

## The effect of the expenditure increase in the morbidity and the mortality of patients with end stage renal disease: the USA case

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### Abstract

The worldwide incidence of kidney failure is on the rise and treatment is costly. Kidney failure patients require either a kidney transplant or dialysis to maintain life. This review focuses on the economics of alternative dialysis modalities such as haemodialysis (HD) and peritoneal dialysis (PD). Important economic factors influencing dialysis modality selection include financing, reimbursement and resource availability. Modality selection is also influenced by employment status, with an association between being employed and PD as the modality choice.

In the United States, there were 101,688 incident HD patients and 6,506 incident PD patients in 2007. Due to the fact that the worldwide incidence of kidney failure continues to rise placing USA in the second position right after Taiwan, the accumulated experience from USA could be used as a characteristic prototype for the analysis of the economics related with modality choices and their influence in the quality of life and life expectancy of end stage renal disease (ESRD) patients.

In the present work we discuss the effect of the expenditure increase in the morbidity and the mortality of patients with end stage renal disease. Data coming from the "USA case" concerning the economic factors which play a vital role in the sequence of events that leads to the choice between different modalities such as HD and PD, will be used as a distinctive example in our study. The relationship between the modality used and employment status is investigated. The cost effectiveness of alternative modalities is reviewed. Examples of statistical models and simulation approaches, studying the increase of the life expectancy in terms of the quality adjusted life years (QALYs) and the incremental cost paid are also presented. Corresponding results originated from different regions of the world are also briefly shown. Hippokratia 2011; 15 (Suppl 1): 16-21

**Key words:** economic factors, cost, ESRD, RRT, haemodialysis, peritoneal dialysis

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Patients suffering from chronic kidney disease can be classified according to kidney function along a continuum from mild renal dysfunction to irreversible kidney failure. Patients with kidney failure require renal replacement therapy (RRT), either a kidney transplant or dialysis, to maintain life. Worldwide, at the end of 2004, approximately 1,800, 000 patients were receiving RRT<sup>1</sup>. Of those patients 77% were on dialysis and 23% were living with a functioning kidney transplant. The global average prevalence for dialysis was 215 patients per million population, although significant regional variations existed. By the year 2010, it is expected that the number of dialysis patients will approach two million<sup>1</sup>.

The expanding size of the end stage renal disease (ESRD) patients and projections that their number will double in the next ten years suggest that the population at risk for kidney disease should be addressed with detection and prevention strategies to reduce the long-term burden of ESRD. Haemodialysis remains the preferred mode of therapy worldwide. At the end of 2004, HD was used to treat 89% of dialysis patients while 11% were treated by PD<sup>1</sup>. Data from USRDS 2009 Annual report<sup>2</sup>

show that in Hong Kong, four of five prevalent dialysis patients were treated with Continuous Ambulatory Peritoneal Dialysis (CAPD) / Continuous Cycling Peritoneal Dialysis (CCPD) in 2007. This therapy was also widely used in Jalisco (Mexico) and New Zealand, at 65.8 and 35.9%, respectively. The 30% of the patients in Australia and 20% in Canada dialyze at home. It is reported that PD is used in fewer than 4% of patients receiving dialysis in Japan<sup>2,3</sup>. In Luxembourg, no prevalent dialysis patients are reported to receive PD.

In USA the prevalent dialysis population grew 30% between 2000 and 2007; reaching nearly 370,000. The annual rate of growth has slowed in the prevalent hemodialysis population, from 8.7% in 1997 to 3.8% in 2007, while the prevalent peritoneal dialysis population has remained quite stable. About 30% of U.S. dialysis patients are candidates for home treatment, though only 8% now do it, Blagg says<sup>4</sup>. The greatest growth has occurred in the transplant population, which has increased 5.0–6.0% each year since 2001. The number of patients who receive a kidney transplant as their first ESRD therapy reached 2,665 in 2007, and since 1996 has grown an av-

erage of 6.8% each year. In the prevalent population, the number waiting to receive a transplant reached 73,555 in 2007, with an average annual growth of 9.9% since 1996, though this rate of change has fallen to 7–8 % in the last three years<sup>2</sup>.

### Cost in USA

In 2007, 111,000 new dialysis and transplant patients initiated ESRD therapy, for an adjusted rate per million population of 354, a 2.1% decrease from the rate of 362 in 2006. More than 527,000 patients were receiving treatment on December 31, 2007, for an adjusted rate of 1,665 per million population, a 2.0% higher than the 2006 rate of 1,632. Nearly 369,000 of these patients were being treated with dialysis, while 158,739 had a functioning transplant. A total of 17,513 transplants were performed during the year, 6,041 from living donors and 87,812 ESRD patients died. Nearly 33,000 patients were added to the transplant wait list in 2007, and 73,555 were on the list at the end of the year; the median time on the list was 1.5 years.

With Medicare spending for ESRD at \$23.9 billion, and non-Medicare spending at \$11.4 billion, total ESRD costs in 2007 reached \$35.3 billion. Medicare costs per person per year were nearly \$62,000 overall, ranging from \$24,572 for transplant patients to \$73,008 for those receiving haemodialysis.

Costs are generally described in four categories: (i) direct medical costs, (ii) direct non-medical costs, (iii) indirect costs and (iv) intangible costs.

(i) Direct medical costs of dialysis include staffing costs, physician fees or salary, costs of dialyzers and tubing in HD, costs of solutions and tubing in PD, costs associated with radiology, laboratory and medications, capital costs of HD machines and PD cyclers, costs of hospitalizations and costs of outpatient consultations from other specialties<sup>5</sup>. Hospitalization costs contribute substantially to total expenditures for dialysis patients<sup>5</sup>. Room costs and inpatient dialysis costs account for nearly half of the cost of hospitalizations for dialysis patients. Some evidence suggests that hospitalization costs are lower for PD than for HD due to a reduced number of hospital days per year<sup>6,7</sup>; however, a comprehensive literature review indicates that hospitalization costs are similar for HD and PD, although the reasons for hospital admission differ.

(ii) Direct non-medical costs may vary widely in different parts of the world but tend to be highest in more developed economies. Direct non-medical costs include building costs, facility utilities and other overhead costs.

Start-up costs occur with all dialysis modalities and result in higher costs for the first year of dialysis compared to subsequent years. Finally, start-up costs for CAPD and home HD include patient training and so also contribute to the cost of modality switches because they are incurred with each change in modality<sup>8</sup>. An activity-based cost analysis is the most appropriate cost approach to apply when comparing modality expenses between home and centre-based therapies.

(iii) Indirect costs, or productivity losses for patients and their families or caretakers, rarely have been assessed and incorporated in dialysis economic evaluations.

(iv) Intangible costs are the costs associated with pain, suffering and impairment in quality of life (QOL), as well as the value of extending life. These costs are often omitted from economic evaluations.

In 2007, Medicare spent \$8.6 billion on the treatment and medications of dialysis patients, from babies to the elderly, according to the Medicare Payment Advisory Commission's March report to Congress. On top of the composite rate, Medicare pays extra for newer, expensive injectable drugs namely erythropoietin, or EPO, a hormone that stimulates red blood cell production, and vitamin D, which plays a role in bone health and lab tests. These extras added an average of \$75, or 50%, to the cost of each treatment in 2007.

A growing body of evidence suggests that longer and/or more frequent dialysis treatments, either at home or in a dialysis center, are far superior to the status quo. Although the USA spends more per dialysis patient than other countries, that does not result in higher survival rates or even, many argue, a better quality of life.

A North American literature review concluded that PD is less expensive than HD and that the difference in cost is dramatic when the PD program is relatively large and well run. Annual costs for HD patients ranged from \$48,000 to \$69,000, while annual costs for PD patients ranged from \$34,000 to \$47,000. The cost ratio of HD to PD varied from 1.22 to 1.52<sup>5</sup>. It has been reported that in-centre HD was about twice the cost of CAPD in France and 30% more expensive than CAPD in Italy and the UK<sup>5</sup>. Another review of the Western European literature also concluded that, with the exception of home HD, PD is less costly than HD. However, that review noted that the magnitude of the cost difference between modalities is difficult to determine due to deficiencies in the available evidence<sup>10</sup>. Many publications fail to adequately describe their methodology or to include all relevant cost components<sup>9</sup>.

Shih et al<sup>11</sup> examined the impact of modality switch from initial dialysis modality choice on Medicare expenditure over a 3-year-period. Data were obtained from the Dialysis Morbidity and Mortality Study (DMMS) Wave 2 from the United States Renal Data System (USRDS) Core CD and USRDS claims data. A total of 3423 incident dialysis patients were included in the analysis. The Medicare perspective was utilized, so costs were estimated based on Medicare expenditures. After adjusting for patient characteristics, annual Medicare expenditure was significantly lower for patients with PD as the initial modality compared to patients with HD as the initial modality (US\$ 56,807 vs. US\$ 68,253,  $p < 0.001$ ). The favorable cost profile of PD was maintained when an as-treated analysis was performed.

Consistent with the payment differential discussed above, the 2009 USRDS Annual Data Report identifies that total unadjusted per person per year Medicare pay-

ments for haemodialysis and peritoneal dialysis, respectively, were US\$ 73,008 and US\$ 53,446 in 2007. Furthermore, the Report shows that the payment gap between the modalities has been widening for several years<sup>2</sup>.

### **Economic factors influencing dialysis modality selection**

One factor to consider in reviewing the economic assessments of dialysis modalities is the perspective taken for the analysis. Important economic factors influencing dialysis modality selection include financing, reimbursement and resource availability<sup>3,12</sup>. Resource availability also influences dialysis modality selection<sup>3</sup>. When centre HD capacity is high, there is a strong incentive to use the capacity rather than place the patient on an alternative dialysis therapy that does not use it.

Relevant perspectives include patient, dialysis facility or provider, physician, payer, dialysis manufacturing industry, government and society as a whole. The costs to payers, facilities and physicians are most likely to affect practice patterns such as modality selection. Costs to society and patients or families are less likely to influence practices<sup>5</sup>. HD cost is driven largely by the fixed costs of facility space and staff. HD machines typically cost \$18,000 to \$30,000. The cost of dialyzers for HD ranges from \$1,000 to \$5,000 per year. For HD, provider costs can be affected by the choice of the dialyzer membrane prescribed and whether or not the dialyzer is used only one time or is reused. Other items that factor into the cost of HD are additional facility costs such as maintenance and utilities, and the costs of transportation to and from the HD facility<sup>5</sup>. In general, where there is no facility reimbursement for PD, or where there is little or no physician reimbursement for PD, utilization is very low<sup>3,13</sup>.

### **Costs and Quality of Life**

The majority of studies that compare dialysis modalities have focused solely on costs, rather than cost-effectiveness or cost-utility<sup>5,9</sup>. In part, this may be because survival and QOL outcomes for HD and PD are generally considered to be similar<sup>5</sup>. A key factor influencing the cost of dialysis care is the timing of referral to a nephrologist. Early referral and planned start result in cost savings and improved survival. Patients who have been exposed to pre-dialysis modality education are more likely to choose PD over HD<sup>14,15,16</sup> and therefore contribute to lower societal and payer dialysis expense in most countries.

### **Modality selection and workplace productivity**

Less than one-quarter of dialysis patients ages 18 to 54 are well enough to work or go to school. The impact of renal insufficiency on workplace productivity is substantial. There is a significant reduction in workforce participation among patients with renal dysfunction aged 18–64 years. A conservative estimate of lost productivity from workforce non-participation associated with renal dysfunction in 1994 was \$665 million<sup>17</sup>. A number of cross-sectional analyses have examined the relation-

ship between dialysis modality and employment status. Most studies have found that PD patients are more likely to be employed than HD patients. However, because of the cross-sectional nature of the research, it is difficult to conclude whether dialysis modality influenced employment status, or whether employment status had an influence on the choice of dialysis modality<sup>5,18-20</sup>.

In the QOL literature, most research indicates that PD and HD patients have similar QOL, regardless of whether QOL is measured by a generic or disease specific measure or whether it is measured by a health profile or health preference instrument<sup>21-24</sup>. However, some evidence suggests that PD may offer an advantage in QOL over HD<sup>25-27</sup>, while other research has found that HD may be superior to PD in certain QOL domains<sup>28-29</sup>. Differences in patient characteristics and research methods may explain some of these conflicting results.

Two studies address the limitations of these cross sectional analyses. A multi-centre, prospective study in The Netherlands followed 359 patients for 12 months. No relationship between treatment modality (HD or PD) and employment status was observed. The authors concluded that many patients become unemployed before starting dialysis. They also concluded that most patients who have a job at the start of dialysis keep working. Finally, the authors suggested that treatment modality does not influence the ability to maintain employment, but employment may influence the choice between HD and PD<sup>30</sup>.

Another study utilized a simultaneous probit model to account for the potential endogeneity between treatment choice and employment<sup>31</sup>. Data were analyzed from Wave II of the United States Renal Data System's Dialysis Morbidity and Mortality Study. The authors concluded that PD has a causal effect on dialysis patients' ability to participate in the labor force; however, the magnitude of the effect is small in absolute terms and much smaller than the effect implied by previous cross-sectional research, in which endogeneity was ignored. In a naive model ignoring endogeneity, PD patients were 60% more likely to be employed than HD patients; however, in a two-stage model accounting for endogeneity, the relative increase in the probability of working for PD patients compared to HD patients was only 14.7%. The authors further stated that most of the effect of PD on employment arises from endogenous selection of PD by patients who wish to maintain employment, rather than from the ability of PD to ease work scheduling<sup>31</sup>.

### **Statistical Models**

Published evidence suggests that frequent haemodialysis (more than three times per week) for patients with ESRD may improve health-related quality of life and has the potential to increase longevity and reduce hospitalization and other complications. Chris P. Lee et al<sup>32</sup> used a Monte Carlo simulation model to compare varying combinations of in-center haemodialysis frequency (three to six treatments per week) and session length (2 to 4.5 h per session) with regard to unadjusted and qual-

ity-adjusted life-years and total lifetime costs for a cohort of 200,000 patients, representing the prevalent ESRD population. The incremental cost-effectiveness ratio was calculated for the various regimens relative to a conventional haemodialysis regimen (three treatments per week, 3.5 h per session). Using conservative assumptions of the potential effects of more frequent haemodialysis on outcomes, most strategies achieved a cost effectiveness ratio of \$125,000, although all had a cost-effectiveness ratio of \$75,000. The cost effectiveness ratio increased with the frequency of haemodialysis. More frequent in-center haemodialysis strategies could become cost-neutral if the cost per haemodialysis session could be reduced by 32 to 43%. No other change in model assumptions achieved cost neutrality. In conclusion, given the extraordinarily high costs of the ESRD program, the viability of more frequent haemodialysis strategies depends on significant improvements in the economic model underlying the delivery of haemodialysis.

In another study, G Mowatt et al<sup>33</sup> conducted an economic evaluation using a Markov model, designed to estimate costs and outcomes over the lifetime of a cohort of typical patients for the different management strategies. A subgroup analysis was performed for cohorts of adults at high, moderate and low risk.

The model included the direct health service costs associated with the treatment options. In order to provide an indication of costs that may be borne by patients and their families, time and travel costs as well as productivity changes are also estimated, although these are reported separately. The model used to estimate the present value of the costs is:

$$PVC_A = C_1 + \sum_{t=0}^n [(P_{1t})(P_{2t})C_2] \div (1 + 0.06)^n$$

where  $PVC_A$  is the present value of the cost of dialysis over  $n$  years for  $t = 0, \dots, n$  years and for  $A$  representing one of the treatment alternatives, and  $C_1$  is the total cost of access surgery/set-up,  $P_{1t}$  is the probability of being alive in year  $t$ ,  $P_{2t}$  is the probability of being in any of the three states of dialysis considered,  $C_2$  is the costs of dialysis, 6% is the discount rate for healthcare costs.

Survival rates for hospital and home haemodialysis patients<sup>34</sup> are shown in Table 1.

**Table 1:** Survival rates for hospital (HspH) and home haemodialysis (HomH) patients, based on Hellerstedt WL et al<sup>34</sup>.

Modality	Cumulative survival rates				
	Year 1	Year 2	Year 3	Year 4	Year 5
HspH	0.87	0.74	0.64	0.57	0.55
HomH	0.94	0.86	0.75	0.64	0.64

The incremental cost-effectiveness results for home haemodialysis compared with satellite and hospital haemodialysis<sup>33</sup> are shown in Table 2.

### Cost effectiveness in other countries

A multi-national survey of Asian nephrologists conducted in 2001 suggests that HD is generally more expensive than PD in the developed Asian economies of Hong Kong, Singapore, Taiwan and Japan. However, the extent of cost savings with PD varies by region. According to the survey results, the ratio of costs for HD compared to PD ranged from a low of 0.99–1.09 in Japan to a high of 1.42–2.39 in Hong Kong<sup>35</sup>.

A multicenter study in UK conducted by Keshwar Baboolal et al<sup>36</sup> shows that the cost of APD or CAPD for patients with ERF is lower than hospital-based HD. The mean annual per-patient costs of providing APD or CAPD were 38% and 56% less, respectively, than the cost of providing hospital-based HD.

### Incentives to improve the productivity in the USA

Medicare policy in the United States provides incentives to private insurers, dialysis facilities, patients and physicians for home dialysis options. These include waiver of the 90-day Medicare coverage waiting period, additional add-ons to the capitated or composite rate for home training, home training supervision fees for physicians, the availability of a training exception rate and an alternative reimbursement option referred to as Method II reimbursement. Method II patients do not receive their home supplies and equipment from their dialysis provider directly. Rather, they receive them from an independent supplier who bills Medicare for actual supplies used on a reasonable charge basis using local prevailing rates up to a capitated maximum that varies by modality.

More recently, the Centers for Medicare and Medicaid Services (CMS) modified the physician monthly capitated payment system to improve care quality in a manner that they believe provides an incentive for home dialysis therapy. CMS believes that the incentive for home dialysis is provided by not requiring a monthly evaluation visit for home patients, not specifying a required visit frequency and fixing the physician payment rate for home dialysis patients at 2% below the rate paid for two to three evaluation visits for in-centre HD patients<sup>37</sup>.

### Conclusions

The preponderance of evidence in developed economies reveals that when total direct therapy care expenses of dialysis patients are considered, peritoneal dialysis, particularly CAPD, is a lower cost modality than non-home haemodialysis. The cost continuum best supported is that expense to payers for dialysis therapy declines in the following order: in-center HD, out-of center HD treatments such as satellite-, limited-care or self-care HD similar to APD and CCPD, and finally, lowest are the home-care modalities, CAPD and home HD.

Supply expenses, dialyzers for HD and solutions for PD do affect the absolute cost of each modality but their net impact can only be discovered by economic analysis which would concurrently evaluate the influence of those supply factors on treatment outcomes and overall patient

**Table 2:** Incremental cost-effectiveness results for home haemodialysis (HomH) compared with satellite (SatH) and hospital haemodialysis (HspH)<sup>33</sup>: base case analysis.

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 10
Total costs						
SatH	£16,215	£26,564	£34,473	£40,739	£46,001	£62,054
HomH	£16,049	£26,891	£35,074	£41,250	£46,551	£63,717
HspH	£16,938	£27,819	£36,133	£42,722	£48,254	£65,131
QALYs						
SatH	1.03	1.51	1.89	2.20	2.48	3.43
HomH	1.08	1.64	2.08	2.42	2.73	3.86
HspH	0.84	1.23	1.54	1.80	2.02	2.80
Extra costs for HomH versus:						
SatH	-£166	£327	£601	£510	£550	£1,663
HspH	-£889	-£927	-£1,059	-£1,472	-£1,703	-£1,415
QALYs gained by HomH versus:						
SatH	0.06	0.13	0.19	0.22	0.25	0.42
HspH	0.25	0.41	0.54	0.62	0.71	1.06
Incremental cost per QALY for HomH versus:						
SatH	HomH dominant	£2,472	£3,204	£2,358	£2,215	£3,914
HspH	HomH dominant	HomH dominant	HomH dominant	HomH dominant	HomH dominant	HomH dominant

The cost and QALY results for the three haemodialysis modalities is presented together with the net costs and QALYs of home haemodialysis compared with the other modalities. Negative values for either net costs or net QALYs mean that home haemodialysis is the dominant modality (i.e. it is the least costly and provides more QALYs).

Home haemodialysis is both more effective and less costly. The gain in utility from home haemodialysis compared with satellite haemodialysis is caused by the increase in survival of home haemodialysis patients compared with satellite haemodialysis patients. Finally, the incremental cost per QALY for home haemodialysis compared with satellite haemodialysis was estimated at £2215 and £3914 for the 5- and 10-year follow-up periods, respectively.

resource utilization including the significantly greater dependence of HD on fixed cost elements such as hardware, facility overhead and staff.

In developing economies, mainly due to inexpensive labor and high imported equipment and solution costs, PD is often perceived to be more expensive than HD. This perception may not be reality, however, as well-conducted economic evaluations are not available. The costs of dialysis vary widely by region and economy. Nonetheless, in-center haemodialysis is consistently found to be more expensive than PD in the many developed economies in which total therapy costs have been evaluated. However, intangible costs associated with

pain, suffering and impairment in QOL, as well as the value of extending life are often omitted from economic evaluations due to the difficulty of their quantitative parameterization.

It seems that the cost-effectiveness, for patients with end stage renal disease, is a complex medical, social and in a sense mathematical problem, where a large number of interconnected parameters have to be taken into account to acquire the desired “best solution”. Even what is accepted as the “best solution” has to be carefully decided. That is why, this is still an open problem to be considered, under the specific conditions imposed by the degree of development of each country.

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