

# Single-Use *versus* Reusable Dialyzers: The Known Unknowns

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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.

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Dialyzer reuse has been practiced in the United States for decades but remains a topic of ongoing controversy. Several large observational studies of variable quality have compared single-use with reused dialyzers, and some have demonstrated an increased mortality risk with reuse of dialyzers. However, it is generally accepted that reuse can be done safely when performed according to the standards set by the Association for the Advancement of Medical Instrumentation (AAMI) (1). Full compliance in a practical setting, however, is difficult to attain, and rigorous quality control standards are vulnerable to poor implementation. This review summarizes the advantages and disadvantages of both dialyzer practices, namely reuse and single use, and provides guidance for future research directions.

## Dialyzer Reuse

### *Rationale for Dialyzer Reuse*

Dialyzer reuse has historically been practiced in light of perceived potential benefits for the dialysis provider and the patient. The three major advantages for the provider include an economic benefit; the ability to use high-flux dialyzers, which traditionally have been more expensive; and a favorable environmental impact as a result of decreased generation of biomedical waste. In light of declining and more restrictive Medicare coverage for hemodialysis treatments, economic considerations are believed to be the driving force for contin-

ued use of dialyzer reuse methods in the United States. The availability of cheaper high-flux dialyzers for single use means that the traditional benefit of the ability to reuse such dialyzers no longer holds true. From the patient's standpoint, the conventional argument for reprocessing of dialyzers is to improve blood–membrane biocompatibility, particularly that of cellulose membranes, and the prevention of first-use syndromes usually associated with the use of ethylene oxide–sterilized dialyzers. In recent years, however, substituted cellulose and synthetic membranes have become the standard of care and have been promoted by published clinical guidelines for hemodialysis adequacy (2), and alternative sterilization methods are slowly replacing ethylene oxide.

### *Dialyzer Reuse Trend in the United States*

The proportion of dialysis centers that reuse dialyzers in the United States increased steadily from the early 1980s, peaking in 1997. Indeed, data collected during the period of 1976 to 2002 by the Centers for Disease Control and Prevention (CDC) reveal that approximately 20% of centers reused dialyzers in 1976, increasing to 80% in 1997, and subsequently declining to approximately 60% in 2002 (3). This trend has further declined in recent years as a result of the change in practice pattern favoring single use in some dialysis provider chains. Experts have estimated that as of 2005, approximately 40% of dialysis centers were likely to be reusing dialyzers (4).

Methods for dialyzer reprocessing in US dialysis centers have also markedly evolved in the last 25 years (3). Indeed, the percentage of centers that used formaldehyde decreased from 94 to 20% between 1983 and 2002. During the same period, the proportion of centers that used peracetic acid increased from 5

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to 72% (3). The use of glutaraldehyde remained more or less the same, and the use of heat slightly increased (3).

The frequency of dialyzer reuse practice in the United States also varies according to the characteristics of dialysis units. Surveillance data demonstrate that until the late 1990s, the percentage of reuse was 87, 77, and 49% in freestanding for-profit, freestanding nonprofit, and hospital-based dialysis centers, respectively (5). Since the early 2000s, as the integrated dialysis service providers started shifting toward single-use dialyzers, the proportion of for-profit centers that reuse dialyzers is estimated to have significantly declined.

### *Health Hazards from Dialyzer Reuse*

Health hazards associated with the use of germicides are important considerations in dialyzer reuse. Patients and health care workers can be harmed by acute accidental exposure to high concentrations of germicides from the dialyzer or water treatment system. In addition, the long-term effects of exposure to low concentrations of germicide residue within the dialyzer can potentially have serious adverse health consequences.

In the United States, peracetic acid and formaldehyde are the two most commonly used germicides. Peracetic acid can be potentially destructive to mucous membranes, especially of the respiratory tract, as well as to the skin and eyes. Inhalation may result in inflammation and edema of the larynx and bronchi, chemical pneumonitis, and even pulmonary edema. Symptoms of exposure include burning sensation, throat discomfort, cough, wheezing, dyspnea, headache, and nausea. Accidental intravenous exposure to formaldehyde can result in hypotension, cardiovascular collapse, lactic acidosis, respiratory failure, hemolysis (with cold agglutinins, anti-N<sub>form</sub> antibodies, and Coombs-positive reaction), and even death. Inhalation of formaldehyde, a known carcinogen, can also impair pulmonary function (4,6). One study reported asthma symptoms in dialysis unit nursing staff that was associated with formaldehyde exposure, which improved when exposure to this germicide was discontinued (7). In some dialysis units that practice reuse, bleach is used in conjunction with peracetic acid or formaldehyde. In this instance, mixture of these compounds may release hypochloric acid vapor or formic acid vapor, which, if not properly drained, can potentially pollute the working and patient spaces (8). In addition to these risks, repeated exposure to chemicals during reprocessing of dialyzers has been reported to cause cracks in the threaded portion of dialyzer headers, which, if not detected on time, can result in significant blood loss (9). Disinfectants can also have possible teratogenic effects, raising concerns both for pregnant patients and for pregnant health care workers.

### *Summary of Epidemiologic Studies on the Safety of Dialyzer Reuse in the United States*

Thirteen large observational studies of dialyzer reuse, totaling 462,777 patients, have been conducted in the United States. These studies were published between 1977 and 2005 and examined the association of dialyzer reuse with morbidity and mortality. Seven studies examined these associations among

patients who initiated dialyzer reuse (truly incident to this practice) (10–16), whereas the remaining six studies assessed prevalent patients who practiced reuse (15,17–21). All except one study included all three reuse modalities, formaldehyde, glutaraldehyde, and peracetic acid. Ten studies examined death as the end point (10–12,14–19,21), one study used hospitalization (13), and two used both outcomes (15,20).

**Mortality Risk.** Among reports comparing the use of formaldehyde as the reuse germicide with single-use practices, one study revealed a 12% decreased mortality risk in the reuse group (11). The six other studies did not demonstrate significant differences in mortality between the two practices (12,15,17–20).

Among studies that compared the use of glutaraldehyde as the reuse germicide with single-use practices, only one study revealed a 13% increased mortality risk in the reuse group (17). Five other reports did not demonstrate significant differences in mortality between the two practices (12,15,18–20).

Similarly, among studies that compared the use of peracetic acid as the reuse germicide with single-use dialyzer practices, two studies revealed an increase in mortality by 10 to 17% (12,17). One study of longer follow-up duration revealed a 15% higher death risk in the reuse group in the first 2 years of this practice, which abated in the subsequent 3-year follow-up period (18). Three other studies did not reveal any mortality difference between the two groups (15,19,20).

Four studies grouped a combination of reuse methods and compared this practice with dialyzer single use (10,13,18,21). Only two studies demonstrated a 5 to 25% increased mortality risk in the reuse group (13,21).

**Hospitalization Risk.** The risk for hospitalizations between single-use and reuse practices was assessed in three studies (13,14,20). When formaldehyde was used, one study documented no difference (14), whereas the other two documented a 29 to 75% increase in hospitalization rates in the reuse groups (13,20). With glutaraldehyde, two studies reported no difference in the rate of hospitalizations (13,14). When peracetic acid was used, three studies documented an 11 to 28% increase in hospitalization rate in reuse groups (13,14,20).

**Summary of Observational Studies.** Overall, these observational studies either are neutral or favor single use except for one study published in the 1980s (11). However, in addition to potential biases inherent in observational studies, many did not adjust for possible confounders, including comorbid conditions, nutritional status, dialysis duration, clustering of patients from various dialysis centers, dialysis membrane types, and number of reuses. More recent studies that adjusted for some of these confounders demonstrated no patient mortality difference between these two practices (10,15,16). Design deficiencies, inconsistent conclusions from these studies, and disputes on conflict of interest (22) make it difficult to decide in favor of single-use or reuse modality. Most would agree that reuse is probably safe when the AAMI standards are followed, but it is unclear whether this holds in a practical setting, where human errors are bound to affect aspects of reuse processes.

### *Disadvantages of Dialyzer Reuse*

A number of potentially serious disadvantages of reusing dialyzers have previously been highlighted (6,23). Residual germicide infusion as a result of the rebound release of disinfectants during dialysis may have theoretical long-term adverse consequences on the patient's health. The potential of inadequate germicide concentration use raises the possibilities of pyrogen reactions and bacteremia outbreaks. Eight of 16 outbreaks of bacteremia or pyrogenic reactions in hemodialysis patients investigated by the CDC from 1980 to 1999 were related to dialyzer reuse, with four outbreaks resulting from a suboptimal disinfectant concentration (24). Changes in the membrane integrity with reuse can also affect membrane polarity as well as the clearance of small and middle molecules. The issue of increased environmental contamination with reuse is also of potential concern.

The possibility of increased rates of bacterial infections with dialyzer reuse warrants a careful analysis. The 2003 annual report of the US Renal Data System (USRDS) registry cited infections as the second leading cause of death in dialysis patients after cardiovascular disease (25). Infections accounted for 15% of deaths, with sepsis constituting approximately one fourth of cases (25). In a study that analyzed patient- and dialysis-related factors that are associated with bacterial sepsis in hemodialysis patients, dialyzer reuse was associated with a 28% increase in the adjusted risk for sepsis (26). It is remarkable that this was comparable to the infection risk associated with diabetes, which conferred a 26% increased adjusted risk for sepsis (26). Technical errors such as inadequate disinfection during reprocessing, changes in membrane pore size or sieving characteristics resulting in increased flux of microbes from dialysate to blood, and reuse-associated changes in a patient's immune system or nutritional status are some of the proposed hypotheses to explain this increased infection risk attributed to dialyzer reuse. These same factors might also increase the risk for viral disease transmission among patients who reuse dialyzers (27).

The delivered dosage of dialysis may also be altered by reuse as a result of deposition of blood materials within the dialyzer lumen as well as by the reprocessing procedure itself (28). One study reported a 1 to 2% decrease in urea clearance per 10 reuses regardless of the membrane and reprocessing method (28). The same study also noted a decrease in  $\beta$ -2 microglobulin clearance with peracetic acid-based reprocessing methods (28). The use of bleach or heated citric acid had a favorable effect on  $\beta$ -2 microglobulin clearance (28). Early reports also demonstrated that albumin loss across polysulfone (F80) dialyzers can be significant with repeated use of bleach (29). Subsequent studies demonstrated negligible albumin loss from bleach-reprocessed polysulfone dialyzers that had been structurally modified by the manufacturer, for up to 20 reuses (30). These interactions between various reuse methods and solute clearance illustrate how dialysis adequacy can be hampered by reuse practices.

### *Potential Legal Consequences of Dialyzer Reuse*

Over the years, reuse and reprocessing of disposable medical devices has raised concerns of legal liability, especially among physicians, hospitals, and device manufacturers (31,32). With

regard to dialysis, the practice of dialyzer reuse has numerous loopholes that might expose physicians and dialysis providers to potential legal liabilities. In an essay on the legal consequences of disposable dialyzer reuse, Hallquist (33) argued that dialyzer reuse for financial benefit regardless of increased patient exposure to serious risk for injuries makes providers vulnerable to legal action in the event of an injury. In this article, it is stated that injured patients may argue that the decision to reuse dialyzer is itself negligent, and proof of negligence may be facilitated by demonstrating violation of regulatory standards or provider's own rules on sterilization procedures. This article stresses that the general poor health of dialysis patients may make proving causation to impose liability difficult, while cautioning that their poor health might increase vulnerability to reuse complications (33). In addition, human errors related to reuse processes further magnify the liability risk. Errors can range from the collection, labeling, storage, and cleaning of used dialyzers to the redistribution of cleaned dialyzers. In addition to a robust quality assurance program and continuing education of the dialysis staff, there is a need to evaluate carefully the use of disposable dialyzers to deter liability (33).

### *Economics of Dialyzer Reuse*

Economic benefit is considered the major motivating factor behind the continued practice of reusing dialyzers in the United States. A national survey of dialysis facility administrators revealed that 37% would increase reuse if dialysis reimbursement were to decrease by 20% (34). This suggests that providers think of reuse as an important cost-cutting strategy. An economic evaluation performed for Canadian dialysis centers in 2002, however, revealed that there may only be a modest cost saving of no greater than CAN \$739 per patient per year with an average reuse number of 13 using lower cost heated citric acid (35). The benefit was estimated to be even less with formaldehyde reuse and was nonexistent when additional personnel cost of reuse was taken into consideration (35). This economic evaluation contrasted a 1993 Canadian study that showed savings of up to CAN \$3629 per patient per year with five reuses using formaldehyde (36). Other studies from this same period also noted significant financial benefit with reuse, with one reporting 95% savings on high-flux dialyzer cost with 20 reuses (37) and another reporting savings of CAN \$309 thousand annually to a Canadian hospital with an average of four reuses (38). These discrepancies highlight the need to reexamine the extent of economic benefit with reuse in the context of increased availability of cheaper high-flux dialyzers and rising cost of personnel and space.

Fresenius Medical Care, the largest integrated dialysis service provider in the United States, has already shifted toward single use, stating that the cost related to reuse is equal to or greater than the cost of a new polysulfone dialyzer (39). Non-integrated providers, especially with Medicare's declining relative reimbursement rate for hemodialysis treatment, may still feel pressured to continue with reuse even though the overall cost -saving with reuse in the United States in the present-day setting is not entirely clear. It is also important to note that economic considerations in developing countries may be sig-

nificantly different and reuse with its potential cost saving may be their only option.

## Dialyzer Single Use

### *Rationale for Dialyzer Single Use*

Single use of dialyzers is lately witnessing resurgence in the United States. Single use allows dialysis providers to cut cost on personnel. With technological advancement resulting in an increased availability of relatively less expensive high-flux dialyzers, single use is now becoming more appealing. Single use also benefits patients by reducing reuse syndromes from residual germicides. Synthetic membranes with improved blood-membrane biocompatibility are now widely available, and first-use syndromes have become less of an issue, particularly as ethylene oxide sterilization is increasingly being replaced by other methods, including gamma irradiation, steam, and, most recently, electron beam sterilization. In 1999, the USRDS annual report revealed a significant trend toward the use of synthetic dialyzers, with an increase from 16% in 1990 to 59% in 1996 to 1997 among incident hemodialysis patients (40). There was a likewise decrease in the use of cellulose membranes during that same period (40). In the past decade, national estimates on these trends are lacking because the USRDS registry stopped reporting on these data; however, clinical guidelines have promoted use of substituted cellulose and synthetic dialyzers (2).

### *Proposed Arguments for Dialyzer Single Use*

Lacson and Lazarus (4) proposed medical, operational, and economic arguments that favor dialyzer single use.

**Medical Argument.** Single use decreases rates of infection and contamination, likelihood of errors and accidents, and risks

associated with exposure to germicides and denatured blood products. There might also be a favorable immune response and a better clearance of small and middle molecules. Some of the aforementioned studies also showed a relative increased risk for hospitalization and death among patients who reuse dialyzers.

**Operational Argument.** Single use simplifies some of the operational aspects of dialysis and is convenient. There is no need for reuse technician training, reuse record keeping, room maintenance for safety and sterilization, and more extensive quality assurance programs that are inevitable in reuse processes. Dialyzer verification also requires much less time, and there is no need for checks on fiber bundle volume. The risk for medicolegal liability is also negligible in single-use compared with reuse techniques.

**Economic Argument.** Finally, these authors argued that single use has a potential for economic benefit to the provider as well. There is a financial advantage of decreased need for personnel and space. The provider can also have significant savings on utility bills, medicolegal expenses, and dialyzer reuse supplies. This last argument is more likely to be true among dialysis providers that are vertically integrated in terms of dialyzer manufacturing capabilities (4).

### *Characteristics of Patients Who Do Not Reuse Dialyzers in the United States*

In a study of a nationally representative sample from 2000, patients who did not reuse dialyzers were more likely to be younger and non-Hispanic, have attained higher education, and have fewer comorbid conditions (41). Patients who received dialysis in hospital-based units were three-fold more

Table 1. Environmental impact of dialyzer reuse and single-use practices

Dialyzer Practice	Favorable Impact	Unfavorable Impact
Reuse	Decreased dialyzer-related solid waste	Increased reuse-related liquid waste (heated water, chemicals, and disinfectants) and chemical vapors (hypochloric acid and formic acid)
	Decreased dialyzer-related packaging waste (cardboard boxes and wrapping material)	Increased reuse-related packaging waste (cardboard boxes and plastic containers for reuse components) Increased reuse-related disposable waste (masks, gloves, plastic aprons, test strips, and labels)
Single use	Decreased reuse-related liquid waste (chemicals and disinfectants) and chemical vapors (hypochloric acid and formic acid)	Increased dialyzer-related solid waste
	Decreased reuse-related disposable waste (masks, gloves, plastic aprons, test strips, and labels)	Increased dialyzer-related packaging waste (cardboard boxes and wrapping material)
	Decreased reuse-related packaging waste (cardboard boxes and plastic containers for reuse components)	

likely not to reuse dialyzers compared with patients in free-standing for-profit units (41). In this study, 80% of patients who did not reuse dialyzers were using either cellulose or modified cellulose membranes (41). This contrasted with a 46% prevalence of synthetic membrane use among patients who reused dialyzers. Finally, 92% of those who did not reuse were on low-flux dialyzers, compared with 61% among those who reused dialyzers (41).

A more recent observational study that examined the effect of abandonment of dialyzer reuse practices on >18,000 patients in the United States demonstrated a decreased relative risk for death after conversion to single-use practices (21). However, this risk benefit was demonstrable only after a minimum lag time of 60 days, suggesting that this benefit might lag behind the change in practice. This study has been criticized because it is based on the experience of a single large dialysis provider chain, where only one type of reuse machine was used and 75% of facilities used formaldehyde as the germicide and bleach as the cleaning agent (23,42). Concerns with conflict of interest have also been raised because this study was funded by a large dialysis provider chain that manufactures and supplies dialyzers (22). Although these issues raise concerns about the generalizability and validity of the results, this study's provocative and hypothesis-generating findings do support the medical argument of abandoning dialyzer reuse practices. Unfortunately, a definitive answer could be attained only through a randomized controlled trial, which is unlikely to take place.

#### Potential Health Hazards of Single-Use Dialyzers

First-use reactions are widely publicized complications of single-use dialyzer practices. Ethylene oxide has traditionally been implicated in this reaction, and the emergence of non-ethylene oxide sterilization techniques has significantly reduced its occurrence (23). However, other chemical contaminants during the manufacturing process might pose some potential hazards if dialyzers are not preprocessed before first use, a common practice in dialysis centers that reuse. One such example is perfluorohydrocarbon, a fiber-leak testing agent, which, as a result of its improper removal during dialyzer manufacturing, was recently blamed for approximately 50 deaths worldwide (43). One can only speculate as to whether preprocessing of such dialyzers might have eliminated patient exposure to this chemical.

### Environmental Concerns with Dialyzer Reuse and Single Use

The dialysis procedure creates a considerable amount of waste (44). Therefore, waste management needs to be at the heart of any modern dialysis provider system (44). The basic waste management hierarchy, in the order of its environmental friendliness, includes reduced use, reuse, recycling or composting, incineration with energy recovery, and, lastly, landfill. The environmental impact of reuse and single-use practices as well as the consequences of switching practices merits further discussion (Table 1).

Reuse of dialyzers raises a number of important environmental concerns. Spillage of heated contaminated water used for

dialyzer rinsing into the sewer system; increased plastic waste from packaging materials used for reuse chemicals; and additional waste generated from disposable items such as masks, gloves, test strips, plastic aprons, and labels, are all important potential pollutants associated with reuse. We predict that approximately 6.4 million gallons of peracetic acid and 1 million gallons of aldehydes are released into the environment every year because of reuse in the United States, assuming that only 40% of patients are reusing dialyzers based on informal estimates from 2005 (4) and that the prevalence use rate of peracetic acid and aldehydes is 72 and 24%, respectively, based on national surveillance data from 2002 (3). Figure 1 provides a hypothetical illustration of how yearly generation of liquid

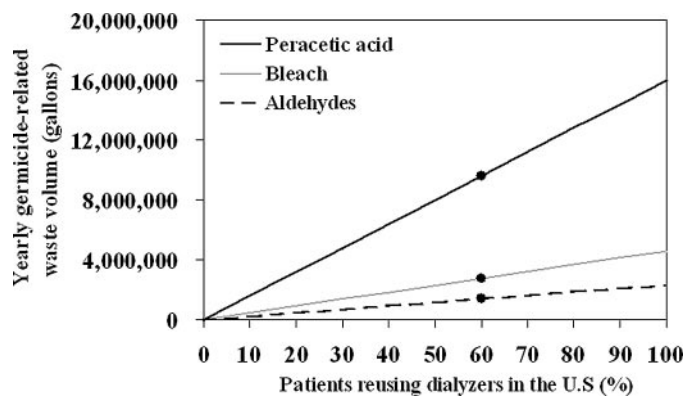


Figure 1. Hypothetically predicted yearly generation of liquid waste from germicides used for dialyzer reprocessing in the United States. For these calculations, the following assumptions were made: (1) Projections were made for 309,269 patients who received hemodialysis in the United States, which is based on point prevalent estimates (as of December 31, 2004) obtained from the US Renal Data System (USRDS) 2006 annual report (48); this translates into approximately 48.2 million yearly dialyses performed on an average of three weekly sessions; (2) the proportion of centers that use peracetic acid (72%) and aldehydes (formaldehyde and glutaraldehyde [24%]) was derived from the 2002 national surveillance of dialysis-associated diseases in the United States (3); (3) the volume of working-strength peracetic acid (at 3%) used to clean and disinfect a high-flux dialyzer was estimated at 1.743 L, using the specifications and instructions for use of the Renalin Cold Sterilant Concentrate for use with the Renatron Dialyzer Reprocessing Systems (49); (4) the volume of bleach (0.1 to 1% sodium hypochlorite) used to clean a high-flux dialyzer (Optiflux F160NR, Fresenius Medical Care) was estimated at 1.5 L, and the projections were restricted to reuse practices that disinfect dialyzers with aldehydes; and (5) the volume of working-strength aldehydes (at 1 to 4%) used to disinfect a high-flux dialyzer (Optiflux F160NR) was estimated at 0.756 L, assuming that it is necessary to run three dialyzer volumes of the working solution of aldehydes through the dialyzer (blood and dialysate compartment volume of 0.252 L) to achieve the desired final germicide concentration (50) and that the reprocessing procedure is automated and not manual. The dots correspond to the 60% prevalence rate of dialysis facilities that practice reuse in the United States, obtained from the 2002 national surveillance estimates (3).

waste from germicides that are used for dialyzer reprocessing in the United States would vary with increasing proportion of patients who reuse dialyzers. Similarly, Figure 2 provides a hypothetical illustration of how yearly generation of cardboard and plastic related to packaging of two types of peracetic acid concentrates (45) for dialyzer reprocessing in the United States would vary with increasing proportion of dialysis facilities that practice reuse. These estimates are provided, because peracetic acid is the most widely used germicide for dialyzer reprocessing.

Single use of dialyzers also poses a challenge to the dialysis community of formulating plans for effective solid waste management with minimal adverse impact on the environment. In a report published by Minntech Corp., a company that is involved in dialyzer reprocessing, it was estimated that, in 1997, hypothetically solely single-use practices in the United States would have resulted in 17 to 18 million pounds of waste generated from dialyzer components that year alone (46). We examined the magnitude of dialyzer waste generated hypothetically from single-use dialyzer practices. For these calculations, the various components of a polysulfone dialyzer (Optiflux F160NR; Fresenius Medical Care, Lexington, MA) were weighed, including the dialyzer housing, the blood and dialysate caps, and the outer package, totaling 0.22 kg. Figure 3 provides a hypothetical illustration of how yearly generation of dialyzer-related polymer waste in the United States would vary with increasing percentage of patients shifting toward single-use practices.

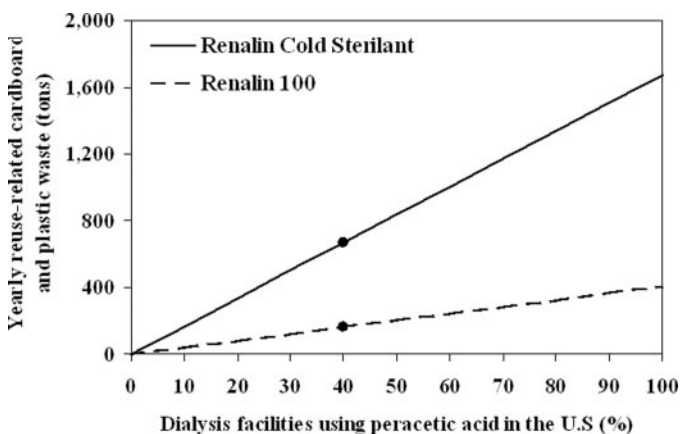


Figure 2. Hypothetically predicted yearly generation of cardboard and plastic waste related to peracetic acid dialyzer reprocessing in the United States. For these calculations, the following assumptions were made: (1) Projections were made for 4732 dialysis facilities that care for patients in the United States, which is based on point prevalent estimates (as of December 31, 2004) obtained from the USRDS 2006 annual report (48); and (2) the yearly cardboard and plastic weight (85 to 354 kg) was generated from a study that compared packaging waste from standard (Renalin Cold Sterilant) versus concentrated (Renalin 100) peracetic acid in a dialysis facility that cares for a monthly average of 78 patients (45). The dots correspond to the more recent hypothesized prevalence rate of dialysis facilities that use peracetic acid in the United States (3).

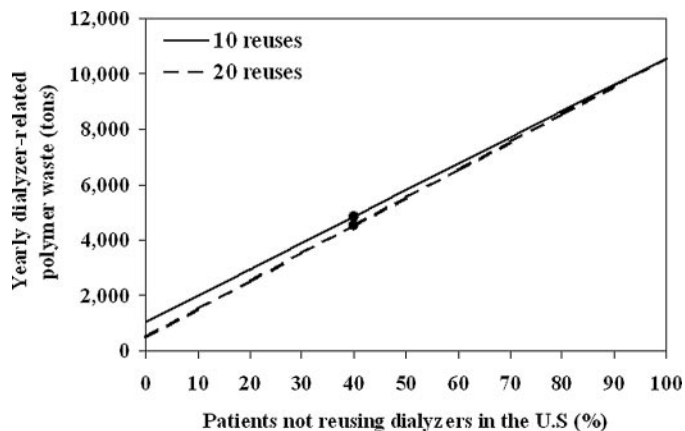


Figure 3. Hypothetically predicted yearly generation of solid waste from dialyzers in the United States. For these calculations, the following assumptions were made: (1) Projections were made for 309,269 patients who received hemodialysis in the United States, which is based on point prevalent estimates (as of December 31, 2004) obtained from the USRDS 2006 annual report (48); this translates into approximately 48.2 million yearly dialyses performed on an average of three weekly sessions; and (2) the solid waste generated from dialyzers was calculated by weighing the various components of a polysulfone dialyzer (Optiflux F160NR, Fresenius Medical Care), including the dialyzer housing, the blood and dialysate caps, and the outer package, totaling 0.22 kg. Polymers originating from the dialyzer include polycarbonate (dialyzer housing and blood and dialysate caps), polysulfone (hollow fibers), polyurethane (potting compound), and polyvinyl chloride (outer packaging material). The dots correspond to the 40% prevalence rate of dialysis facilities that practice single use in the United States, obtained from the 2002 national surveillance estimates (3).

Figure 4 introduces the concept of a “dialyzer shredder” to optimize dialysis waste management. An ideal dialyzer shredder should be able to sterilize biohazardous medical waste (e.g., blood residue) and recycle plastic. A company in Japan has developed a method and apparatus for simple on-site disposal

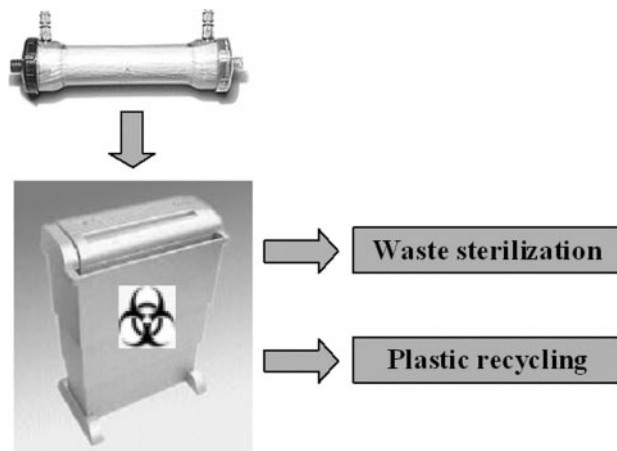


Figure 4. Dialyzer shredder concept to optimize solid waste management.

of medical waste, which might be appealing to dialysis providers (47). This proposed method involves crushing medical waste in a closed container, exhausting air out of the container, sterilizing air before releasing it into the atmosphere, and filling the container with high-pressure steam using a temperature between 110 and 150°C to sterilize the crushed medical waste. There is a need for technological advances and further research in this field and more environmentally friendly ways of dealing with dialysis waste. This is of utmost importance as dialyzer single-use practices continue to gain popularity and as more frequent dialysis regimens become more widely available.

## Conclusions

The advent of biocompatible membranes and favorable sterilization techniques has made it clear that there is no compelling medical indication for reprocessing dialyzers in the new millennium. Moreover, risks from reprocessing have not yet been fully elucidated. Cost saving is clearly driving 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. Efforts should be made to compare the environmental impact of reuse and single-use practices. Although reuse practice is accepted as safe when performed with full compliance to the AAMI standards, errors, lapses, and breakdowns are likely to occur in a real-world setting. It may not be long before the United States follows the European Union and Japan, where single use has been the standard of care. On a final note, we call upon the CDC to reinstate national surveillance surveys on reuse practices in the United States.

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## Disclosures

None.

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