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Maintenance Dialysis Population Dynamics: Current Trends and Long-Term Implications

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Abstract. Despite a general recognition that treatment of end-stage renal disease (ESRD) has become a large-scale undertaking, the size of the treated population and the associated costs are not well quantified. This report combines data available from a variety of sources and places the current (midyear 2001) estimated global maintenance dialysis population at just over 1.1 million patients. The size of this population has been expanding at a rate of 7% per year. Total therapy cost per patient per year in the United States is approximately $66,000. Assuming that this figure is a reasonable global average, the annual worldwide cost of maintenance ESRD therapy in the year 2001, excluding renal transplantation, will be between $70 and $75 billion US dollars. If current trends in ESRD prevalence continue, as seems probable, the ESRD population will exceed 2 million patients by the year 2010. The care of this group represents a major societal commitment: the aggregate cost of treating ESRD during the coming decade will exceed $1 trillion, a thought-provoking sum by any economic metric.

Medical innovators have long applied persistence and ingenuity to the challenge of replacing or restoring missing body parts, diseased organs, or defective physiologic functions. A recent *Lancet* article described a functional prosthetic toe found on an Egyptian mummy dated to approximately 1800 BC (1). Glass eyes, wooden legs, and iron lungs reflect more recent, albeit still relatively unsophisticated, forms of substitutive medicine. The first maintenance organ replacement therapy was pharmaceutical and relied on frequent injection of xenogeneic insulin to treat diabetes caused by exocrine pancreas failure. The current era of vital organ replacement only dates from the late 1950s and early 1960s, when surgeons and engineers introduced transplants and manmade organometallic devices to replace the function of kidney, portions of the heart, the lung, and large joints. Taken together, these therapies currently sustain or vastly improve the lives of more than 20 million recipients (2). In economic terms, high-technology organ replacement accounts for approximately 8% of worldwide health care expenditure (2).

For several reasons, maintenance dialysis is the most remarkable and noteworthy contemporary approach to organ replacement. The physiology of the organ that it replicates is particularly complex. A large number of disparate technologies need to converge to make dialysis therapy practical on the scale at which it is currently practiced. The demographics and costs, which ultimately inform the theme of this article, are already very large and seem inexorably destined for further growth. The scope of contemporary dialysis therapy has exceeded the expectations of even its most enthusiastic early proponents. However, the very success of dialysis has become a two-edged sword: as the therapy grows, so do questions as to whether end-stage renal disease (ESRD) maintenance therapy really represents the "highest and best" allocation of society's finite health care expenditure. In the following sections, first addressed are the basic questions: (*1*) How many patients currently receive maintenance dialysis therapy? (*2*) What is the overall health care cost of this population? (*3*) How are the dialysis population and its associated costs likely to grow during the next decade? A perspective on the implications of the projected future growth then is offered.

Materials and Methods

Demographic data on the current United States *domestic* dialysis patient population are available from the United States Renal Data Service (3); historical data are available from earlier publications (2,4). No comparably reliable contemporary database exists for Europe, Asia, and the rest of the world. Estimates of the current *global* population of ESRD patients are available in an analysis of the dialysis industry by Liang (5) and from our own independent analysis of organ replacement demographics (2). Both of these studies placed a reliance on industry sources and a review of earlier reports; both came to very similar conclusions about the size and cost of contemporary dialysis. For this article, worldwide demographics for years before 1993 were obtained from an earlier analysis (4) and for the years 1993 to 1999 by interpolation.

Costs encompass the total annual therapy-related expenses and include hemodialysis or peritoneal dialysis treatment, hospitalization, erythropoietin, access, physician fees, and treatment of complications such as pneumonia or cardiovascular disease and the like. Estimates of current annual cost per patient per year were based on a critical analysis of United States Renal Data Service data (3), Liang's report (5), and four articles that appeared in the peer-reviewed literature during the 1990s (6–9). Costs for previous years were obtained by assuming a 1% annual growth from 1990 to 2000 (2) and by interpolation between 1972, when the cost was estimated to be $30,000, and 1990. The base figures were denominated in dollars and are primarily related to US practice and experience. These US costs were

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subsequently applied, without adjustment, to patients in other countries. This method represents an oversimplification because some countries spend more per patient than does the US and others spend less, but it is a necessary assumption, if only to avoid the impact of currency fluctuations (the dollar varied by approximately 25% against European currencies in the 18 mo before submission of this article). It also avoids ambiguities associated with the highly disparate accounting and cost-tracking systems applied in different regions of the world.

Total Annual costs for any year were calculated as the product of the midyear patient population and the annual cost per patient that applied to that year. Costs for a full decade were the sum of the constituent years. Predictions for the next decade were based on a 7% annual growth in patient population and a 1% annual growth in cost per patient-year (2). Extrapolations were based on simple formulas for compound growth rate: $P_i = P_o (1.0 + G)^i$, where P_o = starting population, P_i = population in year i, G = (annual percent growth rate)/100, and i = number of years for which population is growing. Both rates of growth represent continuations of existing trends and, if anything, probably err on the side of being too conservative.

This survey did not include renal transplant patients. Had this cohort been added in, both the population and the associated costs would have been approximately 20% larger (2). All dialysis data encompass both hemodialysis and peritoneal dialysis. All past and future costs are given in real dollars, unadjusted for inflation.

Results

Figure 1, based on historical data, illustrates the growth of the year-end maintenance dialysis population from 1975 until the present and also details the associated estimated annual costs per patient per year at 5-yr intervals. Figure 2 is a semilogarithmic plot of the year-end US and global maintenance dialysis population from 1980 to 2000 (historical) and from 2000 to 2010 (extrapolated). The estimate of the current population is just over 1.1 million patients (June 30, 2001). The current cost per patient-year is approximately $66,000. The aggregate expenditure during 2001 of $72 billion is simply the product of the midyear patient population and the cost per patient per year. Figure 3 is a comparison of the total costs of dialysis during the preceding three decades (1971 to 1980, 1981 to 1990, and 1991 to 2000) and the predicted cost of approximately $1.1 trillion for the coming decade (2001 to 2010). Data in Figure 3 represent the total cost for the decade, not the mean annual costs.

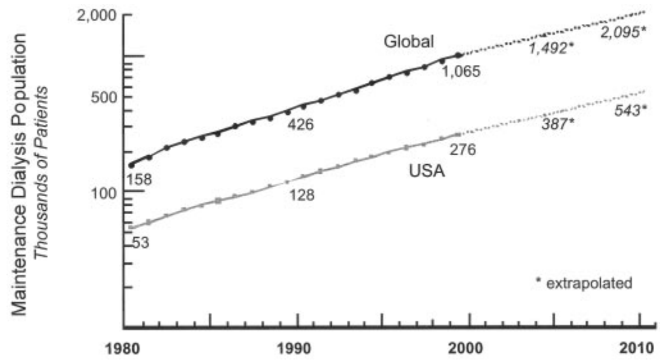

Figure 2. Semilogarithmic extrapolation of global and US maintenance dialysis populations. Upper line is global dialysis population; bottom line is US population. Extrapolations from 2000 onward are at 7% per year for both cohorts. See text for formulas. Callouts are for year-end historical populations in 1980, 1990, and 2000 and extrapolated population in 2005 and 2010.

Discussion

In the section, two issues are raised for discussion: (*1*) Are the projected levels of population and spending credible? (*2*) Does spending $1 trillion on dialysis during the next decade represent a sensible allocation of societal resources?

The sheer size and scope of the projected level of the ESRD population, >2 million patients by the year 2010, and of ESRD-related spending, >$1 trillion during the next decade, naturally provokes skepticism. Is the methodology sound? Will policy persist? Will some new cost-saving technology intervene to drive costs down? By any metric, $1 trillion—one followed by 12 zeros—is a very sizable economic unit. It exceeds the gross domestic product of all but eight nations in the world. It is six times the value of the $175 billion dollars of

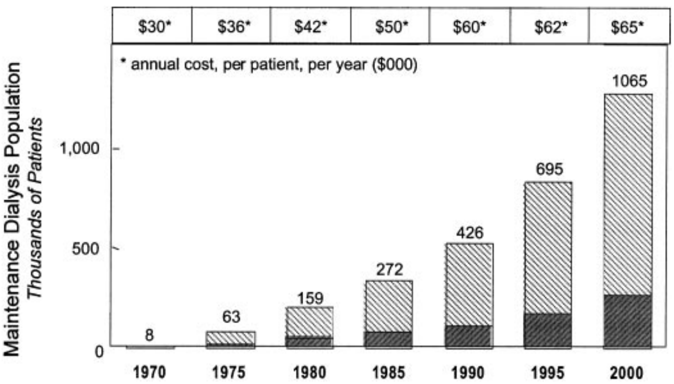

Figure 1. The growth of maintenance dialysis. Bars represent year-end global dialysis population; shaded region within bars represents US year-end population. Costs at top represent annual per-patient health care expenditure in real dollars (*i.e.*, not adjusted for inflation). See text for assumptions and basis of estimates.

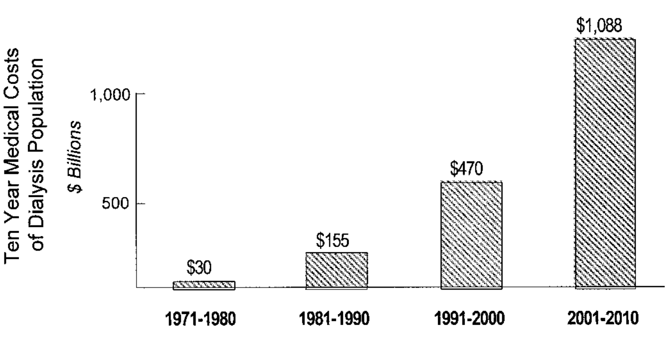

Figure 3. Health care cost of maintenance dialysis population over four decades. The bars represent the estimated historical cumulative 10-yr total health care cost for maintenance dialysis patients during the 1970s, 1980s, and 1990s and the projected cost for the next decade. Cost estimate for 2001 to 2010 is based on a 7% per year growth of patient population and a 1% per year growth of annual cost per patient per year.

gold bullion in Fort Knox. It is twice the amount of all of the initial public offerings funds raised on Wall Street during the 1990s. It represents combined yearly income of >24 million US households. Despite the impressive magnitude of this number, the basis of the estimates are believed to be sound. Start with the increase in patient population. The assumption that dialysis will continue to grow at 7% per year is conservative for several reasons. ESRD concentrates in the older and more rapidly growing segment of the population. Relatively simple techniques for increasing dialysis patient survival and thus population are being teased out of large-scale demographic studies; these include increasing the dosage of dialysis and avoiding undernutrition. Developing nations continue to consider dialysis an important, almost totemic, component of a sophisticated health care system. Transplantation is limited by the availability of donor organs, which is showing no tendency to increase. Xenotransplantation is so mired in issues of both efficacy (acute vascular rejection (10)) and safety (endogenous retroviruses (11)) that even advocates for the approach no longer foresee a serious demographic impact on renal therapy in the coming decade. No tissue-engineered kidney yet represents a credible alternative to extracorporeal dialysis; in fact, the most widely proclaimed bioartificial kidney is being pursued as more effective (and more expensive) treatment for acute dialysis, not as an implantable substitute for maintenance dialysis (12). Gene therapy for renal failure as well as therapeutic organ cloning and related forms of substitutive medicine are probably several decades from clinical reality. Forward-looking nephrologists and clinical investigators certainly recognize that prevention of renal failure—or at least learning to control its progression—is a preferred alternative to remedial therapy, but dietary interventions (13) and biotechnology-based growth factors, *e.g.*, members of the TGF_{β} super family (14), simply do not seem to be on a path toward clinical adoption. None of the "big three" billion-dollar-plus dialysis companies seem to have under way any developments that are targeted at prevention, possibly excluding novel drug therapies for diabetes. No pharmaceutical products currently in clinical trials can prevent or cure renal failure. Some might eventually be discovered, but the decade-long drug development and approval process means that pharmaceutical interventions are unlikely to have a demographic impact during the 10-yr time frame of our projections.

What, then, about our estimated future growth of approximately 1% per year in costs? Might reimbursing agencies simply ratchet down the future cost of dialysis? Although possible, this is not likely and certainly is unprecedented. Third-party payers have not shown an ability to reduce costs in the past; they are out-resourced and outnumbered by the well-entrenched dialysis segment of the medico-industrial complex that has a strong vested interest in more generous reimbursement. Health care costs in general and dialysis costs in particular are likely to percolate upward in the near future.

Combining the cost and population in projections suggests that the coming decade of dialysis can indeed be characterized as a "trillion-dollar sure thing." The corollary examination is the extent to which this commitment of resources makes sense. Here begins subjective judgment. Few would support the hypothesis that maintenance dialysis truly represents the "highest and best" use of medical resources—nor need it be so to be sustainable. Health care is not an institution that has evolved according to a rational architecture; it is very much more a structure derived by happenstance informed by competing interests and diverse socioeconomic philosophies. The system is laced with imbalances and idiosyncrasies and is rife with examples of funds being disproportionately allocated to less worthy areas (*e.g.*, liposuction *versus* vaccination). Imbalances happen and will persist. Criticism becomes meaningful when significant levels of resources are devoted to therapies that are simply ineffective or when resources consumed are inconsistent with the level of benefits received. In this context, the real vulnerability is not that ESRD costs too much but rather that patients benefit too little. A patient who starts on dialysis in 2001 in the United States can expect to live for 31 mo on average (3); this is comparable to the life expectancy for a patient who has a diagnosis of one of many forms of terminal cancer. To be more precise, the age-adjusted survival for a new dialysis patient lies midway between that for a patient who has just received a diagnosis of colon cancer and one who has just received a diagnosis of lung cancer; for patients who are older than 45 yr, the life expectancy is roughly 25% of that for the general population (15). And the years in this shortened life are not blissful. Dialysis patients are becoming increasingly articulate in expressing their intense dislike for "the life" (16,17), and it is precisely here that the paradox emerges. Almost everything that is likely to improve dialysis therapy and patient quality of life would also significantly increase its costs: longer, slower therapy, more pleasant and commodious treatment facilities, better trained and less peripatetic staff, referral to highly qualified surgeons for access placement, quits to the tawdry practice of hemodialyzer reuse, more face time with doctors, and so forth. Consider the last point. At a recent International Society of Blood Purification panel, it was reported that the average US physician sees a patient for only 7 to 8 min per week. Many practitioners might find this to be a generous estimate. Even 7 to 8 min per week is far too little time to manage the complexities of uremia and to quell the anxieties and concerns of a patient with a debilitating chronic disease. More time could certainly be provided to patients but not without an escalation of cost. Presented the dilemma of cost *versus* quality, society has proposed a compromise and the profession has come to accept it. All patients with terminal renal failure will receive a level of therapy above the minimum but far less than what would be provided in the absence of fiscal restraint. Therapy will be adequate but not optimal.

Minimalism in health care is always dicey, especially when applied on the scale of dialysis. A well-organized patient lobbying effort, with a few class-action tort lawyers in the background, might alter the *status quo*. But this seems unlikely. Legislative intervention also seems to be a remote possibility: recent congressional hearings before the select committee on aging were vitriolic but ineffective (17). Far more likely is that the year 2010 will see the therapeutic profile and patient outcomes pretty much the same as they were in the year 2000—except that in 2010, there will be 2 million maintenance dialysis patients and the plaintive history of a $1 trillion expenditure between now and then.

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