environmental consequences before single-use and a more frequent dialysis regimen becomes a standard practice in the United States.

<http://www.uptodate.com/contents/reuse-of-dialyzers/abstract/4>

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## **A deadly error: Routine dialysis leads to Heights woman's death**

Published: Saturday, October 04, 2008, 10:51 PM Updated: Monday, October 06, 2008, 9:02 AM  
Lynn Moore | The Muskegon Chronicle By Lynn Moore | The Muskegon Chronicle

Chronicle/Kendra Stanley-Mills

"He's the only thing keeping me going," said James Allen of his dog, Duke, shown in the background. Allen, 72, of Muskegon Heights, lost his wife, Betty, after a mistake was made at a dialysis clinic.

"He's my baby," Allen said of Duke. "He's all I've got."

It is too much for James E. Allen to talk about the day his wife died -- the day she left for her regular dialysis treatment and never came home.

By the numbers

69: Muskegon County residents newly diagnosed with end stage renal (kidney) disease in 2007.

197: County residents undergoing dialysis for chronic renal failure as of Dec.31, 2007.

17,000: Estimate of county residents with diabetes.

◆ Sources: Renal Network of the Upper Midwest and Michigan Department of Community Health

It is difficult even for him to speak Ethel "Betty" Mae Allen's name. After 26 years of marriage, the two had become inseparable and her death has left him empty and alone.

"She was all I had," Allen says. "She was everything to me."

Aug. 15, 2007, started as many days did for Betty Allen. She showed up at the DaVita Inc. dialysis center in Muskegon just as she had three days a week for the preceding three years.

But routine quickly turned to tragedy as a fatal error on the part of a technician sent a corrosive and acidic cleaning solution -- rather than the life-giving hemodialysis solution -- directly into Betty Allen's artery.

Her eyes rolled back in her head as she went into cardiac arrest. She was rushed two blocks to the emergency room at Mercy Health Partners' Mercy Campus where medical workers decided to send her on to Spectrum Health in Grand Rapids.

There, she clung to life for five days, suffering another two heart attacks and a severe brain injury. Finally, her family said she'd had enough. The next heart attack was her last -- she was not resuscitated and was pronounced dead at 3:49 a.m. on Aug. 21.

"Betty" Mae Allen, died in a dialysis accident Aug. 21, 2007. It was supposed to be a routine dialysis treatment, but a technician's error sent a cleaning solution directly into her artery.

**There is no doubt about what happened to Betty Allen and DaVita's role in it. Her death certificate says she died after "exposure to Renalin during hemodialysis," giving DaVita's Muskegon address. Medical notes from DaVita and Spectrum repeatedly refer to her accidental infusion with Renalin during dialysis, as does the autopsy report.**

Betty Allen's death, clearly an accident that could have been avoided, was never reported to any authorities. DaVita wasn't required to. The technician who failed to rinse the dialyzing filter of its corrosive "Renalin" cleaner was required only to have a high school equivalency diploma.

And, despite the error and the potential dangers of reusing filters -- a practice that many dialysis centers have given up -- DaVita's Web site and a National Kidney Foundation executive indicate that it continues to reuse filters at its centers, including ones in Muskegon, Grand Haven and Fremont. It has received required state approval to reuse filters, according to a state official.

DaVita officials are not talking about the accident.

"This is just a botched job," said Randall Fielstra, a Muskegon attorney representing James Allen in a lawsuit against DaVita.

A horrible death

Hypertension and diabetes -- which plague a higher-than-average number of people in Muskegon County -- are main causes of kidney disease. Nearly 200 Muskegon County residents receive dialysis on a regular basis to rid their bodies of wastes that their ailing kidneys no longer can filter out.

Betty Allen, 71, had suffered from hypertension as well as vascular disease. Her kidneys had failed and so her life depended on the hemodialysis she received at DaVita, 1277 Mercy Drive, provided by technicians whose training consisted only of instruction provided by the huge for-profit company.

During dialysis, patients are hooked up to a machine that pumps their blood from their body and through a dialyzer that cleans the blood with a dialysate solution before it is returned to the patient.

Dialyzers -- a sort of filter -- come in two types: single-use, which is thrown out after each treatment, and reusable.

DaVita uses reusable dialyzers -- assigning each patient their own -- which are cleaned after each treatment by soaking in Renalin, a solution of hydrogen peroxide, peracetic acid, acetic acid and water. After the soak, it is flushed with saline solution and tested to be sure none of the corrosive Renalin remains.

According to DaVita procedures, two employees are required to verify that dialyzers are appropriately cleaned.

But that apparently didn't happen when Betty Allen arrived at DaVita on Aug. 15, 2007. According to Fielstra and Spectrum hospital notes, when she arrived, she was taken to a dialysis machine, but it had a different patient's dialyzer in it. Technicians quickly sought out Allen's dialyzer, found it still soaking in the Renalin bath, removed it and inserted into the machine without the required rinse or testing, Fielstra said.

Allen was hooked to the machine for less than two minutes, the acidic solution coursing into her artery, before it was apparent something was horribly wrong. Betty Allen complained about burning pain at the needle site, according to a DaVita employee's progress notes, and then she became "glassy-eyed."

"Boom, her eyes roll back," Fielstra says. "It must be assumed she was exquisitely horrified and uncomfortable."

Oxygen bubbles had been introduced into Allen's arteries, essentially blocking blood flow. She went into cardiac arrest and her brain suffered severe injury -- perhaps a stroke, hospital notes indicate -- due to a lack of oxygen. It took 12 minutes of cardiopulmonary resuscitation before rescue workers could find a pulse.

From Mercy, she was sent to Spectrum for treatment of the gas embolism with a hyperbaric chamber in an attempt to dissolve the bubbles and resume normal blood flow. But the brain damage was severe, and she wasn't breathing on her own.

Chronicle/Ken Stevens DaVita Dialysis, 1277 Mercy Drive.

James Allen remembers being called to Spectrum after the accident.

"I didn't want to see her like that," he says tearfully, describing her as "gripping my hand" with eyes that were open but didn't seem to see him.

The death certificate leaves no doubt the cause of Betty Allen's death, explaining that she had been "exposed to Renalin during hemodialysis."

"This woman's death was horrible," Fielstra says. "No one deserves to die this way."  
An inherent risk

The Michigan Department of Community Health -- contracted by the federal government to oversee dialysis centers in the state -- was not aware there had been a death as the result of actions taken at the Muskegon dialysis center.

There is no requirement that dialysis centers report a death or severe injury, says Richard Benson, chief of the licensing and certification division of the department's bureau of health systems.

If there is a complaint, the state would investigate, but none was lodged in Allen's case, Benson says. Currently, the federal government expects inspections be conducted about every four years, he says. The last state visit to DaVita was in March because the center added new services, Benson says.

Dialysis centers are not licensed by the state, nor are employees required by the state to have certifications. Centers that want to receive federal Medicare reimbursement, the main form of payment for dialysis patients, get certified by Medicare and are required to have at least one licensed health professional -- physician, registered nurse or licensed practical nurse -- on the premises.

But a new federal law requires that technicians who hook patients up to dialysis machines -- known as patient care technicians -- receive training through state or national certifying organizations and pass a state or national exam by December 2009.

"It will add a certain level of professionalism to the role," says Dolph Chianchiano, vice president for health policy at the National Kidney Foundation.

However, Chianchiano says that does not include the "reuse technicians" who are responsible for cleaning and rinsing dialyzers. According to DaVita's Web site, reuse technicians' qualifications are a high school or equivalent diploma and completion of DaVita's reuse technician training.

Fielstra says he was told the reuse technician on the job at the time of Betty Allen's accident was fired.

DaVita officials, citing patient privacy laws and the pending lawsuit, declined to comment or answer questions about Allen's death and the company's procedures. The company issued a statement saying its "sympathies are with the family as they attempt to deal with this situation."

Chianchiano says there are no national statistics on how many patients die as the result of accidents at dialysis centers. However, he says Allen's death is the only one he has heard of.

Maurie Ferriter, director of programs and services for the National Kidney Foundation of Michigan,

says some dialysis patients watch technicians "like a hawk" while others, especially older patients, are trusting "of anybody who wears a white coat."

"Every single time you get hooked up to a dialysis machine, there is an inherent risk in the process," says Ferriter, who receives regular dialysis.

Making money

Dialysis was first successfully used in 1945 and its use became more common in the 1960s. In 1973, Medicare started paying for it, and most dialysis operations were in nonprofit hospitals staffed by licensed medical personnel.

By 1985, 44 percent of dialysis units were in hospitals and 56 percent were in freestanding clinics; 46 percent were operated by for-profit groups, according to the Centers for Disease Control and Prevention.

By 2002, 85 percent of dialysis units were in freestanding clinics, and 81 percent were for-profit.

"Over the years, as the for-profit industry started to get involved in dialysis, there were big changes ... unlicensed technicians or uncertified technicians instead of nurses," Ferriter says. "It has become more impersonal. When you think about it, it's the same principle as an assembly line."

For DaVita, dialysis is big business that is growing. It serves about 107,000 patients at 1,300 clinics. Dialysis treatments, which numbered 15.3 million in 2007, were up 5.7 percent over 2006, according to DaVita's 2007 annual report. Its net income for 2007 was \$340 million.

The largest dialysis provider is Fresenius Medical Care, serving 173,863 patients worldwide at more than 2,200 clinics. Its net income for 2007 was \$717 million.

One big difference between DaVita and Fresenius is the type of dialyzers they use. DaVita reuses them; Fresenius uses them once and tosses them out, says Chianchiano of the National Kidney Foundation.

"The reason why people reuse is because the dialyzers they use are so expensive," Chianchiano says.

A much smaller dialysis provider is Renal Advantage Inc., which operates a clinic at 1080 W. Norton in Roosevelt Park. It has 85 centers across the nation.

Sharon Burbage, vice president of clinical services for Renal Advantage, says the Roosevelt Park facility uses single-use dialyzers -- a decision made by local staff. Burbage says it is generally considered cheaper to reuse dialyzers, but the corporation leaves it up to each clinic to decide which ones to use.

"The bottom line is that if you reuse, you have to make sure appropriate safety measures are taken at all times," she says.

The loss

With DaVita not disputing that the actions of one or more of its employees caused Betty Allen's death, Fielstra had tried negotiating a settlement with the multimillion-dollar corporation.

But he says he was disappointed in the company's response, and so filed the lawsuit in May. The state

caps noneconomic damages at \$717,000 for medical errors causing brain injury; \$400,000 for other types of injuries.

For James Allen, no amount of money could make up for the loss of the woman he dated since the 1960s and married in 1981. But he wants money to put a marker on his wife's grave at Mona View Cemetery.

"I don't hate them; I can forgive them," he says of DaVita. "Somebody's got to pay for it and do the right thing."

His constant companion these days is Duke, his dog. They sit together on the front porch of his Muskegon Heights home and sometimes "take a ride around the block."

He can't bear to go fishing anymore -- something he and Betty did every day, staking out their favorite spot on Muskegon Lake.

"I'll be thinking about her when I go fishing," he says. "I probably won't go anymore."

[http://blog.mlive.com/chronicle/2008/10/a\\_deadly\\_error\\_routine\\_dialysi.html](http://blog.mlive.com/chronicle/2008/10/a_deadly_error_routine_dialysi.html)

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## **Water Permeability:**

\* Kidney Int. 2007 Aug;72(3):379; author reply 379-80.

### Abstract

Dialysis with high-flux membranes is widely used, in part, because they are thought to increase the removal of middle molecules when compared with low-flux membranes. Dialyzer reprocessing; however, is thought to alter middle molecule clearance. Renalin, a mixture of germicidal agents, has widespread use in dialyzer reprocessing. We determined the effect of Renalin reprocessing on the water permeability of three different dialyzers of Fresenius (F80A and 200A) and Gambro (17R) manufacture using the dead-end filtration method. Two hundred and seventeen, predominantly used but some new, dialyzers were evaluated. Water permeability of the used, but not the new, dialyzers fell abruptly and dramatically with reprocessing. The permeability fell almost 70% in the F80A dialyzer after three reprocessing procedures with similar, but somewhat slower declines, seen in the other two dialyzers. **We conclude that there is a decline in water permeability seen in Renalin reprocessed dialyzers.** This factor and the associated change in solute clearance and ultrafiltration characteristics should be considered in assessing the effectiveness of dialyzer reprocessing.

<http://www.ncbi.nlm.nih.gov/pubmed/17377505>

\*note:

Low water permeability in a dialyzer isn't sounded very good from what I'm reading:

"The potential for CIS convective transport from contaminated dialysate can occur across dialyzer

membranes of relatively low water permeability for which the only relevant mechanism is diffusion"

<http://books.google.com/books>

I might have to translate it to English though.