3.
Equipment Requirements

3. Equipment Requirements

THE MARKET OVERALL

Of the treatment approaches discussed above, hemodialysis has perhaps the greatest requirements for equipment and supplies. Transplantation, of course, requires the various equipment and supplies associated with the operating room, but the equipment is employed once per transplant and, for the most part, will be used in other surgical procedures as well. Peritoneal dialysis has relatively modest equipment requirements overall. Machinery in the form of dialysate exchange equipment is used in intermittent peritoneal dialysis (IPD) and continuous cycling peritoneal dialysis (CCPD). In the more popular continuous ambulatory peritoneal dialysis (CAPD), considerable use is made of the disposable dialysate which, in this treatment, usually comes in a sterile, prepackaged container. Tubing and other miscellaneous supplies are also employed.

The process of hemodialysis involves a range of equipment and supplies. Machinery is required to pump the blood, prepare and deliver the dialysate, and generally monitor the system for safe operation. Water-treatment equipment may also be used, or, alternatively, purified water may be brought in. In addition, dialysate, dialyzers, blood lines, needles, and assorted other items are needed. The industry typically makes a distinction between "equipment," such as the blood pump and delivery system, and "disposable," such as the dialyzers and blood lines, that in principle are disposed of after each use. Those wishing a finer distinction may also distinguish so-called "consumables" from other disposable. Consumables are more specifically used up during hemodialysis and include the dialysate, heparin (drug used to prevent blood clotting), and saline (solution used to prime and rinse the dialyzer). For the most part this case study will employ the former but not the latter distinction.

Table 4 provides estimates of the dollar value of the ESRD market over time. The total U.S. market for equipment and disposable appeared to have been about **$500** million in 1983; and based on 1982 estimates, the worldwide market was roughly three times that size (46).

Equipment and disposable for hemodialysis account for the bulk of the market, but this share

Table 4.—Estimated U.S. Market for ESRD Equipment and Disposable by Year ($ million)

	1975	1976	1977	1978	1979	1980	1983a
Hemodialysis:							
Dialyzers	$ 72.3	$ 94.4	$112.5	$131.8	$1442	$153.7	$148.2
Blood lines	18,0	25.4	32.9	40.2	45.5	49.8	53.9
Other supplies.	40.0	556	71.2	837	98.8	1146	1139
Dialysate delivery systems and other equipment[b]	14.0	17,0	20.4	23,9	275	31.6	395
Total hemodialysis	$144,3	$1919	$2370	$299.6	$316.0	$349.7	$385.5
Peritoneal dialysis:							
Continuous ambulatory peritoneal dialysis	$ —	$ —	$ —	$ 0.3	$ 3,2	$ 16.6	$ 99.8
Intermittent peritoneal dialysis[c]	10.0	12.5	150	16,8	18.5	16.5	9.1
Continuous cycling peritoneal dialysis	—	—	—	—	—	0.2	175
Total peritoneal dialysis[d]	$ 10.0	$ 12.5	$ 15.0	$ 17.1	$ 21,7	$ 33.3	$126.4
Total dialysis	$154.3	$204.4	$252.0	$296.7	$3377	$383.0	$511.9

[a]Projected in 1981
[b]Includes parts and service
[c]Includes acute treatments
[d]Includes equipment costs

SOURCE Sanford C Bernstein & Co Inc *The Kidney Dialysis Industry* (New York February 1981)

has been decreasing over time, primarily because of the increasing popularity of CAPD. The single most important item overall is the dialyzer. Its 1980 sales accounted for 40 percent of the market. For reasons discussed later in this case study, this share is expected to decline.

Dialyzers are an important segment of the market in dollar terms and thus are worthy of some attention. However, this segment of the market is also of special interest because it appears to be especially sensitive to pressure to reduce the costs of the ESRD programs and more generally sensitive to the resolution of some important policy issues. Thus, it can help illuminate many policy issues and effects. Since much of the analysis in this case study will focus on dialyzers, the next section describes this part of the market in more detail.

DIALYZERS

The Dialyzer Market

Dialyzers consist essentially of three basic parts: a compartment for the blood, a compartment for the dialysate, and a semipermeable membrane separating the two. The three principal types of dialyzers—parallel plate, coil, and hollow fiber—differ essentially in how these basic parts are arranged. All three types of dialyzers are generally described by manufacturers as "single-use disposable," but in fact are often reused. The Kiil dialyzer, a type of plate dialyzer, is specifically designed for reuse but its inconvenience has made its popularity quite limited (117).

Although the specific features of the dialyzers vary among manufacturers, each type of dialyzer has certain basic characteristics. Parallel plate, or simply, plate dialyzers consist of a stack of semipermeable membranes sandwiched between support "plates." Blood passes between the membranes while the dialysate passes in the opposite direction through grooves or spaces in the support plate. In a coil dialyzer, blood passes through semipermeable membrane tubing. The tubing is wound around itself, or "coiled," and a supporting screen separates the coils. The dialysate passes at a 90° angle through the space created by the screen. A hollow fiber dialyzer contains thousands of hollow fibers bundled within a compact cylinder. Blood flows through the semipermeable hollow fiber while the dialysate fluid passes outside the fibers (117).

The growth trend in unit sales, or numbers, of dialyzers is illustrated in table 5. The figures show a continuing decline in the rate of growth of dialyzer sales and most recently an absolute decline in sales. The 1983 data were obtained from a source different from that of the other years' data, so comparisons should be made with caution. Nevertheless, the pattern observed is consistent with the view that the market is contracting (79). The principal explanation for this lies in the increase in dialyzer reuse, a subject addressed later in this case study.

Note also the changing mix of dialyzers sold. The hollow fiber dialyzer has clearly come to dominate the market, while the coil dialyzer has declined markedly in use. The plate dialyzer has managed some increase in share, but market

Table 5.—Estimated Dialyzer Unit Sales by Year

	1975	1976	1977	1978	1979	1980	1983
Total units sold (1,000s)	3,585	4,555	5,410	6,130	6,800	7,445	4,400
Share by dialyzer type (o/o):							
Hollow fiber	19.1%	21.5%	28.9%	39.3%	47.1%	52.5%	70%
Coil	67.0	63.0	54.0	41.4	33.3	26.3	2
Parallel plate	12.4	14.4	16.5	18.9	19.3	21.1	28
Other	1.5	1.1	0.6	0.4	0.3	0.1	—

SOURCES For 1975-80 data, Sanford C Bernstein & Co , Inc , *The Kidney Dialysis Industry (New* York February 1981), for 1983 data, Information Resources International, Inc , *Biomedical Business International*, VI, Mar. 16, 1983

analysts expect this share to drop somewhat as hollow fibers continue to gain **(79).**

There appear to be two principal reasons for the hollow fiber dialyzer's gain in market share. First, hollow fiber dialyzers have excellent dialysis performance characteristics. They are small, efficient, and relatively easy to use. Coils, on the other hand, are more cumbersome and difficult to work with and require relatively high blood volumes. Plate dialyzers are generally regarded as much superior to coils but are viewed by some in the market as slightly less efficient than hollow fibers (79).

The second reason for the hollow fiber gain in market share is its relative suitability for reuse. Although all three types can be reused, the hollow fiber dialyzer has come to be regarded as especially suitable for reuse. The hollow fiber dialyzer's advantages arise because, in practicing reuse, it is important to monitor the changing performance characteristics of the dialyzer as it is reprocessed. This dialyzer's characteristics allow for a relatively straightforward determination of the reused dialyzer's efficiency. This is because the dialyzer's ability to perform its function is directly related to the hollow-fiber cell volume, which can be fairly easily and readily measured. In contrast, the membrane used in plate dialyzers is compliant, and simple volume measurements cannot provide a reliable indicator of performance properties (16,22). Furthermore, cleaning plates is difficult to monitor because blood can get caught between the plates. Finally, many simply regard the hollow fiber dialyzer as more "rugged" and able to withstand the reprocessing treatments (120).

Reuse of Dialyzers

To understand the dialyzer's position in the market, it is important to understand the practice of reuse: it occurs when a dialyzer, after its original use, is reprocessed, stored, and then used again on the same patient, often multiple times. The reprocessing generally begins with an initial rinsing of the dialyzer after dialysis. The dialyzer is subsequently cleaned and disinfected or resterilized (117). The actual reprocessing procedure and the number of reuses tend to vary among facilities. However, various medical and industry groups have been developing guidelines for the reprocessing procedure (e. g., see (71) and (77)). These guidelines include a test of the dialyzer's residual functional capabilities after each use. When the dialyzer functions at an unacceptable level, it is discarded. There are apparently no systematic data on the number of reuses actually achieved nationwide. A recent Health Care Financing Administration (HCFA) analysis of the cost savings from reuse assumes five reuses (103). At a recent workshop, one program reported some success in achieving a "target rate" of eight reuses per dialyzer (84).

In any case, dialyzer reuse, although widely practiced, is quite controversial. This section considers some of the major issues surrounding the practice. As a beginning, some of the history of the practice is recounted. Then its cost and medical consequences are discussed.

History of Reuse

Most dialyzers today are labeled by the manufacturer as intended for single use only. They are "disposable." However the practice of using a dialyzer more than once goes back to the early years of dialysis. In 1964, Shaldon and his associates reported a technique for reuse through refrigerating coil dialyzers (83). A technique for reuse of the Kiil dialyzer, aimed at eliminating the need for disassembly and rebuilding, was described in 1967 (70).

In recent years there has been a renewed interest and indeed a growth in the reuse of "disposable" dialyzers. In a well-known study, Deane found that in 1978 about **17** percent of patients were involved with multiple use **(23).** A 1982 survey by the Centers for Disease Control indicates that 51 percent of patients were dialyzed in centers that practiced reuse (27). In Europe the practice is also followed but on a somewhat smaller scale. Estimates actually show a decline in the percentage of patients reusing disposable dialyzers from about 14 percent in 1975 to 9 percent in 1981 (41). However, this decline is attributable, at least in part, to the marked expansion of the overall patient base. The actual number of patients reusing dialyzers increased over this period.

Whereas in the early years of dialysis the rationale for reuse was largely convenience (13,22), the driving force behind reuse today is a desire for cost savings. Of course, reuse may have medical effects, both positive and negative. An appropriate assessment of reuse must recognize the various factors involved.

Cost Savings

Estimates of the cost savings associated with reuse are illustrated in table **6.** The estimates vary from **$1,600** to $6,000 per patient per year because of differences in the assumptions underlying them (e.g., with respect to dialyzer prices, labor, and materials costs, etc.) and because of differences in the actual reuse and reprocessing procedures. They also differ in the time periods on which the estimates are based. As a result they may not fully reflect experiences today.

If one assumes a savings of **$2,000** per patient per year with reuse and a patient population on reuse of **40,000** (roughly 50 percent of the ESRD population), then the yearly savings amount to $80 million. As the industry has pointed out, savings of this magnitude represent a relatively small portion of ESRD program costs (117). In this hypothetical case the savings are less than 5 percent of program costs. Nevertheless, economies of this magnitude are certainly attractive.

Table 6.— Selected Estimates of Savings From Dialyzer Reuse

Source of estimate	Savings per patient year[a] ($ current)
Fawcett and Mangles (1974) .	**$3,000**
Foxen (1983)b	1,900
Hoff stein, et al. (1976) . .	1,600-2,400
Scribner (1977)	2,500-6,000
U.S. DHHS, HCFA (1981)[b].	2,000

[a]Rounded to nearest $[illegible]

[b]Estimates are for dialyzer reuse without reuse of blood tubing

SOURCES. B Scribner, testimony at hearing before U S House of Representatives, Subcommittee on Health of the Committee on Ways and Means, Apr 251977, P A Hoffstein, et al , "Dialysis Costs' Results of a Sample Study, " Kid *Int*. 9266.293, 1976, and K C Fawcett and M D Mangles, "Reuse of the Gambro Lundia 17-Layer Dialyzer, " *Dialysis and Transplantation* 3(1) 38-40, 1974 Figures are derived from the summary in G T Willingmyre, Reuse *of Single-Use Hemodialyzers* (Washington, DC Health Industry Manufacturers Association, 1979) Data from Fawcett and Mangles (above) and L G Foxen, "IS Reuse Cost Effective? A Case Study, " in Reuse *of Disposables*, Association for the Advancement of Medical Instrumentation, Technology Assessment Report No 6-83, Arlington, VA, 1963, were converted from cost savings per treatment by assuming 156 treatments per year. HCFA data are from U S Department of Health and Human Services, Health Care Financing Administration, Memorandum on Hemodialysis Reuse from Edward L Kelly to Carolyne K Davis, July 31 1981

Of course, one might still challenge the validity of such figures. Note that the more spent on reprocessing, the less the cost savings of reuse. Representatives of the dialyzer industry have suggested that with appropriately rigorous reprocessing, savings might be much less than are now envisioned. Although manufacturers are subject to Federal regulations concerning good manufacturing practices (GMP), clinics and hospitals reusing dialyzers generally are not. These regulations, part of the Food, Drug, and Cosmetics Act, mandate minimum quality assurance requirements in the manufacturing or processing of a medical device. If the GMP regulations were to be applied to hospitals and clinics, it is argued that reprocessing might well become more costly **(42,43, 44,117).**

However, even if clinics and hospitals were to perform reuse according to GMP regulations, the cost of reprocessing, as estimated by one member of the industry, would still allow a saving from reuse (44). As further evidence consider market-generated estimates of reprocessing costs. Multi-Use Systems, Inc., a new private company that reprocesses dialyzers, charges **$6.50** per dialyzer for reprocessing, including pickup, delivery, and labeling. The firm uses automated reprocessing equipment and, according to the firm, follows careful and rigorous procedures **(24).** With the assumption of five reuses and a new dialyzer price of **$20,** savings per patient year for the facility would come to roughly $1,800 and would still presumably allow a profit for the reprocessing company.

Medical Consequences

Of course, any estimates of cost savings must rest on a medical assessment of reuse. If reuse were medically harmful to patients, then the costs of increased morbidity or mortality would probably dwarf the direct cost savings associated with it. Thus, an appropriate assessment must be based ultimately on considerations of the practice's clinical safety and effectiveness.

Various concerns have been expressed about the possible negative medical effects of reuse (e.g., see (43)). However, others have suggested that reuse may actually have some salutary effects. A. Peter Lundin (54) has offered a summary of "presumed

and proven" medical indications and contraindications for reuse. These are presented in table **7.** There are bits and pieces of evidence in support of these items, but the consensus of a recent National Workshop on the Reuse of Consumables in Hemodialysis concludes that overall there is only "a small but finite risk of morbidity and negligible or no risk of mortality with reuse in the immediate treatment setting" **(77).**

In coming to such a conclusion, workshop participants also pointed out that the safety and effectiveness of reuse depends on appropriate reprocessing standards. They also recognized that the long-term risks are unknown. Accordingly, the consensus statement urges further study of the potential medical effects of reuse.

In an assessment of reuse, there is often a tendency to ignore the patient's perspective. Patients face the issue from their own special perspectives (see, e.g., **(54) and (62)).** They recognize the desirability of cost savings in the ESRD program and are even attracted by potential benefits such as the prevention of new dialyzer syndrome, a possible negative reaction to using new dialyzers resulting in respiratory distress, wheezing, back or chest pain, chills, or fever **(67). Yet** they are concerned about the presently unknown long-term risks and emphasize the need for more scientific study.

In considering the patient's position, one should note that the cost savings from reuse or the costs of complications from reuse do not all accrue to patients. Medicare, the dialysis facility, and patients can all be affected, and each group can have its own perspective and incentives. Ethicist Arthur Caplan (18) notes that the dialysis patient, by virtue of his or her illness, maybe particularly "vulnerable. " He argues strongly that the ethics of therapy require that patients be informed fully about reuse and allowed to consent or not consent to the practice.

Table 7.—Suggested Medical Effects of Reuse

Medical contraindications to reuse	Medical Indications for reuse
1, Induction of hypercoagulability.	1 Prevention of new dialyzer syndrome,
2 Requirement of larger heparin doses	2 Less accumulation of manufactured residuals,
3. Format Ion of anti-N-llke antibodies.	3. No other way to avoid problems (1) and (2),
4, Format Ion of other auto-antibodies.	4, Equivalency or superiority to single dialyzer use.
5. Toxic effects of disinfectants	
6. Lack of strict standards.	
7. Inferiority to single dialyzer use,	

SOURCE A P Lundin Economy at Whose Expense The Ethics of Dialyzer Reuse and Informed Consent n Reuse *of Disposables* Assoc rat ion for the Advancement of M edc al I nstru men tat o n Technology Assessme ntReport N o 683 A rlin gton V A 1983