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Does hemodialyzer reuse have a place in current ESRD care: “To be or not to be”?

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“If you can look into the seeds of time, and say which grain will grow and which will not, speak then unto me.” -William Shakespeare. Macbeth. Act 1 scene 3.

Because of reliable technology over several decades of experience and apparent cost effectiveness and safety, many in the dialysis industry would have assumed that dialyzer reuse would be a continuing fixture. But dialyzer reuse has become less common in favor of a single-use. In 1997, 82% of dialysis facilities practiced dialyzer reuse for some or all of their patients, but by 2005 this figure had declined to 39% (1, 2). Is there is a continuing role for dialyzer reuse in ESRD programs in the US? To address this, we briefly review the outcomes seen historically and presently between the practices of reuse vs. single-use, and then we discuss the factors that likely contributed to the decline of reuse across the US over the last decade and their implications in making a decision to reuse or not.

1. Why did the employment of dialyzer reuse decrease so dramatically?

Many changes have occurred in hemodialysis techniques since Kolff’s pioneering efforts in 1943, some of which have directly influenced the decision about reuse. In 1973, after the passage of the *Social Security Amendments of 1972* to cover dialysis for end-stage renal disease, the dialysis industry responded with mass production of all chemical, mechanical, logistical, financial, and delivery components. As just one aspect of this phenomenon the cost per dialyzer decreased for dialyzers of most sizes, sterilization techniques, and types of biocompatible membranes. Again, as part of the massive growth within the industry, many US dialysis facilities are affiliated with large dialysis organizations (LDOs) with lucrative volume-related discounts with dialyzer manufacturers. Even smaller organizations or unaffiliated dialysis facilities may engage in and benefit from volume-related discounts.

Three decades ago, the era of dialysis vertical integration began in the US when dialysis machine and dialyzer manufactures Fresenius and Gambro became dialysis service providers. Because of the composite rate payment system in the US, dialyzer reuse and subsequent cost savings from it were standard practice. Gambro (through its Hospital partnership) was probably the first and most creative of these vertically integrated organizations to offer discounted prices for the perceived highest quality biocompatible dialyzers. After Fresenius’ merger with Renal Care Group, it expanded its policy of single-use, using sophisticated Fresenius dialyzers (3). It utilized this single-use philosophy as a

marketing strategy aimed at recruiting patients and nephrologists to Fresenius facilities, which would have implications to insurers and other payers. Very shortly after this (in part, we believe to counter Fresenius' promotion of LDO wide single-use), DaVita reported its successful survival outcomes practicing reuse (4). By December 2013, about 40% of DaVita treatments were with reprocessed dialyzers in a decision made jointly between the medical director of each facility and DaVita (personal correspondence, Robert Provenzano).

However, vertical integration has not necessarily led to reduction in costs. The vertically integrated Gambro sold its dialysis services operations to DaVita and abandoned dialysis unit ownership in the US, leaving Fresenius as the only large vertically integrated company. Fresenius dialysis facilities purchase dialyzers from another Fresenius business component on the manufacturing side. While both the service and manufacturing components are within the parent company, they remain independent business entities. Thus, the dialysis facilities still purchase the dialyzers and probably see both volume and company-affiliated discounts. The bottom line on actual costs is not published in this specific detail. But in the end, for all dialysis facilities within Fresenius, DaVita, or any other organization, most single-use dialyzers are of high quality, biocompatible (including sterilization technique), have adequate surface area, and are relatively cheap.

Another contribution to this major change in dialysis practice is the desire to alleviate the tedious oversight needed to assure proper reuse practices. Regulatory oversight is an important necessity for a medical practice where significant harm can potentially occur. Dialyzer reuse has been under intense scrutiny precisely for that reason. In performing reuse, the facility has to strictly comply with numerous federal and local guidelines to ensure that reuse processes and evaluations meet minimal standards. Most dialysis facilities already feel heavily burdened by many other regulations, and the added weight of reuse regulations is often enough to tip the decision against reuse. (More on this topic is in section 4.)

2. Do clinical outcomes differ between reuse and single-use practices?

An Urban Institute study initially found significant differences in mortality favoring single-use when the agents peracetic acid mixture or glutaraldehyde were used in reprocessing low-flux dialyzers. However, these results actually favored reprocessing with peracetic acid mixture in hospital-based facilities (5). Lower mortality was observed in reuse of high-flux dialyzers reprocessed with peracetic acid mixture or glutaraldehyde compared to facilities using non-reprocessed low-flux dialyzers. Co-morbidities were not controlled and the comparison was of reuse with high-flux dialyzers to single-use with low-flux dialyzers, so different dialyzers were also confounders.

Feldman et al addressed the issue of safety between the two types of dialyzers finding increased mortality in freestanding facilities employing reuse with peracetic and acetic acid reprocessing (6). This difference vanished when the locale of treatment shifted to hospital-based facilities.

The findings of these two studies favor increased risk being associated more with reprocessing chemical techniques as opposed to simple reuse vs. single-use based on the disappearance of effect in hospital-based facilities. In 2001, controlling for many potential

confounders compared to previous studies, the USRDS reported no significant differences in mortality between reuse vs. single-use (7). It is quite possible that this lack of difference may also have been a reflection of improved quality control prompted by the previous observational studies.

The comparison of clinical outcomes in reuse versus single-use has achieved equipoise in our opinion.

3. Is there truly a difference in cost between reuse and single-use?

We interviewed several medical directors and consistently found that many were uncomfortable discussing this topic and could not pinpoint why. One unit of 650 patients has conducted detailed analyses of its costs, noting that it consistently saves approximately \$500,000 annually by reuse. This may or may not be typical. In a meta-analysis Manns et al found what they described as a “small” cost savings favoring reuse when heated citric acid reuse was compared to single-use. However, they acknowledge an increased relative risk of hospitalization with reuse (8). Chuang et al found both cost savings and improved mortality rates when comparing reuse to single-use in their facility (9). It is clear that each facility should analyze their spending and costs to truly evaluate the finances of reuse.

4. Arguments other than simple clinical outcomes and apparent costs

Some reuse practices allow up to 30 reuses, although 20 is more typical and the average is often < 20. So, dialyzer waste reduction is significant. Facilities pay for waste disposal by volume, thus numbers of dialyzers and the way lines and dialyzers are packaged as bulk waste play roles in this expense. Bond et al argue that limiting medical waste favors reuse (4). We suspect that most medical directors and administrators are not paying attention to these details.

In some locales, medical waste ends up buried in a landfill where degradation occurs quite slowly. While the landfill is designed to protect the surrounding environment, accidents occur and barriers are breached. Another method of disposal is by incineration, sometimes to produce electricity, but with its own environmental impacts. In contrast, the chemicals required for reuse have potential for environmental damage.

The roles of the facility staff must be considered. In reuse, disconnecting tubing and needles is necessary, thus increasing blood exposure. Subsequently, the act of reprocessing includes cleaning, sterilization, and storage, with expertise and labor intensity required at every step. Making sure the correct dialyzer is used is tedious and critical. As USRDS director Allan Collins pointed out to the authors, “The operational issues are really on point. The effort to keep staff trained and vigilant on reuse is considerable. The extra staff needed is also a consideration. Although there are many providers that do a good job with reuse, I’m sure there are more challenged providers where risks increase related to infections and poor clearance.” This brings up the response of the medical director we interviewed in section 3, who said “I consider myself a “less than strong” proponent of reuse. We continue to employ reuse because it is present already in the facility and functions well, but despite the cost

savings, the additional work required of the unit staff could indeed be a reason in and of itself to switch to single-use.”

With reuse there is an increased oversight burden on the medical director, but also for the practicing nephrologists because reuse is associated with a lower urea clearance (10), an issue of relevance in section 5.

5. Future possibilities with reuse

If single-use is more expensive than reuse, maybe we can reduce supply and labor costs in other ways. In addition to the arguments above, consider the possibility posed by our associate Jamie Dwyer, M.D., one of our facility medical directors. He suggested that heparin-free dialysis might be enhanced by single-use. For example, with high blood flows generated with fistulas or grafts and less aggressive ultrafiltration requirements (i.e. lower interdialytic weight gains), the risk of fiber clotting is reduced. Monthly measures of dialytic performance (e.g. urea reduction ratio) may show that dialyzers remain functional without heparin. Thus, identifying which patients could perform heparin-free dialysis might reduce costs during dialysis and reduce exposure to heparin.

6. Does reuse have a place in current practice?

We favor reuse only in those units where it is already utilized in a cost-effective manner, with all necessary safety oversights. It makes little sense to employ reuse in a new facility. The additional strain to implement reuse in an already complex system outweighs the potential cost benefit for an individual patient and facility.

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