

HEALTH POLICY

Health Insurance and Cardiac Transplantation

A Call for Reform

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Cardiac transplantation is an accepted therapy for patients with end-stage heart failure (ESHF). Presently in the U.S., patients with ESHF need to have health insurance or another funding source to be considered eligible for cardiac transplantation. Whether it is appropriate to exclude potential recipients solely due to lack of finances has received considerable interest including being the subject of a recent major motion picture (John Q, New Line Cinema, 2002). However, one important aspect of this debate has been underappreciated and insufficiently addressed. Specifically, organ donation does not require the donor to have health insurance. Thus, individuals donate their hearts although they themselves would not have been eligible to receive a transplant had they needed one. By querying Siminoff's National Study of Family Consent to Organ Donation database, we find that this situation is not uncommon as ~23% of organ donors are uninsured. Herein we also discuss how the funding requirement for cardiac transplantation has been addressed by the federal government in the past, its implications on the organ donor consent process, and its potential impact on organ donation rates. We call for a government-sponsored, multidisciplinary task force to address this situation in hopes of remedying the inequities in the present system of organ allocation. (J Am Coll Cardiol 2005;45:1388-91) © 2005 by the American College of Cardiology Foundation

A middle-aged African American woman was rehospitalized with refractory end-stage heart failure (ESHF). She was known to have a nonischemic cardiomyopathy with severely depressed left ventricular ejection fraction and severe mitral regurgitation. Via right-sided heart catheterization, she was documented to be in cardiogenic shock with a cardiac index of 0.9 l/min/m² and a mixed venous saturation of 36%. She was dependent upon inotropic therapy and was felt too ill for repair of her mitral valve. Her attending cardiologist noted the urgent need for cardiac transplantation. She had no private insurance, and her income made her ineligible for public insurance despite a long history of steady employment. Therefore, she was not evaluated for transplantation, as it was known that she could not be listed for a transplant in the absence of funding for the procedure. Over several weeks, her condition continued to deteriorate despite maximal medical therapy and she was made "do not resuscitate" at her request before expiring. The hospital discharge note included the following statement, "All attempts at transplant were thwarted by lack of funding."

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INTRODUCTION

In our heart failure clinic in an urban public hospital, we have encountered a number of low-income patients with ESHF who do not have health insurance (1). As illustrated in the above case report, cardiac transplantation, a widely accepted but expensive therapy for ESHF, is not generally available in the U.S. to those who do not have health insurance, as such patients usually do not have the financial wherewithal to pay for the procedure and its associated costs. Whether it is appropriate for a potential recipient's socioeconomic status (SES) to be a factor in the allocation of donated organs has received attention from the federal government (2) and, more recently, the film industry in the major motion picture John Q (New Line Cinema, 2002). However, we believe one important aspect of this debate has been underappreciated and insufficiently addressed. Specifically, organ donation does not require the donor to have health insurance. Thus, uninsured deceased patients (or family members who donate on their behalf) can donate their hearts although they themselves would not have had access to receive a transplant had they needed one.

We believe this situation to be untenable and to violate one of the basic tenets of bioethics, the principle of justice, commonly defined in health care as the equitable allocation of resources (3), but herein used more specifically to describe the general inequity inherent in asking a group of people to contribute to a pool of resources not generally available to them. Although inequities in the health care system related to SES are widespread, organ transplantation is unique

Abbreviations and Acronyms

DHHS	= Department of Health and Human Services
ESHF	= end-stage heart failure
ESRD	= end-stage renal disease
NOTA	= National Organ Transplant Act
OPTN	= Organ Procurement and Transplantation Network
SES	= socioeconomic status
UAGA	= Uniform Anatomical Gift Act

because of its dependence on the willingness of other members of society to donate willingly their own organs or the organs of their loved ones. The purpose of this paper is to review various aspects of this complex issue in an effort to further a national dialogue on ways to ensure an equitable system of heart allocation in the U.S., recognizing that many of the points discussed are equally relevant to transplantation of other solid organs such as liver and lung.

CURRENT STATUS OF HEART TRANSPLANTATION

The decision to register a patient as a candidate on the United Network of Organ Sharing waiting list is made by transplant cardiologists and surgeons at the patient's treating hospital. Many factors influence this decision and most focus on the severity of the patient's cardiac illness and possible contraindications to transplant (4). However, transplant centers also consider a prospective transplant recipient's ability to pay for the procedure, for lifelong medications, and for follow-up care. The financial demands associated with transplantation are considerable. The estimated first year costs for heart transplant are \$391,000, and subsequent annual costs, estimated to be \$21,200 in 1996, would be \$35,200 per year if adjusted using the consumer price index (5,6). If patients are uninsured or underinsured and do not have other means to pay for the procedure and costs of follow-up, regardless of the likelihood of a successful transplant, they usually will not be placed on a transplant list (7-10).

NUMBER OF UNINSURED WITH HEART FAILURE AND OF UNINSURED DONORS

It is not known how many people in our country are in need of a heart transplant but are excluded due to a lack of funds. To our knowledge, there is no prospective registry that tracks such patients, and referral bias (i.e., physicians not referring uninsured patients for transplant evaluation and hospitals or transplant centers not accepting transfer of uninsured ESHF patients) hampers retrospective gathering of such data. However, it is possible to create an estimate using recent statistics released from the Census Bureau for 2002, which reveal that 43.6 million (15.2% of the population) (11) are uninsured. Between the ages of 45 to 64 years, the most common age group to receive a heart transplant, 13.1% are uninsured. Another 31 million people are underinsured (12,13).

The Census Bureau data provides the crude estimate that

13% to 15% of patients with ESHF who could benefit from transplantation do not have insurance to pay for this procedure. However, this estimate may be too low because patients with ESHF have impaired functional capacity and may be frequently hospitalized, factors that would hinder their ability to maintain employment and obtain employer-sponsored health insurance. Conversely, this estimate may be overinflated, as patients without health insurance have limited access to preventive care and may have increased rates of other chronic medical conditions that may exclude them from transplantation. Therefore, prospective data are needed to accurately determine the number of patients not considered for cardiac transplantation solely due to a lack of funds.

The number of organ donors in our country who are uninsured is also unknown. Using the Census Bureau estimate, one might surmise that, of ~2,350 hearts donated yearly (14), approximately 14% (n = 330) would be donated by uninsured donors. To refine this estimate, we queried Siminoff's National Study of Family Consent to Organ Donation database. This study examined the experiences and attitudes of 420 families who were asked to donate organs in Ohio and Pennsylvania (15). Health insurance status of the potential donor was determined retrospectively by a review and analysis of medical records. Characteristics of the 298 donors are shown (Table 1). A total of 23% of the donors were uninsured suggesting, if these data are representative of the national experience, that nearly one in four donated hearts in this country come from uninsured individuals.

ABILITY TO PAY FOR TRANSPLANT—LEGISLATION

The federal government has visited the issue of ability to pay for transplant on several occasions. In 1986, a federally appointed task force, convened in accordance with section 104(c) of the 1984 National Organ Transplant Act (NOTA) (16), recommended that, "[a]ll patients should have access to all efficacious organ transplantation procedures regardless of ability to pay..." (2). The task force cited two arguments in support of its recommendation: 1) organs are a public resource, donated altruistically by members of the public with the expectation that they will be distributed in an equitable manner; and 2) society has chosen to fund comparable procedures, most notably the Medicare End Stage Renal Disease (ESRD) program, and that to deny similar care for those in need of other organ transplants based solely on inability to pay would be inequitable (2,17).

Table 1. Characteristics of Donors in Siminoff's (15) National Study of Family Consent to Organ Donation (n = 298)

Age, yrs	36 ± 20
White	263 (88)
Male gender	188 (63)
Insurance status	
Commercial	152 (51)
Government	78 (26)
No insurance	68 (23)

Data are shown as mean ± SD or number (%).

In 1998, then Secretary of the Department of Health and Human Services (DHHS), Donna Shalala, proposed a Final Rule for the NOTA governing the operation of the Organ Procurement and Transplantation Network (OPTN) (9). In Section 121.4(3) of the proposed Final Rule, Secretary Shalala would have required the OPTN Board of Directors to develop policies that reduce inequities resulting from SES. The proposed Final Rule engendered much public debate. Many were concerned that if hospitals were required to fund organ transplantation for those unable to pay, transplant programs might be forced to close for fear of negatively impacting hospital finances (8,9). In response to these criticisms, the DHHS noted that the Secretary merely required that the OPTN “consider” policies designed to reduce inequities in the allocation of organs for transplant (9). An Institute of Medicine report released shortly thereafter, although principally focused on geographic disparities in organ allocation, concluded that low SES was a barrier to being listed for organ transplantation (18). An amended Final Rule, effective March 16, 2000 (19), required that the registration fee, approximately \$500, be waived if it posed a financial burden and that the OPTN create procedures for transplant hospitals to make “reasonable efforts” to obtain funds from all available sources.

In sum, although the federal government has acknowledged the inequities of the status quo, little governmental action has been taken to date, undoubtedly reflecting the potential financial consequences involved in expanding access to organ transplants to those without funds. Nevertheless, in the context of present governmental efforts to expand the donor pool (20), which likely will increase the absolute if not proportional number of uninsured donors, we believe there is increasing impetus for the government to address this inequity.

ABILITY TO PAY FOR TRANSPLANT—RELATIONSHIP TO THE CONSENT PROCESS FOR ORGAN DONATION

The Uniform Anatomical Gift Act (UAGA) (1987) (21) established the driver’s license or donor card system used by many organ donors to indicate their intent to donate. Under the provisions of the UAGA and similar state laws, this expression of intent is sufficient, and the family of the deceased need not be consulted. Nevertheless, families are routinely consulted before organs are procured, in large part to avoid insensitivity to grieving families and as part of the normative expectation that family consent will be obtained. In recent years, 11 states have attempted to increase organ donation rates by enacting “first person consent” laws (22). Under these laws, if the deceased is registered as a donor and has signed a consent document, families will be informed of their loved one’s intent but will no longer be consulted for their consent before the donation.

Extensive efforts are employed to ensure that families are well informed and comfortable with the donation process (23). Nevertheless, it is likely that such discussions do not address the lack of access to organ transplantation endured

by uninsured and underinsured patients. A review of the widely adopted “Model Elements of Informed Consent for Organ and Tissue Donation” (24) revealed no mention of the SES of potential recipients. We recognize that some in the medical community will not consider it necessary to discuss this issue as part of the informed consent process, though we would argue that it should be openly discussed, especially when the potential donor is uninsured.

POTENTIAL IMPACT ON RATES OF ORGAN DONATION AMONG AFRICAN AMERICANS

African Americans agree to donate their organs at about half the rate of whites (23) for a variety of reasons including more commonly believing that the resources devoted to organ transplantation should be redirected toward other medical needs (25) and that the system of organ allocation in the U.S. is unfair (15,25,26). Prior studies have found that a major barrier to access to organ (e.g., kidney) transplantation among ethnic minorities with lower SES is placement on the transplant list (18,27). Because African Americans are more likely than whites to be uninsured (28), the funding requirement for placement on the transplant list affects African Americans disproportionately, and undoubtedly contributes to their perception of an unfair system. We believe that removing the present funding requirement for transplant, while rectifying an unacceptable inequity in the current system, has the *potential* to expand the overall donor pool as members of economically disadvantaged segments of the population, including African Americans, may be more willing to donate their organs if they perceive the allocation system to be equitable. In the absence of data, however, this hypothesis remains speculative.

POTENTIAL COSTS OF CARDIAC TRANSPLANTATION IN UNINSURED PATIENTS

A detailed review of the costs that might be associated with an indigent heart transplant program and possible funding sources for such a program are beyond the scope of this paper. Nevertheless, to begin the discussion, we provide an estimate of the costs of funding 330 heart transplants, a proportion (~14%) of annual heart transplants equal to the proportion of uninsured donors. The initial year would cost \$130 million (6) while the cost of follow-up over the next five years for these initial 330 patients would be approximately \$60 million (5). The costs would compound as more and more uninsured patients were enrolled in the program. Although it may be argued that such costs would be prohibitive, it is important to recognize that the total costs associated with heart transplantation presently represent <1% of the ~\$40 billion spent annually for heart failure (29).

One potential source of funding for such a program would be the federal government. Given that the Medicare program presently pays for kidney transplantation in those with ESRD, it would seem equitable that a similar mechanism could be used to pay for cardiac transplantation in those with ESHF. Such a governmentally sponsored pro-

gram would have the additional benefits of allowing recipients to return to work without fear of losing disability-related health insurance and minimizing employer concerns regarding health care liabilities.

CALL FOR GOVERNMENTAL REVIEW: ESTABLISHMENT OF A REGISTRY AND TASK FORCE

The interplay between lower SES as manifested by lack of health insurance, comorbidities including a previous history of noncompliance, and poorer outcomes after transplantation is complex (30–33). However, to maximize the benefits realized from donated hearts, all patients with ESHF who do not have medical contraindications and are willing and able to comply with the demands of the posttransplant regimen should be considered as potential recipients irrespective of insurance or financial status. As a first step, a registry should be created of all patients otherwise eligible for cardiac transplantation denied such based solely on inability to pay.

Further, we hope this paper will spark debate on this subject and will lead to a government-sponsored, multidisciplinary task force that addresses the inequities in the present system. Providers, payers, transplant physicians and teams, transplant recipients, and donor families should be involved. The following issues need to be addressed: 1) the number of patients currently not eligible for transplant because of insufficient funding and the number of uninsured donors; 2) disclosure requirements for informed consent; and 3) proposals to enhance equitable access to cardiac transplantation.

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REFERENCES

1. Mehta SK, Toto KH, Nelson LL, Drazner MH. Therapy of heart failure in African Americans: lessons from an urban public hospital. *Congest Heart Fail* 2004;10:40–3.
2. Organ Transplantation: Issues and Recommendations. Task Force on Organ Transplantation, U.S. Department of Health and Human Services, Public Health Service, Health Resources and Services Administration, 1986.
3. American College of Physicians. Ethics manual. Available at: <http://www.acponline.org/ethics/ethicman.htm>. Accessed March 3, 2005.
4. Steinman TI, Becker BN, Frost AE, et al. Guidelines for the referral and management of patients eligible for solid organ transplantation. *Transplantation* 2001;71:1189–204.
5. Hauboldt RH. Cost Implications of Human Organ and Tissue Transplantations, An Update 1996. Milliman and Robertson Inc., 1996. Available at: http://www.milliman.com/pubs/HR_16.pdf. Accessed March 3, 2005.
6. Hauboldt RH, Ortner NJ. 2002 Organ and Tissue Transplant Costs and Discussion. Milliman USA, 2002. Available at: http://www.milliman.com/pubs/HRR_07-2002.pdf. Accessed March 3, 2005.
7. DHHS. Testimony on Organ Transplant Policy by the Honorable Donna Shalala, Secretary, U.S. Department of Health and Human Services, September 10, 1998. Senate Committee on Appropriations, Subcommittee on Labor, HHS, and Education. Washington, DC: 1998.
8. Evans R. Money matters: should ability to pay ever be a consideration in gaining access to transplantation? *Transplant Proc* 1989;21:3419–23.
9. Organ procurement and transplantation network—HRSA. Final rule with comment period. *Fed Regist* 1998;63:16296–338.
10. Caplan AL. Current ethical issues in organ procurement and transplantation. *JAMA* 1994;272:1708–9.
11. Mills RJ. Health Insurance Coverage: 2002. United States Census Bureau, 2003. Available at: <http://www.census.gov/prod/2003pubs/p60-223.pdf>. Accessed January 15, 2004.
12. Shearer G. Hidden From View: The Growing Burden of Health Care Costs. Washington, DC: Consumers Union, 1998.
13. Kuttner R. The American health care system: health insurance coverage. *N Engl J Med* 1999;340:163–8.
14. Organ Procurement and Transplantation Network Data. Available at: <http://www.optn.org/latestData/rptData.asp>. Accessed January 15, 2004.
15. Siminoff LA, Gordon N, Hewlett J, Arnold RM. Factors influencing families' consent for donation of solid organs for transplantation. *JAMA* 2001;286:71–7.
16. Organ Procurement and Transplantation Network. U.S. Code Title 42, Section 274. Available at: <http://caselaw.lp.findlaw.com/casecode/uscodes/42/chapters/6a/subchapters/ii/parts/h/sections/section%5F274.html>. Accessed March 3, 2005.
17. Benjamin M. Medical ethics and economics of organ transplantation. *Health Prog* 1988;69:47–52.
18. Institute of Medicine. Organ Procurement and Transplantation: Assessing Current Policies and the Potential Impact of the DHHS Final Rule. Washington, DC: National Academy Press, 1999.
19. Organ Procurement and Transplantation Network. 42 CFR Part 121, 1999. Available at: <http://www.gpoaccess.gov/fr/index.html>. Accessed March 3, 2005.
20. HHS Secretary Tommy G. Thompson launches the Gift of Life Donation Initiative. Available at: <http://www.hhs.gov/news/press/2002pres/20020422.html>. Accessed May 24, 2004.
21. National Conference of Commissioners on Uniform State Laws. Uniform Anatomical Gift Act (1987). Available at: <http://www.law.upenn.edu/bl/ulc/fnact99/uaga87.htm>. Accessed March 3, 2005.
22. United Network for Organ Sharing. Fact sheet. Available at: <http://www.unos.org/Resources/FactSheets.asp>. Accessed January 15, 2004.
23. Siminoff LA, Lawrence RH, Arnold RM. Comparison of black and white families' experiences and perceptions regarding organ donation requests. *Crit Care Med* 2003;31:146–51.
24. Association of Organ Procurement Organizations. Model elements of informed consent for organ and tissue donation. Available at: <http://www.aatb.org/model.htm>. Accessed December 19, 2003.
25. Siminoff LA, Saunders Sturm CM. African American reluctance to donate: beliefs and attitudes about organ donation and implications for policy. *Kennedy Inst Ethics J* 2000;10:59–74.
26. Siminoff LA, Arnold RM. Increasing organ donation in the African American community: altruism in the face of an untrustworthy system. *Ann Intern Med* 1999;130:607–9.
27. Ozminkowski RJ, White AJ, Hassol A, Murphy M. Minimizing racial disparity regarding receipt of a cadaver kidney transplant. *Am J Kidney Dis* 1997;30:749–59.
28. Institute of Medicine. Coverage Matters: Insurance and Health Care. Washington, DC: National Academy Press, 2001.
29. O'Connell JB, Bristow MR. Economic impact of heart failure in the United States: time for a different approach. *J Heart Lung Transplant* 1994;13:S107–12.
30. Dew MA, Roth LH, Thompson ME, Kormos RL, Griffith BP. Medical compliance and its predictors in the first year after heart transplantation. *J Heart Lung Transplant* 1996;15:631–45.
31. Kalil RS, Heim-Duthoy KL, Kasiske BL. Patients with a low income have reduced renal allograft survival. *Am J Kidney Dis* 1992;20:63–9.
32. Schweizer RT, Rovelli M, Palmeri D, Vossler E, Hull D, Bartus S. Noncompliance in organ transplant recipients. *Transplantation* 1990;49:374–7.
33. Pamboukian SV, Costanzo MR, Meyer P, Bartlett L, McLeod M, Heroux A. Influence of race in heart failure and cardiac transplantation: mortality differences are eliminated by specialized, comprehensive care. *J Card Fail* 2003;9:80–6.