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MEDICARE AND HEART TRANSPLANTS: WILL LIGHTNING STRIKE TWICE?

by Gregory de Lissovoy

Prologue: The challenge of determining what a new medical benefit will cost any health insurance program, public or private, has a history in the United States that reflects the political nature of the process. Perhaps the most memorable episode is the gross underestimation Congress embraced in 1972 when it extended Medicare coverage to individuals suffering from end-stage renal disease. The issue surfaced most recently when the Health Care Financing Administration (HCFA) and the Congressional Budget Office offered sharply differing estimates of the cost of a new Medicare outpatient prescription drug benefit. In this article, Gregory de Lissovoy discusses the issue of cost estimation within the context of the Department of Health and Human Services’ decision to extend Medicare coverage to heart transplantation surgery. De Lissovoy, a health services researcher who is well grounded in the theory and practice of economics, holds a doctorate granted by the Department of Health Policy and Management at the University of North Carolina. De Lissovoy is an assistant professor of economics and finance at The Johns Hopkins University School of Hygiene and Public Health. He also is affiliated with Hopkins’s new Program on Medical Practice and Technology Assessment, which was created to examine new medical technologies and procedures with respect to their benefits and costs. In writing this paper, de Lissovoy sought to achieve three objectives: to reassess projections made by the National Heart Transplantation Study (NHTS) and HCFA as to the number of heart transplant procedures that would be performed under Medicare, to point out what he considers a fallacy in the NHTS/HCFA approach to forecasting utilization of the heart transplant technology—basing projections on the patient selection criteria then in effect—and to present an economic paradigm for medical technology diffusion as a market process.
On June 27, 1986, when Department of Health and Human Services Secretary Otis Bowen announced that Medicare would soon offer routine coverage for heart transplant surgery, he stressed that the decision was expected to have little impact on total Medicare expenditures. Only a small number of persons were expected to qualify for Medicare-paid heart transplants; Bowen predicted that sixty-five procedures would be covered in the first year (fiscal year 1987), rising to 143 procedures by the fifth year (fiscal year 1991). The Health Care Financing Administration (HCFA) was more cautious in the subsequent Federal Register notice setting forth proposed heart transplant coverage guidelines. Citing “the uncertainty of actual outcomes,” HCFA characterized its projections of heart transplant program size and growth as “an opinion, rather than an estimate.”

Those numbers—sixty-five Medicare-covered heart transplants during the first year and 143 by the fifth year—are the focus of this article. I summarize assumptions used to forecast program enrollment and then identify recent developments that may affect actual results. I then review recent data on heart transplants performed and conclude with a “back-of-the-envelope” projection for Medicare-covered heart transplants in fiscal year 1991.

The Coverage Decision

The Washington Post called HCFA’s heart transplant coverage decision a “major policy change” that would begin “a new era for the government ... opening the door for decisions in the future on liver, pancreas, and other such (transplant) procedures.” Other observers saw no major policy change, but, rather, history repeating itself: like the end-stage renal disease (ESRD) program, heart transplantation would become yet another burden on the strained Medicare trust fund.

The portrayal of heart transplant coverage as a major policy change was erroneous. Medicare had paid for heart transplants performed at Stanford as an experimental procedure during 1979 but ceased after a year because of poor survival rates. With the advent of cyclosporin (a drug that helps counteract the body’s immune response to a transplanted organ), graft and patient survival rates dramatically improved, and the procedure gained acceptance in the medical community. Most commercial health insurers and Blue Cross plans routinely covered heart transplants.

Comparisons between Medicare’s new heart transplant coverage and the existing renal disease benefits were also inaccurate. Legislation establishing the ESRD program made victims of kidney failure categorically eligible for Medicare-paid health care. By contrast, heart transplant
coverage would only be available to persons who have established Medicare eligibility by attaining age sixty-five, qualifying for disability status, or other means. The ESRD regulations specifically authorized coverage for an “artificial organ” alternative to transplantation (hemodialysis), and it is proliferation of dialysis services that largely accounts for the unforeseen growth in Medicare ESRD expenditures. Medicare’s heart transplant program only covers transplantation of a human heart.

A key difference between the kidney and heart transplant programs, which does break new ground for Medicare policy, is that coverage is only available when the procedure is performed at a HCFA-designated heart transplant institution. Eighteen such centers now have been certified (Exhibit 1). HCFA seeks maximum return on its expenditures by limiting coverage to sites that meet survival and facility standards and that perform a volume of procedures large enough to ensure technical proficiency.

What the ESRD and heart transplant coverage decisions did have in common is that both were preceded by expert studies endorsing the effectiveness of the therapy and estimating enrollment in a Medicare-funded program. The 1967 Gottschalk Report represented the consensus of a national panel of kidney specialists and called for public-funded treatment for all victims of end-stage renal disease. The National Heart Transplantation Study (NHTS), performed by the Battelle Institute and completed in 1985, was an exhaustive analysis of the efficacy of, need for, and cost of the procedure. Both reports cautioned that enrollment projections were based on then-current technology and clinical practice. Unforeseen developments, such as broadening of patient selection crite-

<table>
<thead>
<tr>
<th>Exhibit 1</th>
<th>HCFA-Certified Heart Transplant Centers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baylor University-Methodist Hospital (Houston, TX)</td>
<td>St. Louis University Hospital (St. Louis, MO)</td>
</tr>
<tr>
<td>Brigham and Women’s Hospital (Boston, MA)</td>
<td>Stanford University (Palo Alto, CA)</td>
</tr>
<tr>
<td>Cleveland Clinic (Cleveland, OH)</td>
<td>Temple University Hospital (Philadelphia, PA)</td>
</tr>
<tr>
<td>Henry Ford Hospital (Detroit, MI)</td>
<td>Texas Heart Institute-St. Luke’s Hospital (Houston, TX)</td>
</tr>
<tr>
<td>Jewish Hospital (Louisville, KY)</td>
<td>University of Alabama (Birmingham, AL)</td>
</tr>
<tr>
<td>Johns Hopkins Hospital (Baltimore, MD)</td>
<td>University of Arizona (Tucson, AZ)</td>
</tr>
<tr>
<td>Loyola University-Foster McGaw Hospital (Chicago, IL)</td>
<td>University of Minnesota (Minneapolis, MN)</td>
</tr>
<tr>
<td>Medical College of Virginia (Richmond, VA)</td>
<td>University of Pittsburgh-Presbyterian Hospital (Pittsburgh, PA)</td>
</tr>
<tr>
<td>Methodist Hospital (Indianapolis, IN)</td>
<td>University of Utah (Salt Lake City, UT)</td>
</tr>
<tr>
<td>Oregon Health Sciences University (Portland, OR)</td>
<td>Washington University-Barnes Hospital (St. Louis, MO)</td>
</tr>
</tbody>
</table>

Source: Health Care Financing Administration, August 1988.
ria, might lead to higher utilization. That is exactly what has occurred in the case of the ESRD program. Enrollment has continuously expanded, regularly surpassing projections.

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**The Heart Transplant Projections**

The number of Medicare-covered heart transplants is a function of three factors: (1) the demand for heart transplants among Medicare eligibles; (2) the supply of organ donors whose hearts become available for transplant; and (3) the degree of success in matching persons awaiting a transplant with organs that become available. Exhibit 2 summarizes the logic and data underlying the NHTS projections.

**Demand for heart transplants.** Using 1979 and 1980 mortality, morbidity, and hospital discharge data, the NHTS estimated that about 85,000 Medicare-eligible persons annually would develop end-stage heart disease that might benefit from an organ transplant. That number shrinks drastically after applying the age selection criterion then in effect: “suitable” heart transplant candidates would be no younger than age ten and no older than age fifty-five. Only an estimated 1,012 persons remained after this first cut. Those falling within the age screen would be evaluated to assess their medical and psychological suitability for the transplant procedure. Stanford accepted only one out of seven potential candidates, and the NHTS adopted this figure. Thus, in the patient screening and selection process envisioned by the NHTS, annual demand from some 85,000 Medicare beneficiaries who might benefit from a heart transplant dwindles to a mere 140 admitted as candidates.

**Supply of donor hearts.** Heart transplant activity is ultimately constrained by the availability of donor organs. To estimate organ availability, the NHTS used data sources ranging from hospital discharge abstracts to public opinion surveys concerning willingness to be an organ donor. Potential organ donors are hospitalized persons under age forty-five who are diagnosed as brain-dead; there were some 18,000 such cases in 1980, according to the NHTS. Organs are “harvested” (the transplant field’s euphemism) from only a fraction of potential donors. Based on kidney transplant data, the NHTS estimated that there were 2,200 organ donors in 1982. Not every organ donor is a heart donor for a variety of reasons ranging from prior heart disease to use of medications rendering the organ unsuitable for transplant. Assuming that 15 to 40 percent of kidney donors would also be heart donors, the NHTS estimated that between 325 and 866 hearts were available in 1983.

**Matching transplant candidates and donor hearts.** While there was great uncertainty surrounding the potential supply of donor hearts, the
Exhibit 2
Assumptions Underlying NHTS/HCFA Projections For Medicare-Covered Heart Transplants

Base population
226 million
1979–1980

Potential organ donors
~ 16,000

Medicare eligibles who could benefit from transplant
~ 85,000

Organ donor?
No

Age 10–54?
No

Yes

Potential heart transplant candidates
~ 1,000

Other selection criteria met?
No

Accepted for transplant (14 percent)
~ 140

Heart donor?
No

Available hearts
~ 325–866

Yes

Patient matched with organ donor?
No

Transplant performed (60 percent)
~ 85

Yes
number was clearly smaller than the pool of persons awaiting a transplant. The NHTS assumed that organs would be distributed equitably among transplant candidates—Medicare eligibles as well as other persons. Again based on the Stanford experience, the NHTS calculated that 60 percent of the projected 140 Medicare-eligible transplant candidates would survive the wait for a matching donor. The resulting NHTS estimate of some eighty-five annual Medicare-covered heart transplants was massaged by HCFA actuaries, who established a five-year forecast of 65 to 143 recipients.

**Recent Developments In Heart Transplantation**

In this segment I examine recent trends that may affect the accuracy of these forecasts.

**Demand for heart transplants.** The NHTS used a cutoff at age fifty-five to estimate demand for transplants among Medicare beneficiaries, the clinical standard at the time. Recent data demonstrate that age alone is not necessarily a barrier to a heart transplant. The International Heart Transplant Registry reports that the five-year survival rate for patients above age fifty-five appears equal to or better than the rate for persons in the nineteen-to-fifty-five-year age range. Many of the leading transplant centers have now raised their upper age limits in light of this favorable experience: Stanford’s is reportedly age fifty-nine, while Pittsburgh uses age sixty-one. Anecdotal information from several transplant centers leads me to believe that “official” age limits are routinely exceeded. Because the incidence of heart disease increases rapidly with age, widening the age range greatly expands potential demand for heart transplants. Figures from the NHTS indicate that cut-off at age fifty-nine would at least double the demand for transplants among Medicare eligibles.

**Supply of hearts for transplant.** The size of the pool of persons who might become organ donors does not appear to have changed significantly since the NHTS analysis. Males in their teens and twenties who were victims of motor vehicle accidents are the primary source of organs. Several states observed declines in fatalities following introduction of compulsory seat belt legislation, and campaigns against drunken driving have also been mounted in recent years. However, these measures have had little effect in reducing motor vehicle mortality, and alcohol-related deaths may actually be on the rise. Furthermore, gains in automobile safety are being offset by trauma among users of motorcycles and three-wheeled “all terrain” vehicles.

While the size of the potential donor pool may be stable, the annual
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The number of persons brain-dead in a hospital may have grown over the past few years as an unexpected outcome of improved emergency medical services programs. Better prehospital care of trauma victims is undoubtedly saving many lives that would otherwise have been lost, but some proportion of these critically injured persons do not survive. Helicopter medical-evacuation services may be playing a key role in expanding the organ donor pool. There are now more than 125 hospital-affiliated helicopter ambulances, supplemented by a network of military "med-evac" systems serving a civilian population. Methodist Hospital of Dallas reports that 60 to 90 percent of organ donors are originally helicopter-transported trauma victims. A Pennsylvania hospital is establishing a new kidney transplant program as a direct result of the volume of organ donors attributed to its helicopter ambulance.

Empirical evidence for growth in the number of organ donors is available through the Medicare renal disease program. In 1986, Medicare-certified facilities transplanted 7,089 kidneys from cadaveric donors, while a total of 10,747 cadaveric kidneys were reported as available for transplant. Assuming that two kidneys were harvested per donor, there were between 3,545 and 5,374 organ donors in 1986, a considerable increase over the NHTS 1982 figure of 2,200. HCFA's 1987 kidney transplant data suggest a leveling off in the organ donor growth rate.

New legislation may further expand the donor supply. Provisions of the Omnibus Budget Reconciliation Act (OBRA) of 1986 require that hospitals participating in the Medicare program establish procedures for identifying potential organ donors and making this information available to transplant agencies.

Matching of donor and recipient. The OBRA legislation also gave a boost to the concept of a unified national organ matching system to replace the current fragmented structure of independent and sometimes competing organ procurement agencies. Transplant programs receiving federal funds will now be required to join the United Network for Organ Sharing (UNOS), headquartered in Richmond, Virginia. It may take several years for these organizational innovations to have a measurable impact on the organ supply.

One of the constraints on the heart supply has been the short length of the allowable interval between removal of the donor organ and implantation in the recipient (ischemic time). Advances in organ preservation technology are now extending the usual three-hour maximum ischemic time to as much as five hours. In the case of heart-lung transplants, radical new preservation techniques can prolong the current one-hour ischemic time to six hours and beyond. Longer preservation times are important because they extend the geographic range for organ procure-
ment and increase the probability of successfully matching transplant candidate and organ.

While one group of researchers is struggling with organ preservation time, another is working to extend the survival of patients. This involves the use of mechanical circulatory support systems that partially or completely replace a failing heart. There is a popular perception that a moratorium has been imposed on the use of “artificial hearts” due to the rather dismal experiences of patients such as Barney Clark and William Schroeder. But this is not true. Mechanical heart pumps are increasingly used as a “bridge” to maintain the patient until a human heart transplant can be arranged. In 1986 there were nearly sixty bridge procedures, double the previous year’s level. Perfection of a fully implantable heart substitute is now the object of worldwide competition. Medicare’s heart transplant program does not cover the bridge procedure, but its use may add to the number of persons who survive long enough to attain Medicare eligibility under the disability provision.

Revising The Medicare Projections

Medicare’s heart transplant program has completed its first year. Preliminary data suggest that Secretary Bowen’s forecast of sixty-five procedures was indeed a reasonable figure. HCFA has received claims for approximately fifty patients who underwent the procedure during fiscal year 1987. About thirty claims were submitted by hospitals that had received Medicare certification as a heart transplant center by the date the procedure was performed; other claims were from hospitals that were in the process of certification. Whether or not each of these patients was in fact eligible for Medicare has not been established. Adjudication of these claims will take some time.

Although the number of claims received by HCFA is unremarkable, the age distribution of these patients is rather startling. About half of the fifty claims were for patients older than the magic age of fifty-five and at least three patients were age sixty-five or older. This pattern has obvious implications for Medicare’s expenditure projections. A critical assumption underlying the estimate of 143 Medicare-covered heart transplants in the fifth year of the program (fiscal year 1991) is no longer valid: persons beyond the presumed maximum age of fifty-five are now routinely accepted as transplant candidates. What might a new fiscal year 1991 forecast look like?

A “back-of-the-envelope” approach is first to project the total number of heart transplant procedures in fiscal year 1991 and then to estimate the proportion covered by Medicare. Exhibit 3 gives the numbers of U.S.
HEART TRANSPLANTS

Exhibit 3
Heart Transplants And Estimated Organ Donors

<table>
<thead>
<tr>
<th>Year</th>
<th>Heart Transplants</th>
<th>Increase over prior year</th>
<th>Organ Donors</th>
<th>Increase over prior year</th>
</tr>
</thead>
<tbody>
<tr>
<td>1982</td>
<td>103</td>
<td>-</td>
<td>1,841</td>
<td>-</td>
</tr>
<tr>
<td>1983</td>
<td>172</td>
<td>67%</td>
<td>2,164</td>
<td>18%</td>
</tr>
<tr>
<td>1984</td>
<td>373</td>
<td>117</td>
<td>2,632</td>
<td>22</td>
</tr>
<tr>
<td>1985</td>
<td>731</td>
<td>96</td>
<td>2,910</td>
<td>11</td>
</tr>
<tr>
<td>1986</td>
<td>1,368</td>
<td>87</td>
<td>3,545</td>
<td>22</td>
</tr>
<tr>
<td>1987</td>
<td>1,441</td>
<td>5</td>
<td>3,530</td>
<td>-0.4</td>
</tr>
</tbody>
</table>


Heart donors computed as one-half of cadaver kidneys transplanted.

Heart transplants by year and the percentage change from the previous year. Although the annual number of heart transplants has grown rapidly, the plunge in the rate of increase for 1987 may indicate that a plateau is being reached. Because donor availability is the ultimate constraint on transplant volume, Exhibit 3 also gives the annual number of organ donors (based on kidney transplants) for the same period.

Exhibit 4 presents a range of estimates for Medicare-covered heart transplants in fiscal year 1991. The first row of the exhibit shows a low, medium, and high projection for the total number of heart transplants, computed by applying a constant compound growth rate (5 percent, 10 percent, or 15 percent) to a baseline 1987 count of 1,441 U.S. heart transplants. Similarly, a low, medium, and high figure was used for the proportion of heart transplants that would be covered by Medicare. The low number is in accord with the original NHTSA estimate, while the higher figures reflect the trend toward accepting older patients.

The result of these calculations is a rather wide range of projections for Medicare-covered heart transplants in fiscal year 1991: from a low of 175...
to a high of 500. If a 10 percent annual growth rate in organ donors can be sustained, then the likely range is from 210 to 420 Medicare-covered transplants. That level of increase appears feasible, given anticipated structural improvements in the national organ procurement system and continued progress in organ preservation technology.

**Policy Lessons**

Is there a lesson here for policymakers? Lightning won’t strike twice; the scarcity of organ donors constrains the heart transplant program’s ultimate growth, a limit that did not exist in Medicare’s end-stage renal disease program. Heart transplants will never consume more than a small fraction of the total Medicare budget.

On the other hand, it is evident that heart transplantation is growing faster than anticipated. From a Medicare perspective, the most significant revelation is that the “acceptable” upper age limit for transplant candidates has increased rapidly. Medicare can no longer rely on the twenty-nine-month waiting period for disability coverage—a seemingly formidable barrier—as a brake on expenditures. HCFA projected a cost of $25 million for 143 heart transplants in fiscal year 1991. Extending that figure to the more likely range of 210–420 procedures suggests that program costs may actually be $37 million to $73 million.

With expanded catastrophic coverage, and new organ replacement technologies looming on the horizon, estimating potential numbers of program beneficiaries and annual expenditures becomes an increasingly critical task. Forecasting is inherently risky, but future technology assessments could be improved by squarely confronting the likelihood and consequences of broadened patient selection criteria.

These criteria may expand for a variety of reasons. Technical mastery is one explanation. Success in applying the therapy in one class of patient gives clinicians the confidence needed to take on somewhat different and therefore riskier cases. As an example, the typical new patient in the Medicare kidney disease program is older and sicker than in previous years. It should come as no surprise that something similar is happening in the heart transplant program. Favorable economic incentives also influence selection criteria. Supply and demand for a good or service—even an organ transplant—inevitably increases when its consumption is subsidized. Prior to Medicare’s coverage decision, financial realities reinforced the clinical rationale for selecting only younger patients. Now the federally insured sixty-five-year-old patient is on an equal footing with his or her privately insured juniors.

In making future coverage decisions, policymakers should determine
the sensitivity of program costs to changes in patient selection criteria (that is, physician discretion). Fiscal projections should include budgetary “worst-case” scenarios. These results must receive serious consideration, even if implausible in the context of current clinical practice.

If the intent of coverage policy is to impose an absolute limit on utilization of a medical technology, experience demonstrates that reliance on physician discretion to select only “suitable” patients is a dubious approach to controlling-program growth. It conflicts with the physician’s professional ethics and the advancement of medical science. The only certain way to limit use of a technology is to impose explicit patient selection criteria, such as an upper age limit for Medicare-funded heart transplants. Barring that, policymakers must anticipate broadening of patient selection criteria, with attendant fiscal consequences, as one of the natural laws of medical technology diffusion.

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NOTES

10. Ibid., Table 14-1.
13. Ibid., Table 19-7.
14. Ibid., Table 12-48.
36. G. de Lissovoy, “Patient Selection in the Medicare End-Stage Renal Disease Program,” Medical Care (September 1988).