Dialyzer Best Practice: Single Use or Reuse?

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ABSTRACT

Outcome studies have shown either no additional risk or a small additional risk for hospitalization and mortality associated with reprocessing dialyzers. Although the risks from reprocessing dialyzers have yet to be fully elucidated, reuse can be done safely if it is performed in full compliance with the standards of Association for the Advancement of Medical Instrumentation (AAMI). Like most industrial processes, however, complete control of the reuse process in a clinical environment and full compliance with regulations at all times is difficult. Potential errors and breakdowns in the reuse process are continuing concerns. The quality controls for reprocessing of dialyzers are not equal to the rigor of the manufacturing process under the purview of the U.S. Food and Drug Administration (FDA). Therefore, if one were to determine "best practice," single use is preferable to reuse of dialyzers based on medical criteria and risk assessment. The long-term and cumulative effects of exposure to reuse reagents are unknown and there is no compelling medical indication for reprocessing of dialyzers. The major impediment when deciding to convert from reuse to single use of dialyzers is economic. The experience in Fresenius Medical Care—North America (FMCNA) facilities demonstrates that converting from a practice of reuse to single use is achievable. However, the overall economic impact of conversion to single use is provider specific. The dominance of reuse has been negated of late by a major shift in practice toward single use. Physicians and patients should be well informed in making decisions regarding the practice of single use versus reuse of dialyzers.

There is no single, adequately powered, prospective, randomized clinical trial that provides definitive evidence regarding superiority or equivalence when comparing single use and reuse (i.e., reprocessing) of dialyzers. Therefore nephrologists rely on information from nondefinitive studies and expert opinions borne from clinical experience as well as periodic reviews of the above-published information. Facilities that reuse dialyzers were in the minority in 1976 (18%), but the practice grew, equaling facilities that practice single use of dialyzers by 1983 (1). Financial pressures caused by constrained reimbursement in the United States have encouraged dialyzer reuse (2–5). Reuse eventually became the prevailing standard of care, peaking at 82% of facilities in 1997 (1). Most practicing nephrologists today were trained or have spent the majority of their practice of dialysis patient care in an environment where the norm is dialyzer reuse.

The move by Fresenius Medical Care—North America (FMCNA), along with other providers, to abandon the practice of dialyzer reuse in recent years has changed the proportion of facilities and patients that practice single use of dialyzers (6). As of 2005, based on sales of single-use dialyzers, we estimate that approximately 61% of hemodialysis patients are treated with single-use dialyzers, including those who receive treatment with single use in facilities that routinely reuse dialyzers. A U.S. Renal Data System (USRDS) study showed that among patients who do not reuse dialyzers within facilities that routinely reuse dialyzers, 26% of patients choose to refuse reuse (7). Refusal to reuse was strongly associated with higher education level in that study, and the authors speculated: "Educated patients may be more aware of the potential demerits of reuse and therefore more likely to refuse reuse because of safety concerns."

The shift in dialyzer practice, along with patient concerns, suggests the need to determine "best practice." In this review we consider criteria for best practice primarily from the patients' perspective. A summary of the points of comparison between single use and dialyzer reuse is shown in Table 1 and will be discussed in detail below.

Medical Rationale

In the 1970s and 1980s, reprocessing of unmodified cellulose (e.g., cuprophane) dialyzers, most commonly with formaldehyde, was reported to improve biocompatibility and avoid "first-use syndrome" (8–10), decrease intradialytic symptoms (9,10), and even showed improved patient survival (11). However, by year-end 1999, the use of unmodified cellulose dialyzers had decreased to about 5%, and when combined with modified cellulose membranes, comprised less than 25% of all dialyzer membranes in use (12). The new synthetic membranes (e.g., polysulfone) in dialyzers have since been shown to be more biocompatible (13–15). Furthermore, enhanced rinsing and removal of ethylene oxide, a common sterilant for new dialyzers implicated in "first-use syndrome," has markedly reduced

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TABLE 1. Summary of the comparative evaluation of single use and reuse of dialyzers

Criteria	Single use (S)	Reuse (R)	Advantage (S versus R)
Medical			
Infections/contamination	Sterile	Rare	S+
Small molecule clearance	To specifications	Slight decline	None to S++[a]
Middle molecule clearance	To specifications	Large decline	S+ to S++
Immune response	Same or less	Some leukocyte activation	None to S+
Exposure to sterilants	None	Cumulative exposure	S+
Exposure to denatured blood products	None	Minimal; some anti-N-antibody	S+
Hospitalization	Same or less	Same or more	None to S++
Mortality	Same or lower death risk	Same or higher death risk	None to S++
Errors and accidents	Negligible risk	Small risk	S+ to S++
Operations			
Reuse technician training	None	Most programs	S++
Dialyzer verification	Much less time	More time	S++
Fiber bundle volume	Per specifications	Checks required	S++
Quality assurance program	Minimal	Extensive	S++
Reuse record keeping	None	Required	S++
OSHA compliance/records	None	Required	S++
Room maintenance[b]	None	Required	S++
Reprocessing procedure	None	Required	S++
Medical-legal risk/liability	Negligible risk	Small risk	S+ to S++
Economics			
Cost of the dialyzer	One dialyzer per treatment	One dialyzer per 10 to ≥ 30 treatments	R+++[c]
Salary of reuse technician	None	1 FTE/70–90 patients	S+++
Cost of water/electricity	None	Necessary	S++
Cost of reuse reagents	None	Necessary	S++
Cost of reuse supplies[d]	None	Necessary	S++
Cost of waste disposal	Same or more	Same or less	None to R+
Reuse room in the facility	None	Most programs	S++
Medical-legal expenses	None	Some	S+ to S++
Opportunity costs	Less staff burden	Staff burden	S+

[a] May change depending on the number of reuses, type of dialyzer, or type of reuse sterilant.
[b] Includes reuse machine (if present), ventilation, lighting, incubator, workplace safety, etc.
[c] This is the strongest argument for reuse of dialyzers.
[d] Includes gloves, aprons, masks, test supplies, labels, port caps, etc.

its occurrence (4,16). The decline in the use of cuprophane membranes along with improved rinsing of ethylene oxide may have reduced the "double hit" of complement activation and release of cytokines that may synergistically mediate such a reaction.

In addition to secular changes in dialysis practice, the prevalence of formaldehyde as the reuse reagent declined from 94% in 1983 to 20% by 2002, being replaced by a peracetic acid mixture (henceforth referred to as peracetic acid) in 72% of facilities (1). Two independent studies raised the possibility that a higher death risk may be more strongly associated with peracetic acid use than formaldehyde use (17,18). Key results of these two early studies that raised a "red flag" and spurred subsequent studies (also shown) can be found in Table 2.

Thus the medical rationale in support of the practice of dialyzer reuse has been abrogated and only economic reasons remain. Consequently the focus has shifted to ensuring the safety of dialyzer reprocessing (19). Initially there was concern over the occurrence of pyrogenic reactions related to reuse that continued through the late 1990s (20–22), the scope of which has been documented periodically by reports from the Centers for Disease Control (CDC) since 1986 (23,24). In addition, several outbreaks of bacteremia were associated with breakdowns in the reuse process (25–29). The standards imposed by the Centers for Medicare and Medicaid Services (CMS) for reprocessing dialyzers (42 CFR, part 405, section 2150; October. 1, 1997) are based on full compliance with guidelines issued by the Association for the Advancement of Medical Instrumentation (AAMI), updated in 2002 and amended in 2003 (30), with the support of the National Kidney Foundation (NKF) over at least two review periods (4,19). This regulation was designed to limit potential breakdowns in the reuse process.

Patient Safety

The incidence of pyrogenic reactions and outbreaks of bacteremia has decreased substantially and is no longer highlighted by the CDC, as evident in its latest report (1). Compliance with the AAMI guidelines is probably responsible for this improvement. However, the reprocessing process described in these guidelines, outlined in Fig. 1, is not simple (29). Each of the system steps has multiple substeps subject to standards, documentation, and quality assurance (29). Automation of parts of the sterilization process decreased breakdowns, but there remains continued risk for human error (e.g., labeling, failure to remove sterilants, etc.) and nonprocess breakdowns (e.g., backleaks in the water system). This becomes apparent when the AAMI standards are compared with the FDA standards that regulate the manufacture and distribution of new dialyzers (CFR, title 21, parts 1, 26,110, 211, 860, 876; April 1, 2003).

TABLE 2. A listing of often cited, nondefinitive outcome studies with epidemiologic analyses using large databases providing information on hemodialysis patients treated in free-standing hemodialysis facilities in the United States

Reference	No. of patients (follow-up)	Reuse type(s)	Outcomes versus single use	Remarks
11	4661 incident patients (1977 to 1982)	Formaldehyde	12% lower death risk for long-term reuse facilities	Marked change in practice over time for the use of formaldehyde and cellulose dialyzers
17	66,097 prevalent patients (1989/1990 followed for 1 year)	Formaldehyde, glutaraldehyde, peracetic acid	(F) Not different; (G) 13% higher death risk ($p < 0.001$); (P) 17% higher death risk ($p = 0.01$)	Facility-level analyses and patient-level analyses had similar results; limited comorbidity to DM
18	27,938 incident patients (1986/1987 to 1991)	Formaldehyde, glutaraldehyde, peracetic acid	(F) Not different; (G) not different; (P) 10% higher death risk ($p = 0.02$) with 2.9 months shorter median survival	Used facility-level classification of reuse versus single use (although the use of sensitivity analyses did not alter results); comorbidities not controlled
59	16,153 prevalent patients (followed for 1 year)	Formaldehyde, glutaraldehyde, peracetic acid	(F) Not different; (G) not different; (P) not different	Used SMR for patient mortality; Disclosure: FMCNA data and coauthorship
60	13,926 prevalent patients (1989/1990 followed for 1 year)	Formaldehyde, glutaraldehyde, peracetic acid	(F) Not different; (G) not different; (P) 15% higher death risk ($p < 0.05$)	Facilities with > 25% high-flux dialyzer use were excluded; complex analyses that mixed facility-level and patient-level data; Disclosure: support by Minntech Corporation
	20,422 prevalent patients (1991, 1992, and 1993 followed for 1 year)	Formaldehyde, glutaraldehyde, peracetic acid	(F) Not different; (G) not different; (P) not different	
56	27,264 incident patients (1986/1987 to 1991)	Formaldehyde, glutaraldehyde, peracetic acid	Hospitalizations: (F) +7% ($p = 0.04$); (G) not different; (P) +11% ($p < 0.01$) Excluding access: (F) not different; (G) not different; (P) +13% ($p < 0.01$)	Reuse combined: increased risk of all hospitalizations by +8% ($p = 0.01$) Reuse combined: increased hospitalization risk (excluding vascular access-related) by +6% ($p = 0.04$)
57	1491 incident patients (1986/1987 to 1991)	Combined	25% higher death risk ($p = 0.023$)	Adjusted for baseline comorbidity; mixed facility-level and patient-level data
61	12,791 prevalent patients (1994/1995 with 1–2 years follow-up)	Formaldehyde, peracetic acid	Hospitalization: (F) +29% ($p = 0.008$); (P) +28% ($p = 0.018$)	
		Formaldehyde, glutaraldehyde, peracetic acid (each ± bleach)	(F) Not different; (G) not different; (P) not different	(P) with 10% higher death risk than (F), up to 36% higher with cellulose-type dialyzers
58	49,273 incident patients (1998/1999 with 1–1.5 years follow-up)	Formaldehyde, glutaraldehyde, peracetic acid (each ± bleach)	(F) Not different; (G) not different; (P) not different	Same results for hospitalization, no significant differences; Disclosure: support by Minntech Corporation
62	55,385 incident patients (2000/2001 followed for 1 year)	Combined (breakdown not stated)	Not different	Adjusted for chain effects; mixed facility-level and patient-level data; Disclosure: support by Minntech Corporation
63	71,122 prevalent patients (July 1, 2001 + lag period, then follow-up for 1 full year)	Combined (majority was formaldehyde, followed by peracetic acid)	All lag points show higher death risk by 5–10%: lag 0, p = ns; lag 30, p = ns; lag 60, $p = 0.011$; lag 90, $p = 0.004$; lag 120, $p = 0.005$	Effect of change from reuse to single use is significant after a ≥ 60-day lag period; the reuse exposure is very accurate when compared to prior studies; Disclosure: FMCNA data and coauthorship

DM, diabetes mellitus; FMCNA, Fresenius Medical Care—North America; SMR, standardized mortality ratio.

Therefore, although the absolute bacterial infection risk has declined, the difference in infection risk between single use and reuse of dialyzers is greater, just from the likelihood of process breakdown. This risk may move beyond bacteria and into the realm of viruses and prions. For example, hepatitis C viral RNA was isolated from blood port caps even after soaking overnight in a peracetic acid solution (31). However, a direct link between incident hepatitis C infection and dialyzer reuse has yet to be demonstrated.

Another safety concern regarding reprocessed dialyzers is maintenance of adequate solute clearance. The key indicator of acceptable urea clearance is the total cell volume (TCV) test, originally proposed in 1980 by Gotch (32). Although originally performed on low-flux cellulosic dialyzers, subsequent small studies have shown that the criteria of greater than 80% intact TCV corresponding to a greater than 90% original urea clearance appeared to hold true with modified cellulose and synthetic membranes, at least when reused up to 20 times (33–35). However, at

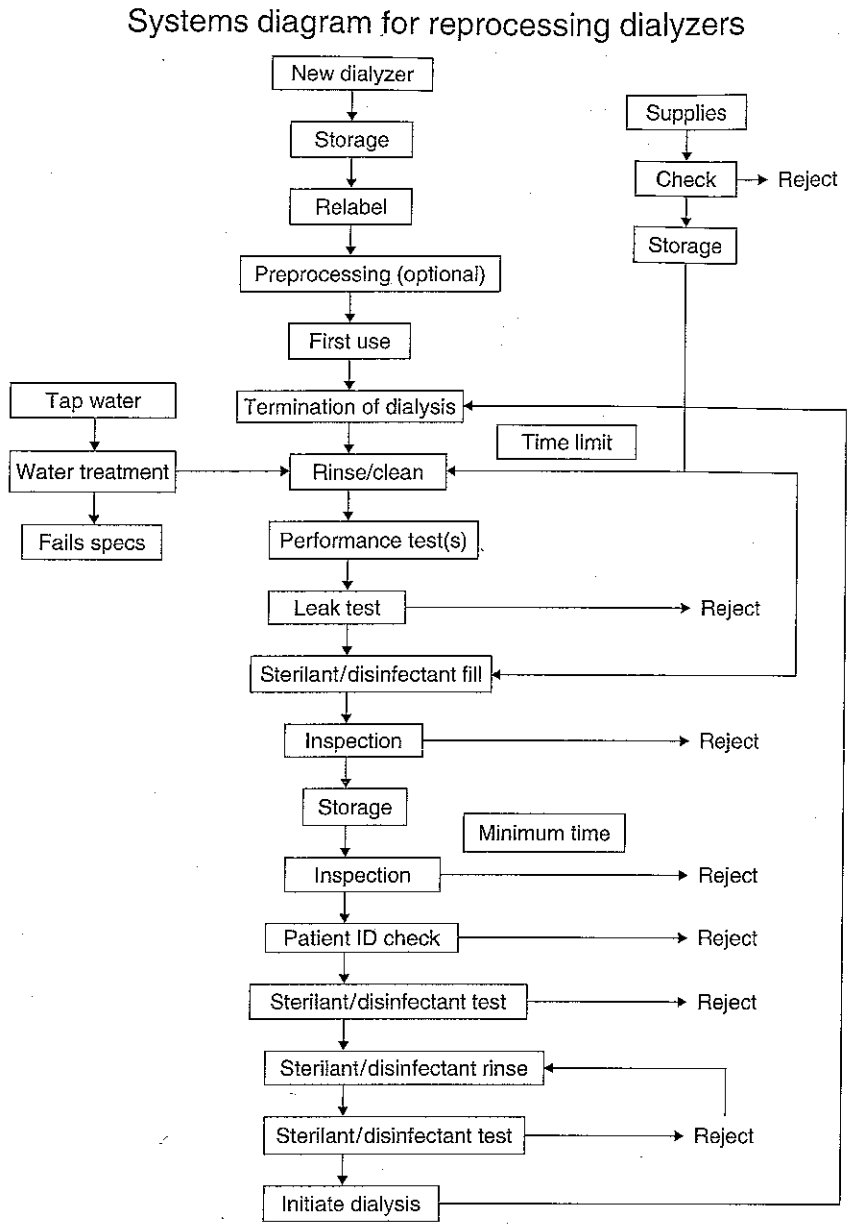

FIG. 1. Complexity of the reuse procedure. Reproduced with permission from AAMI 2002/2003 (29).

least one study reported that low-flux cuprammonium dialyzers reused for 15 times delivered reduced (less than 90%) urea clearance despite greater than 80% intact TCV (36). Furthermore, Sherman et al. (37) have shown that there is a small decline in dialysis dose (0.05 *Kt/V* units) when comparing a reuse mean frequency from 3.8 to 13.8 times. The Hemodialysis (HEMO) study thus limited the frequency of dialyzer reuse up to only 20 times (less for some dialyzer and sterilant combinations), yet there was a linear clearance decline of 1.1–2.9% per 10 reuses within the study (35).

These results, along with a scarcity of information regarding validation of dialyzer performance beyond 20–30 reuses, raised concern about the number of times dialyzers are reused in clinical practice (38). The CDC documented the frequency of reuse annually beginning in 1986, spanning a decade up to 1995, during which the mean frequency of reuse was 15 times and the mean of the maximum frequency of reuse was 36 times (39). The same report showed that maximal reuse of individual dialyzers hovered around 140 times for most of the 10-year period, but in 1995 reached 192 times.

In addition to the loss of urea (and small solute) clearance in reprocessed dialyzers, clearance of larger solutes, including the spectrum referred to as "middle molecules," are also affected (35,38,40). The change in clearance varies depending on dialyzer type and reuse reagent/sterilant (35,41). In general, the use of bleach tends to increase larger solute clearance, while not using it is associated with a decline in larger solute clearance. In some instances, increasing larger solute clearance may lead to a loss of albumin through the reused dialyzer

(41,42). However, with manufacturer engineered changes in the membrane characteristics, recent studies show that albumin loss is negligible and the decline in solute clearance may be acceptable, with nonexcessive (less than 15–20) reuse frequencies (43,44). However, such membrane changes that limit albumin loss for bleach-reprocessed dialyzers at 15–20 reuses may result in less clearance of larger solutes during the initial (less than 10) dialyzer reuses (45).

The specific implications of changes in solute clearances and protein loss depend on the reuse frequency and the combination of membrane type and reuse reagents. The addition of bleach may increase solute clearance, although in a way that is uncontrolled and of variable magnitude within the range of frequency of reuse. The clinical significance of such effects are postulated to be beneficial, but they may potentially be harmful to the patient as well and have not been properly tested in prospective randomized clinical trials. Regardless, there is currently no clear advantage to reprocessing dialyzers from a perspective of solute clearance.

With improved membrane biocompatibility, the patients' organic residue that adheres to the membranes of reprocessed dialyzers is no longer deemed "protective," but is now suspected to be potentially hazardous (46). Denatured blood components, especially with formaldehyde use, have been shown to result in anti-N-antibodies, associated with potential hemolytic anemia and transplant failure of unwarmed kidney grafts (46–48). Formaldehyde is known to be cytotoxic and potentially carcinogenic (49). Glutaraldehyde is a known irritant and allergen (50). Peracetic acid may be carcinogenic and was found to be weakly genotoxic to human leukocytes (51,52).

A majority of facilities that reprocess dialyzers are now using a peracetic acid mixture as the primary reuse reagent (1). In this dialysis reuse formulation, peracetic acid is in solution with hydrogen peroxide and acetic acid, with a concentrate pH of about 1; thus it is classified as a strong corrosive acid. Although the full concentrate is very unlikely to be directly infused into a patient, death has resulted from such inadvertent human error. A more likely occurrence is that residues may remain in the dialyzer if there are breakdowns in the reuse process or if the detection limits of the test strips for residual reagents allow for minute amounts of the reagent to remain in the dialyzer (53,54). The individual component toxicities of the peracetic acid mixture are listed in Table 3.

In one report, the FDA ranked several liquid disinfectants based on relative cytotoxicity in exposed patients and health care personnel and found a several hundred-fold difference among them (55). Among the compounds that are used in the dialyzer reuse process (although the study was not specific to this purpose), the FDA suggested that formaldehyde and hydrogen peroxide may be classified as mild, bleach (sodium hypochlorite) as moderate, and glutaraldehyde and peracetic acid as severely cytotoxic, at least based on tests performed in vitro. However, the cumulative and long-term effects of chronic, low-dose exposure to reuse reagents are unknown. Thus avoidance of potential exposure to reuse reagents with single-use dialyzers is preferred.

Patient Outcomes

Overall the epidemiologic studies that link reuse to the risks of hospitalization (56–58) and mortality (11,17,18,57–63), as shown in Table 2, vary in their conclusions. Inherent to these studies using large databases is the inability to prove direct causation, with associations that are often hypothesis-generating rather than conclusive.

That the models vary in terms of inputs and biases is apparent. For example, misclassification bias with regard to reuse exposure is present in all studies except two (61,63) because patients were classified as having reused the dialyzer if the facility is known to practice reuse. This is inaccurate because at least 8–10% of patients in facilities that reuse dialyzers at the time do not reuse (7,18). In the case of determinant variable inputs into statistical models, patient-level data (e.g., comorbidity, labs, etc.) as well as facility-level characteristics (e.g., staffing, profit status, etc.) have been blamed as potential confounders or the true cause of any differences observed. The economic benefits of dialyzer reuse lead to discussions on the relevance of provider characteristics to patient outcomes, since reuse was more prevalent in "for-profit" rather than "not-for-profit" facilities (7,17). More detailed opinions on the interpretation of these outcome data have been reviewed elsewhere (38,64–67).

One key observation is clear: regardless of which study is reviewed from the 1990s and onward, there is no link to increased hospitalization or mortality risk associated with the single use of dialyzers. The potential for increased mortality risk and hospitalization was demonstrated in

TABLE 3. Health hazard information for individual components of the peracetic acid reuse mixture

Hydrogen peroxide
Mild to severe irritation of tissue
May cause blistering of skin by solution contact
Highly irritating to skin, eyes, mucous membranes via oral/respiratory routes
Acetic acid
Irritant and corrosive via inhalation, oral, and dermal routes
Can cause burns, lacrimation, and conjunctivitis
Attacks skin easily to cause dermatitis and ulcers
Peroxyacetic acid
Destructive to mucous membranes, upper respiratory tract, eyes, and skin
Inhalation may result in inflammation and edema of the larynx and bronchi, chemical pneumonitis, and pulmonary edema
Symptoms of exposure include burning sensation, coughing, wheezing, laryngitis, shortness of breath, headache, nausea, and vomiting

some studies and applies only to dialyzer reuse (17,18,56,57,63), prompting questions regarding its safety. Based on the current level of knowledge, it is impossible to definitively quantify this risk, such that reuse of dialyzers continues to be a relatively common practice, with the caveat that applicable reprocessing standards from AAMI are followed with 100% compliance (4,30). However, if one considers "best practice," it would seem reasonable to opt for a new dialyzer rather than one that has been reprocessed—with all the potential risks outlined.

Reprocessing Operations

The AAMI guidelines for dialyzer reuse is a comprehensive document with 14 sections, the last 11 of which deal directly with the recommended requirements for a "safe and effective" reuse program (30). When FMCNA began switching from reuse to single use of dialyzers, it became apparent that the reuse process had become embedded in dialysis facility operations. The program added to or modified aspects of dialysis facility construction, operations, personnel and training requirements, computer systems, and manuals, policies, and procedures. Reprocessing dialyzers, when done in compliance with AAMI standards, is an operations infrastructure in itself.

For record keeping alone, intensive personnel training was required in order to maintain updated reuse manuals, dialyzer reprocessing records, equipment maintenance records, personnel health monitoring records, complaint investigation records, and quality assurance and quality control records. The curriculum required regular updates. Personnel turnover required ongoing training sessions at multiple time points during the year. The appropriate room or space setup accommodated the water system and the reuse equipment as well as adequate storage space for the reuse reagents and supplies. Inventory management, cleaning, and maintenance of this physical plant infrastructure were a necessity. In addition, safe handling of reuse reagents is very important, especially since accidental mixing can result in the release of toxic gas or create an uncontrolled reaction (68).

With the use of formaldehyde, facilities are required to comply with the Occupational Safety and Health Administration's (OSHA) Formaldehyde Standard (29 CFR 1910.1048), which encompasses exposure monitoring, personal protective equipment and clothing, medical surveillance, hazard communication, etc. In addition, with accidental occurrence of a 37% formaldehyde spill, a licensed, fully equipped hazardous waste emergency response contractor is required to address the unknown spill concentration. In the event that a decision is made to develop such a team in house, then OSHA's Hazardous Waste Operations and Emergency Response (29 CFR 1910.120) and Respiratory Protection (29 CFR 1910.134) regulations would apply.

The reprocessing process entails multiple steps, from receiving a used dialyzer to sending it back out to be reused by a patient, each with the potential for human error and process breakdown (please review Fig. 1 for a process overview). The patient care staff requires training and quality control for preparing and labeling the used dialyzer, as well as for making sure that the same dialyzer is set up only for the same patient each time. Inadvertent switching of dialyzers between patients has been a constant concern. Rinsing out and checking for residual germicide is of paramount importance, yet accidental infusion of reuse reagents has been reported.

This entire reuse infrastructure became obsolete in FMCNA facilities once they switched to single use. Reuse personnel willing to retrain for other duties provided newly available manpower. All the precautions, redundancies, and process checks were no longer necessary. A significant burden was lifted from dialysis operations. This relief qualifies it for "best practice" from an operations perspective.

From a medical-legal perspective, the presence of any program with a potential risk for lapses or breakdown, specifically one that involves potentially harmful or corrosive substances or equipment, poses a litigation risk. Regardless of merit, any legal challenge entails time and cost. Moreover, high-profile lawsuits can negatively impact the reputation and integrity of a dialysis provider and each individual clinician. Therefore discontinuation of the reuse program alleviates such associated medical-legal risks.

Economics

Economics requires mention because it is now the sole reason for reprocessing dialyzers (3,4,30,56,63,65–67). The declining relative value of the composite rate payment by Medicare for each hemodialysis treatment encourages dialysis provider practices that decrease operating expenses, including reuse of dialyzers. On the other hand, reprocessing dialyzers reduces economic pressure for seeking an increase to the composite rate payment by Medicare for each hemodialysis treatment (3), which many feel to be inadequate. Indeed, the cost of a single dialyzer multiplied by the number of hemodialysis treatments per year is a large expense for a dialysis provider compared to the cost of only one dialyzer per patient per month, even with the added cost of reprocessing. It is likely that financial pressures lead to administrative decisions to further increase the number of times each dialyzer is reused (2).

However, the economic evaluation of whether or not to reprocess dialyzers is similar to all comparative cost analyses: evaluating the cost difference between single-use and reuse strategies. "Cost" refers to the total cost and includes the direct costs of products, the direct costs of production, indirect costs, and the opportunity costs associated with each strategy. The direct costs of product comparison is simply the difference between the costs of dialyzers (greater for single use) and the direct costs of supplies (chemicals and other materials) required for the reuse process (greater for reuse). The direct production costs associated with single use include increased storage space for more dialyzers and disposal costs for those dialyzers. The direct production costs associated with reuse include the amortized costs of reprocessing machines, the space allocated (reprocessing the dialyzers and storage of supplies and reprocessed dialyzers), the costs

of reuse technicians, water costs, and so forth. Indirect costs include the personnel, clerical, and other costs required for record keeping and other compliance activities related to the reuse program.

Opportunity costs include tangible and intangible considerations, including the perception of patients, providers, and the larger clinical and public communities. They also include differences in potential costs that could be incurred as a result of adopting one strategy or the other. Litigation costs resulting from injuries to patients or staff are attributed to the reuse practice. Reprocessing creates the need for procedures and materials, and results in activities at the dialysis facility that are not otherwise necessary for performing the dialysis treatment. Thus there are substantial opportunity risks associated with utilizing a reuse strategy.

An internal study was implemented to assess if reuse was associated with increased mortality in patients treated at FMCNA facilities and it showed no such relationship (59). However, realizing that the medical rationale for reprocessing dialyzers was becoming obsolete, senior management continued an appraisal of the reuse process. Company engineers expressed a vision for advancing membrane development technology that was hindered by the complexities posed by repeated exposure to reuse reagents.

The large FMCNA patient population and the ability of its dialysis products division to increase dialyzer manufacturing volumes enabled the company to reduce the overall cost of converting from reuse to single use. The reduction in operational expenses brought about by the removal of the reuse infrastructure alleviated some of the impact of converting to single use; the reuse technician position could be eliminated, with many of them retrained and reassigned to other responsibilities. In addition, the cost of utilities could be reduced, especially water use (e.g., it took 100 L of water for every 10 dialyzers reprocessed). In the reverse osmosis purification system alone, every liter of water utilized for the reuse process was accompanied by a liter of waste, with the water tempered to 75°F. The reduction in supplies was not limited to reuse reagents, but included test strips, labels, port caps, and even gloves, aprons, and masks. Ultimately these factors led to a decision to formulate a plan to discontinue reprocessing dialyzers (69).

On the other side of the coin, there was an increase in dialyzer waste volume with conversion to single use. However, there was an ongoing initiative to improve the efficiency of medical waste disposal in hemodialysis facilities during the period of converting to single use. The quality initiative minimized the effect of additional medical waste from discarded dialyzers. Reprocessing of dialyzers also has associated waste that can be avoided with single use. Shifting from one reuse reagent to another in a facility with an average of 70–80 patients per month demonstrated an annual reduction of 780 lb of cardboard and plastic waste (70); perhaps a similar reduction contributed to minimize the effect on the cost of waste disposal with abandonment of the reuse practice. Although it was not a cost issue at FMCNA, increased dialyzer waste may impact other providers differently.

The last economic argument in support of dialyzer reuse has nothing to do with the reuse process per se, but rather on the allocation of available money toward new technology and not new dialyzers (71). The example in the past has been that reuse provides flexibility for providers to offer more technologically advanced synthetic, high-flux dialyzers (3,64–67). Indeed, dialysis units that reprocess dialyzers predominantly utilize high-flux synthetic dialyzers (72). Furthermore, patients who do not reuse dialyzers while being treated in dialysis units that routinely reprocess dialyzers were seven times more likely to be treated with low-flux dialyzers ($p < 0.0001$) according to the USRDS (54). FMCNA has eliminated this argument by offering single use utilizing the company's most advanced Optiflux line of high-flux synthetic dialyzers with polysulfone membranes to all patients as part of the proprietary Ultracare program.

The economic evaluation of reuse versus single use is a dialysis provider-specific issue. Our experience along with that of others demonstrates that the conversion from reuse to single use of dialyzers is achievable. Although FMCNA has the advantage of having a vertically integrated corporate structure, there are other dialysis providers that are treating patients with single use dialyzers without such a structure. Ultimately each provider will have to decide whether reuse or single use is appropriate for its specific situation, cost profiles, and rigor of their reuse program.

Conclusion

There is no compelling medical indication for reprocessing of dialyzers. Although the risks from reprocessing dialyzers have yet to be fully elucidated, reuse can be done safely if it is performed with full compliance to AAMI standards. However, errors, accidents, lapses, and breakdowns can occur during the reuse process, just as in any medical or industrial process, putting patients and employees at risk. As for "best practice," single use is preferable to reuse of dialyzers based on medical and other criteria, summarized in Table 1. Perhaps this statement reflects what is already a foregone conclusion in the European Union and Japan, where the norm is single use, and the United States is merely playing catch-up (63,67,73). Currently, with an increasing proportion of patients being dialyzed with single use dialyzers, physicians must be well informed regarding the pros and cons of single use versus reuse. More importantly, physicians should educate their patients about dialyzer use and options.

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