Should the Medicare ESRD Program Pay for Daily Dialysis? An Ethical Analysis

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End-stage renal disease (ESRD) is a growing problem in the United States and has now reached epidemic proportions. The mortality rate and other complications related to conventional dialysis remain unacceptably high necessitating improvements in dialytic therapies. One strategy has been to increase dialysis frequency through daily dialysis since the Hemodialysis study showed that clinical outcomes are not improved by simply increasing delivered dialysis dose per session. Most studies of daily dialysis are observational and limited by small sample size, variable dialysis techniques, high patient dropout, and lack of adequate control group. These studies have shown consistent improvements in blood pressure and solute clearance, but improvements in patient survival, anemia, and health-related quality of life are less clear. The costs of providing daily dialysis on a large scale are likely to be substantial. However, if there are significant improvements in the outcome measures outlined earlier as well as decreased hospitalization rates, daily dialysis may prove cost-effective or budget neutral from a global standpoint. A scientific basis is needed to justify a change in the Medicare ESRD Program to fund daily dialysis. Decisions regarding the allocation of limited medical resources such as the Medicare budget should consider ethically appropriate criteria including likelihood of benefit, urgency of need, change in quality of life, duration of benefit, patient selection, equitable distribution, and the amount of resources required. In examining the evidence base on daily dialysis according to these ethical criteria, we find that there are not yet sufficient grounds to recommend funding of daily dialysis by the Medicare ESRD Program. Randomized controlled trials comparing conventional hemodialysis to short daily and long nocturnal hemodialysis are much needed.

Index Words: Daily dialysis; Medicare funding

Despite long experience with hemodialysis and a growing patient population, the mortality rate of conventional thrice weekly hemodialysis remains unacceptably high for US patients.[1,2] The rates of other complications related to end-stage renal disease (ESRD) such as cardiovascular disease, anemia, hypertension, bone disease, poor nutrition, and poor physical and cognitive function also remain high.[2-8] Observational studies have suggested that inadequate hemodialysis dose may be responsible in part for the high mortality and morbidity of conventional hemodialysis.[9,10] However, as shown by the Hemodialysis study, attempts at improving clinical outcomes by increasing the dose of dialysis delivered at each session have not been successful.[11] In the last decade, more attention has been directed at increasing dialysis frequency in the form of short daily and nocturnal hemodialysis.[12,13]

More recently, there has been a renewed interest in daily (also termed quotidian) dialysis because in part of technologic advances and improved clinical outcomes with daily hemodialysis. As a consequence of the HEMO study, the focus has shifted from increasing the per-session dialytic dose to increasing treatment frequency or duration to improve clinical outcomes.[12,13] Most studies of daily dialysis are observational and are limited by small sample size, variable dialysis techniques, high patient dropout, and lack of adequate control groups.[14-16] These studies report variable benefits with daily dialysis.[14-17] Consistently reported benefits include improved blood pressure control,[14,15,17] reduced medication requirements, and improved solute clearance.[15] Other outcome measures such as improvements in anemia,[15] health-related quality of life,[18] mineral metabolism, and patient survival[19] have been noted in some stud-

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ies but not in others. The costs of providing daily dialysis on a large scale are likely to be substantial. However, if there are significant improvements in the outcome measures outlined earlier as well as decreased hospitalization rates, daily dialysis may prove cost-effective or budget neutral from a global standpoint.

In the modern-day practice of evidence-based medicine, more than a pathophysiologic rationale is needed to support the introduction of a procedure or treatment such as daily dialysis; scientific studies documenting beneficial outcomes are necessary.[20] A scientific basis is all the more important to justify changing the Medicare ESRD Program to fund daily dialysis because the Medicare ESRD Program is large (more than 300,000 patients per year on dialysis in the United States), costly (over 20 billion dollars per year in 2003), and consumes a disproportionate share of Medicare resources (6.7% of Medicare budget for 1.2% of Medicare covered patients in 2004).[21] Decisions regarding the allocation of limited medical resources such as the Medicare budget should consider ethically appropriate criteria such as the likelihood of benefit, urgency of need, change in quality of life, duration of benefit, patient selection, the amount of resources required, and equitable distribution of those resources.[22] In this article, daily dialysis will be considered in light of these ethical criteria to see if there is sufficient justification for the Medicare ESRD Program to fund daily dialysis.

Likelihood Benefit

This criterion is essential because the ethical principle of beneficence obliges physicians to promote the benefit of their patients. One aspect of beneficence is utility. Utility requires that nephrologists maximize benefits compared with burdens to produce the best overall results for their patients.[23] In the case of conventional hemodialysis (CHD) versus short daily hemodialysis (SHD), Medicare needs to consider whether SHD produces benefits comparable with or greater than CHD in order to justify its expected greater cost. In their book *Clinical Ethics: A Practical Approach to Ethical Decisions in Medicine* (ed 6), Jonsen et al[24] urge an approach to ethical analysis that considers first whether a treatment is "medically indicated." A treatment is medically indicated if the potential benefits justify the risks. In the case of CHD versus SHD, the risks, benefits, and probable outcomes of SHD need to be considered to determine whether the probabilities of successful treatment with SHD are at least comparable with CHD and thereby justify its use. The ethical criteria of likelihood of benefit and duration of benefit are both factors that need to be evaluated to determine if a treatment such as SHD is medically indicated.

Clinical benefits of daily dialysis include cardiovascular benefits of better blood pressure control[25-30] and regression of left ventricular mass,[31,32] improved small solute clearance,[32,33] and better phosphorus control and B2 microglobulin clearance in patients on nocturnal hemodialysis (NHD).[34,35] The effects of quotidian dialysis on anemia and erythropoietin requirements are not entirely clear. Most studies have failed to show any significant change in erythropoietin utilization.[26,27,31,36-40] SHD has been shown to improve appetite and protein intake,[26,41] but effects of SHD on normalized protein equivalent nitrogen appearance and serum albumin are variable. Patients on NHD have fewer dietary restrictions than all other modalities.

The potential drawbacks of quotidian dialysis that may limit benefit include patient fatigue or burnout leading to problems with compliance and failure of the dialysis modality. Complications related to increased blood loss during dialysis via dialyzer losses, bleeding, and frequent blood draws remain a concern. Problems related to vascular access also remain an important consideration because of more frequent cannulation and infections.[28,42-46]

In combination with an ethical assessment of likelihood of benefit of daily dialysis (beneficence), the ethical principle of justice also supports the ethical criteria we have identified to evaluate whether Medicare should pay for SHD. In settings of limited resources such as the Medicare ESRD Program budget, justice examines the distribution of burdens and benefits within the context of a society. One of the main principles of justice is utilitarianism, a principle that calls for promoting the greatest