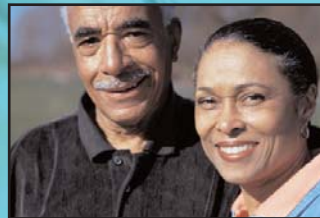


# HEALTH CARE AT THE CROSSROADS:

Strategies for Narrowing the Organ Donation Gap and Protecting Patients



**Joint Commission**

*on Accreditation of Healthcare Organizations*  
*Setting the Standard for Quality in Healthcare*

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Strategies for Narrowing the Organ Donation Gap  
and Protecting Patients



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# JOINT COMMISSION PUBLIC POLICY INITIATIVE

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This white paper emanates from the Joint Commission's new Public Policy Initiative. Launched in 2001, this initiative seeks to address broad issues that have the potential to seriously undermine the provision of safe, high-quality health care and, indeed, the health of the American people. These are issues which demand the attention and engagement of multiple publics if successful resolution is to be achieved.

For each of the identified public policy issues, the Joint Commission already has state-of-the-art standards in place. However, simple application of these standards, and other unidimensional efforts, will leave this country far short of its health care goals and objectives. Thus, this paper does not describe new Joint Commission requirements for health care organizations, nor does it focus on new requirements that may be forthcoming in the future.

Rather, the Joint Commission has devised a public policy action plan that involves the gathering of information and multiple perspectives on the issue; formulation of comprehensive solutions; and assignment of accountabilities for these solutions. The execution of this plan includes the convening of expert roundtables and national symposia, the issuance of white papers, and active pursuit of the suggested recommendations contained therein.

This paper is a call to action for those who influence, develop or carry out policies that will lead the way to resolution of the identified issues. This is specifically in furtherance of the Joint Commission's stated mission to improve the safety and quality of health care provided to the public.

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## PREAMBLE

“Dear Oprah, Do you ever wake up in the middle of the night crying?” So begins the passionate letter of Katie Margolis, who, at 22, is awaiting her third kidney transplant. Since the time she was a little girl, Katie’s own kidneys have not functioned. Now, time has run out on the kidney donated by her mother. Back on debilitating dialysis, Katie’s appeal to super-celebrity Oprah Winfrey is an appeal to get the message out.

In her videotaped presentation, shown recently at a national conference on organ donation hosted by the Joint Commission, Katie expressed her desire to spread the word that people are dying while in need of transplantation because not enough organs are being donated. She described how living on dialysis, a stop-gap for those with failed kidneys, offers little in the way of quality of life – it just sustains, and drains life. And it just could be so much better if more people knew – if they understood the power of what they have to give – and the personal gratification that comes to those who do. With a lifetime spent in an almost constant exchange with the health care system, Katie and her family know that – for all the medical wonders that have been accomplished, including transplantation – more can and must be done to bring potential donors and recipients together.

Mr. B., a 62-year-old African American man in renal failure, time and again refused to be put on dialysis.<sup>1</sup> According to Bonnie Salomon’s account of her encounter with Mr. B, she and the other physicians treating him in the emergency department were incredulous. They reminded Mr. B. that he had his wife, his children, and his grandchildren to live for. Mr. B. was unmoved. He responded, “Everyone knows the black people and the poor people get put on dialysis, and the white patients

get transplants.” To give in to dialysis, to Mr. B.’s thinking, would be to give in to the institutional racism and failed policies that are all too evident in the experiences of minority and poor Americans who need life-saving transplants. Equity in the organ allocation and transplantation equation has yet to be achieved.

For Katie, for Mr. B., for the tens of thousands now waiting for transplants, and for the untold others whose remaining lives do not include a transplantation option, current efforts to expand access to transplantation are falling well short of the mark. To be sure, there have been remarkable efforts and success stories. And progress has been made in increasing the numbers of donors, in improving the care of individuals who receive organ transplants, and in expanding the participation of minorities as donors and recipients. These efforts, the encouraging trends, and some of the success stories are discussed in this paper. But this paper is even more so a discussion of where we as a country are failing and what needs to be done.

Whatever failings this health care delivery system has had, it has progressively and systematically prolonged the lives of many by curing or mitigating the effects of diseases which once killed, and advances in technology and therapeutics have truly made organ transplantation the gift of life. The challenge today is make that gift of life available to all who need it. Meeting that challenge will require a concerted effort by the multiple parties of interest who are identified in this paper. And it will take leadership – by physicians, health care organization leaders, and eventually by public policymakers.

The time for action is now.



## INTRODUCTION

The numbers are well known – more than 85,000 people are currently on the waiting list for an organ; over 6,000 people per year are dying while waiting<sup>2</sup> – and their numbers will continue to climb.

Diseases that once culminated in certain death, are now abated through organ transplantation. Such is scientific progress since 1954 – when the first kidney was transplanted – that liver, heart, lung, pancreas and intestinal transplants are now performed on a regular basis. And the steadily expanding armament of powerful pharmaceuticals has made long-lasting, high-quality survival a reasonable expectation. However, this progress has unleashed a level of need that cannot now be met. A small improvement in the rate of organ donation from deceased donors in the U.S. – which jumped 4.8 percent in 2003<sup>3</sup> after averaging increases of 3.7 percent per year over the last decade<sup>4</sup> – has had little impact on the lengthening waiting list for organs, which grows by an average of 19 percent every year.<sup>5</sup>

With only about half of the families of potential organ donors consenting to organ donation,<sup>6</sup> there remain far too few organs for the tens of thousands already waiting, or for the untold numbers who may join them. In this country, alarming epidemics of morbid obesity, hypertension and diabetes, and the continuing prevalence of infectious diseases such as hepatitis C, have the potential to drive the demand for organs to extreme proportions.

While organ donation should be a priority of all hospitals, large hospitals are the richest potential source for organ donation. In fact, 80 percent of organ donations are from 20 percent of all hospitals.<sup>7</sup> These large hospitals are typically high stress environments, in which meeting an array of patient needs and providing life-saving treatments are challenge enough. Many are operating at peak capacity on any given day, particularly in their intensive care units, where patients may be lined up in the emergency department, waiting for ICU beds. Shortages of nurses and other key health care personnel compound the limitations on performance capabilities in these environments.



THE RATES AT WHICH HOSPITALS SUCCESSFULLY OBTAIN CONSENT FOR ORGAN DONATION RANGE FROM MORE THAN 90 PERCENT TO LESS THAN 10 PERCENT.





The rates at which hospitals successfully obtain consent for organ donation range from more than 90 percent to less than 10 percent.<sup>8</sup> High performing hospitals have created cultures in which organ donation is a priority, and they work in partnership with their regional organ procurement organizations (OPOs). Low rates of organ donation appear to be primarily a problem of focus and attention – reflecting organizational priorities – rather than willful disregard. However, that is small comfort for the many individuals who are wait-listed for organ transplants.

Increasingly, those in need have turned to living donors. In fact, living donors now outnumber deceased donors as sources for kidney transplantation.<sup>9</sup> Living donors are also a source for liver transplantation, and to a much smaller extent for lung, pancreas, and, very rarely, intestinal transplantation. Despite the risks to their own health, family members, friends, and even altruistic strangers, have been increasingly compelled to provide the “gift of life” when there are no other alternatives.

However, with the increasing reliance on living donation have come new concerns about the supporting infrastructure for this undertaking. The living donation process requires adherence to clinical guidelines, advocacy for patient rights, and attentive clinical monitoring. Indeed, the selfless generosity of the living donor requires a moral commitment

on the part of responsible physicians and hospitals to assure that these patients receive the very best care. These admonitions are not hypothetical. Recent, highly publicized cases in which living donors have died have catalyzed efforts on the part of hospitals, health care authorities, and the transplant community to direct greater attention to protecting the well-being and best interests of these individuals.

There are other issues as well. A recent Institute of Medicine report found clear disparities in access and quality of health care for racial and ethnic minorities, regardless of their insurance status or ability to pay.<sup>10</sup> Sadly, these disparities are evident in the field of organ transplantation as well. Despite their high rate of need – African Americans represent 35 percent of all individuals with end-stage renal disease —these individuals wait longer for organs, are offered transplantation far less often, and have lower graft survival rates than Caucasians.<sup>11</sup>

Still others have even more modest opportunity for organ transplantation. Some individuals with mental and physical disabilities, despite their need and medical suitability for transplantation, are not wait-listed to receive organs.





What has been tried to date has simply not been enough. Hoping to stem the continuing expansion of the donation gap, the U.S. Department of Health and Human Services (DHHS) has launched the Gift of Life Donation Initiative to make improvement in the supply of donated organs, as well as protection of living donors, top public health priorities. Under the DHHS initiative, best practices have been identified for hospitals and OPOs to together create organizational cultures that promote organ donation.

As part of its efforts to improve organ donation, the DHHS Secretary appointed a blue-ribbon Advisory Committee on Organ Transplantation (ACOT). This panel has developed 35 recommendations for increasing the rate of organ donation, strengthening attention to ethical considerations, aligning financial incentives, improving the safety of organ donation and transplantation, and creating accountability for meeting these objectives. In fact, many of the Advisory Committee's recommendations are seconded in this report.

Many dedicated transplant and organ procurement professionals – and donors, donor families, and recipients – have also committed their personal efforts and time to addressing the obstacles to organ donation. And new federal and state legislative initiatives have recently been enacted to support and encourage organ donation. Momentum may well be building in the quest for more organs.

But, what will be the tipping point for organ donation? In order to frame the complex factors and issues that inhibit organ donation and compromise the well-being of living donors, and to identify solutions for addressing these problems, the Joint Commission convened an expert Roundtable. Among the specific issues addressed by the Roundtable were OPO and hospital relationships, variability in organ procurement rates, patient safety, patient and donor advocacy, alternative social models of organ donation, and public education. Based on the Roundtable discussions, a series of recommendations to help create this tipping point – the point at which things dramatically change<sup>12</sup>– for organ donation and transplantation were developed. These recommendations are summarized on the following pages.



WHAT HAS BEEN TRIED TO DATE HAS SIMPLY NOT BEEN ENOUGH.



## **I. CREATE A CULTURE IN WHICH ORGAN DONATION IS A PRIORITY**

- Focus resources for improving organ donation rates on the hospitals with the greatest potential to yield organ donors.
- Encourage physicians and hospital staff to work in partnership with OPOs to optimize the rate of organ donation.
- Follow the Leaders – implement the HRSA/Organ Donation Breakthrough Collaborative’s Best Practices.
- Place in-hospital coordinators in Level 1 Trauma Centers wherever it is economically and logistically feasible.
- Use ethnically “like requestors” whenever possible, and foster the cultural competency among other requestors.
- Make organ donation a priority – from the top of health care organizations on down.
- Educate all hospital leaders and staff on organ donation practices to dispel myths and inspire enthusiasm.
- Change CMS policy to provide for the reimbursement of costs related to maintaining potential organ donors prior to declaration of death.
- Make organ donation a criterion in public sector pay-for-performance models.
- Develop and implement new requirements for the periodic assessment and improvement of organ donation conversion rates.
- Develop standardized consensus measures respecting organ donation performance.

## **II. BRING EQUITY, FAIRNESS AND SAFETY TO THE TRANSPLANTATION PROCESS**

- Employ grassroot efforts such as those used by MOTTEP to raise awareness, change behavior and increase the rate of donation among ethnic and minority groups, and among persons with disabilities and their families.
- Periodically re-evaluate the priorities for organ allocation to identify opportunities to equalize access to transplantation.
- Conduct further studies to enhance knowledge about the underlying causes of transplantation disparities and to create a basis for problem-solving.
- Undertake initiatives (e.g. diversifying the health care workforce, improving health literacy) to reduce racial and ethnic disparities in access to transplantation.
- Establish life-time immunosuppressive drug benefits for patients who have undergone successful organ transplantation.
- Develop American with Disabilities Act compliance and clinical training materials and certification mechanisms to enhance health care professional knowledge and abilities to serve persons with disabilities.
- Establish protocols for assessing the ability of disabled patients to comply with post-transplant regimens.



- Establish a national living donor registry to track complications and outcomes, and to increase knowledge about the risks of such donations to donors.
- Establish requirements for living donor advocacy and protection that are independent of the transplant team.
- Provide employee leave policies for living donors.
- Extend recipients' private and/or federal life and health insurance plans to living donors.
- Adopt safe practices and systems for protecting the safety of patients and the integrity of procured organs.
- Develop and apply standardized IT systems and evidence-based practices that support determinations of organ suitability for transplantation and improve the rate and quality of organ recovery.

### **III. TAKE ALTERNATIVE PATHS TO MEET THE DEMAND FOR ORGAN DONATION**

- Enforce the provisions of the amended UAGA that protect the intent of the organ donor without the concurrence or consent of the donor's family.
- Enact the amended UAGA in the 11 states that have not done so.
- Implement donor registries in states currently without them and educate the public to increase enrollment.
- Conduct demonstration projects, funded by federal and state governments, to test the impacts of alternative social programs on increasing donation rates and make public education a fundamental component of these demonstration projects.
- Implement protocols for the recovery of organs from donors after cardiac death.
- Provide enhanced resources for and focus on preventive and health promotion programs aimed at preventing organ failure and reducing the demand for organ transplantation.
- Promote the expansion and use of living donor exchanges.
- Support the progression of new sciences and technologies that have the potential to narrow the donation gap and decrease the risk of organ rejection.
- Continue efforts to improve immunosuppressive therapy to reduce undesirable side-effects and adverse outcomes.

**This paper provides supporting documentation  
for its conclusions, describes specific recommendations,  
and assigns accountabilities for carrying out these  
recommendations.**



# I. CREATE A CULTURE IN WHICH ORGAN DONATION IS A PRIORITY

## THE LAW OF THE FEW<sup>13</sup>

According to a recent study, nearly 20 percent of hospitals account for 80 percent of all potential organ donors in the U.S.<sup>14</sup> These hospitals typically have 150 or more beds, neurology services and emergency departments.<sup>15</sup> The number of potential deceased donors from all hospitals ranges from 10,500 to 13,800 per year.<sup>16</sup> This same study found that, on average, 54 percent of potential donor families consented to organ donation, 39 percent of families did not consent, and 16 percent of families were never asked.<sup>17</sup> The sum of the opportunities lost is the approximately 6,000 potential donors who could have been added to the donor pool. There is concentrated, but sizable opportunity in this nation's largest hospitals. The study's authors suggest that by focusing resources on these large hospitals, establishing strong working relationships between hospitals and OPOs, and implementing best practices for obtaining consent, the rate of organ donation could be significantly elevated.<sup>18</sup>

While organ donation rates vary across hospitals and across regions of the country, there are, in fact, a small but growing number of

hospitals and organ procurement organizations that are performing at high levels in obtaining consent for organ donation. These organizations are the “mavens” of organ donation – they have the knowledge and commitment to build momentum toward a tipping point for organ donation.<sup>19</sup>

## DONATION MAVENS

As part of the DHHS Gift of Life Donation Initiative, the Health Resources and Services Administration (HRSA) launched in April 2003 the “Organ Donation Breakthrough Collaborative” to identify and promote best practices in organ donation for adoption by hospitals and OPOs. The goal of the initiative is to raise the overall average donor conversion rate – the percentage of potential donors who become actual donors – to 75 percent among the hospitals and OPOs participating in the Collaborative, and to ultimately “spread” that success across all hospitals with significant donor potential.





In its first phase – in which 95 hospitals and 42 OPOs are participating – the Collaborative’s achievements include improved performance on a variety of organ donation measures, such as timely notifications to the OPO of potential donors, utilization of appropriate requestors for donation, and increases in the numbers of referred donors and rates of organ donation conversion.<sup>20</sup>

In launching the Collaborative, best practices were first identified through data analysis, site visits, and in-person interviews. Through this process, six OPOs and 16 affiliated hospitals were selected as among the organ donation high performers.<sup>21</sup> While these six organ donation “partnerships” vary in their organ donation practices, the common theme is their cultural commitment to organ donation. Organ donation is fully integrated into what these organizations do on a daily basis. The select six, taken from the HRSA final report, are:

- New England Organ Bank (Newton, Mass.) and Beth Israel Deaconess Hospital, Boston Medical Center, Brigham and Women’s Hospital, Massachusetts General Hospital (all in Boston)

- LifeLink of Florida (Tampa, Fla.) and Lakeland Regional Medical Center (Lakeland), Tampa General Hospital (Tampa)
- University of Wisconsin Hospital & Clinics Organ Procurement Organization (Madison, Wis.) and Gundersen Lutheran Hospital (Lacrosse), Theda Clark Regional Medical Center (Neenah), University of Wisconsin Hospital & Clinics (Madison)
- Mid-America Transplant Services (St. Louis, Mo.) and Barnes-Jewish Hospital, St. John’s Mercy Medical Center (St. Louis)
- LifeGift Organ Donation Center (Houston, Tx.) and Ben Taub General Hospital, Memorial Herman Hospital (Houston)
- Donor Alliance (Denver, Co.) and Denver Health Medical Center, Memorial Hospital (Colorado Springs), St. Anthony Central Hospital (Denver)



THE IMPORTANCE OF LEADERSHIP — FROM THE TOP ON DOWN — IN CREATING A CULTURE SUPPORTIVE OF ORGAN DONATION CANNOT BE OVERSTATED.



## WHAT WORKS

Based on the study of these six successful partnerships between OPOs and hospitals, the Collaborative's final report on best practices delineates seven overarching principles and 15 specific practices for increasing the rate of organ donation.

### The seven overarching principles are:

1. Integrate organ donation fully into routine roles and responsibilities.
2. Set high standards for donation performance to reduce the unacceptable shortage of live-saving organs.
3. Involve OPO and hospital staff in ongoing standards setting and redesign of means to achieve these standards.
4. Hold OPOs, hospitals, and their staff accountable for achieving these standards and recognize the staff accordingly.
5. Establish, maintain, and revitalize a network of interpersonal relationships and trust involving OPO and hospital staff, donor families, and other key agents.
6. Collaborate to meet the range of needs of potential donor families and achieve informed consent to donate.
7. Conduct ongoing data collection and feedback to drive decision-making toward performance improvement.

### The 15 best practices are:

1. Orient organizational mission and goals toward increasing organ donation.
2. Do not be satisfied with the status quo; innovate and experiment continuously.
3. Strive to recruit and retain highly motivated and skilled staff.
4. Appoint members to OPO board who can help achieve organ donation goals.
5. Specialize roles to maximize performance.
6. Tailor or adapt the organ donation process to complementary strengths of OPO and individual hospitals.
7. Be there: integrate OPO staff into the fabric of high potential hospitals.
8. Identify and support organ donation champions at various hospital levels; include leaders who are willing to be called upon to overcome barriers to organ donation in real time.
9. All aboard: secure and maintain buy-in at all levels of hospital staff and across departments/functions that affect organ donation.
10. Educate constantly; tailor and accommodate to staff needs, requests, and constraints.
11. Design, implement, and monitor public education and outreach efforts to achieve informed consent and other donation goals.
12. Referral: anticipate, don't hesitate, call early even when in doubt.
13. Draw on respective OPO and hospital strengths to establish an integrated consent process. One size does not fit all, but getting to an informed "yes" is paramount.
14. Use data to drive decision-making.
15. Follow up in a timely and systematic manner. Don't let any issues fester.

For a detailed description of these best practices, see the complete report at [www.organdonor.gov](http://www.organdonor.gov).





## WINNERS AND LEADERS

The importance of leadership – from the top on down – in creating a culture supportive of organ donation cannot be overstated.

Leadership commitment lies at the core of Houston-based Memorial Hermann Hospital’s achievement of becoming among the nation’s best-performing donor hospitals. In the words of hospital CEO Jim Salyer, “Organ donation is woven into our hospital.”<sup>22</sup> Among the ways in which organ donation has become part of the fabric of the organization has been the tone set by senior leaders. These leaders set the expectations for hospital performance on organ donation consent and conversion rates, and then closely monitor those rates. This tone is further reinforced through the close partnership the hospital has with its OPO, LifeGift Organ Donation Center in Houston, with whom Memorial Hermann shares joint accountability for its organ donation performance.

The close collaboration between LifeGift staff and Memorial Hermann leaders has allowed the OPO to work at all levels of the organization – with medical staff committees, the quality improvement unit, and individual clinicians, administrators, and volunteers – to ensure that best practices for organ donation and recovery are a way of institutional life. In turn, Memorial Hermann’s senior leaders are actively involved on the LifeGift Board, and support its public policy and volunteer activities to help further the organ donation cause. One of the most important factors in increasing Memorial Hermann’s rate of organ donation has been their willingness to have an

in-hospital coordinator program for organ procurement. LifeGift staff has their own office within the hospital and work there in support of organ procurement on a continuous basis. LifeGift also has an in-house coordinator program in Houston’s other Level I Trauma Center, Ben Taub General Hospital.

Because of their patient demographics and patient volume, the 231 Level I Trauma Centers in this country are five times more likely to be donor hospitals than other hospitals.<sup>23</sup> However, the potential for organ donation in these hospitals is often hindered by the constrained resources and complexity of these organizations. LifeGift’s work with the two Level I Trauma Centers in Houston has been groundbreaking in providing the evidence-base that underscores the role of the in-hospital organ procurement coordinator in these complex environments.

LifeGift has placed two in-hospital coordinators in each of the Houston Trauma Centers.<sup>24</sup> The in-hospital coordinators are LifeGift staff – nurses who are trained as organ procurement coordinators.<sup>25</sup> They are responsible for specific activities that include encouragement of early referral and evaluation of potential donors; donor family coordination and contact before brain death; expert donor management; and hospital staff education.<sup>26</sup> With appropriate sensitivity to racial and ethnic disparities in organ donation, efforts are also made to match “like requestors” – those of the same cultural or ethnic group – with the potential donor’s family.<sup>27</sup>





Over a six-year period, consent for organ donation has climbed 37 percent to reach a 67 percent consent rate at the two hospitals.<sup>28</sup> This increase encompasses all ethnic groups. For African Americans, the rate of consent climbed to 60 percent – an astonishing 88 percent increase from the days before the in-hospital coordinator program.<sup>29</sup> Hispanic consent rates have risen 34 percent to a level of 63 percent during the six-year period.<sup>30</sup> As another measure of success, there were no missed referrals of potential organ donors at either of the trauma centers.

Managing the organ donation process from the inside – rather than from the outside, as most OPOs do today – clearly has positive impacts in promoting organ donation.<sup>31</sup> At the same time, where in-hospital coordinator programs exist, adherence to ethical standards is essential for maintaining the public’s trust. Thus, it is imperative that the in-hospital coordinator’s identity as OPO staff be transparent to the families of patients with whom they have contact. In-hospital coordinators should also perform only those duties that fall within the roles and responsibilities of organ procurement coordinators and that are conducted under the aegis of the OPO.

While successful where they exist, in-hospital coordinator programs do introduce new costs and are less feasible where OPOs are affiliated with hundreds of hospitals across a large region.<sup>32</sup> Given the potential yield of organ donors from large trauma centers, focusing resources on these organizations may provide the best business case for an in-hospital coordinator program.

## EMPHASIZING EDUCATION

At Health First, a health system based in Melbourne, Fla., organ donation rates dramatically increased after the launch of an organ donation program that emphasized staff education and community outreach.<sup>33</sup> Health First worked with its affiliated OPO to educate executive leaders, board members and staff.<sup>34</sup> Staff from across the organization, including those not directly involved in any way with the organ donation process, received education, since their attitudes would nevertheless shape the culture of the organization.<sup>35</sup> In fact, even among people working in health care settings, there are many misconceptions about organ donation and transplantation.<sup>36</sup>

Hospital culture can have a significant impact on hospital employees’ attitudes toward donation, as well as on the attitudes of donor families. A family that is not treated well in the emergency department or the ICU – perhaps enduring a long wait in the midst of a traumatic event, with infrequent or brusque communications with the staff – may have this negative experience color their receptivity to a later request for donation.

Staff in hospital areas in which the prospect for organ donation is high, such as the Emergency Department and Intensive Care Unit, should receive focused education, so they are better prepared to work cooperatively with OPO staff, as well as with potential donors and their families.



The Health First organ donation program also includes community outreach.<sup>37</sup> Hospital workers volunteer for a multi-disciplinary committee that includes executive leaders and OPO representatives. The committee meets monthly, and plans and partakes in community events to raise awareness. These may include speaking at drivers' education classes and church functions, among others. Committee members also act as in-hospital champions for organ donation, circulating newsletters and participating in new employee orientations and other educational activities. Since the inception of its donor awareness program, Health First reports a 500 percent increase in the rate of organ donation over a four-year period.<sup>38</sup>

## FAME IN SPAIN

An oft-cited organ donation success story is the “Spanish Model.” Over a ten-year period, the rate of organ donation in Spain rose 146 percent to the highest rate of organ donation per million people in the world – 33.6 donors per million as compared to 21.8 per million people in the U.S.<sup>39</sup>

While Spain has an “opt-out” system of Presumed Consent for organ donation, it is not enforced. In fact, Spain’s laws and practices respecting organ donation are similar to those in the U.S. and other western countries. Following brain death, organs can only be retrieved after obtaining consent from the family, and no compensation can be provided for donated organs. The increase in organ donation in Spain was not driven by statutory changes, and there has not been an increased reliance on living donors to fill the donation gap as there has been in the U.S. Almost all – 99 percent – of organ donations in Spain are from deceased donors.<sup>40</sup>

Spain’s success can be attributed to the creation of the National Transplant Organization (ONT) in 1989, and its network of specially trained physicians who are paid to work as hospital transplant coordinators. These physicians work part-time as transplant coordinators while they maintain their medical practices – primarily as intensivists or nephrologists.<sup>41</sup> These physicians are responsible for identifying potential donors, managing donors and approaching families.<sup>42</sup>



...HOSPITAL CULTURE CAN HAVE A SIGNIFICANT IMPACT ON HOSPITAL EMPLOYEES' ATTITUDES TOWARD DONATION, AS WELL AS ON THE ATTITUDES OF DONOR FAMILIES.



They are not part of the hospital's transplant team but do report directly to the hospital director, even though they are functionally linked with the OPO and have clear accountabilities for improving organ donation.<sup>43</sup> The OPO serves as a support agency, providing training, maintaining the waiting list and transplant registries, and performing other administrative functions.<sup>44</sup>

The physicians who serve as transplant coordinators are characterized as extremely dedicated and committed to the improvement of organ donation. However, to fend off burnout, which is a prevalent risk in the job, transplant coordinators receive ongoing training and support, or "revitalization."<sup>45</sup>

The success of the transplant coordinator role in Spain is also due in large part to the culture in which these individuals practice. This makes duplication of the Spanish Model in other countries challenging. Paying physicians to work part-time as transplant coordinators in the U.S. would be difficult because the practicing physician's earning power here is far greater than it is for physicians practicing in Spain.<sup>46</sup> Further, Spain has more physicians per capita than the U.S., which lessens the patient care demands per physician.<sup>47</sup>

Countries that share characteristics of the Spanish health care infrastructure, such as Italy, have been able to duplicate the Spanish Model to some extent.<sup>48</sup>

## CARROTS AND STICKS

Altruism has certainly been a major motivator underlying the creation of hospital cultures that drive successful organ donation programs.

But where altruism may not be a sufficient driver, regulatory, accountability and financial alignment mechanisms need to be mobilized to help close the donation gap.

Centers for Medicare & Medicaid Services (CMS) requirements stipulate that patient deaths and imminent deaths, be reported to the hospital's OPO, and that a request for organ donation be made by the OPO representative or another specially trained requestor. Joint Commission standards for hospital accreditation mirror these requirements. Many report that these requirements have improved hospital performance in identifying potential organ donors and in interacting with OPOs.

In order to strengthen the impact that the accreditation process can have in fostering higher organ donation conversion rates, the Joint Commission plans to develop standards language that will require hospitals having donor potential to continuously measure, assess and improve their organ donation conversion rates as part of their ongoing performance improvement activities. By tracking their organ donation conversion rates, hospitals will be better able to gauge the accuracy of potential donor identification, the timeliness of notification to the OPO, timeliness of OPO response, and the effectiveness of donor maintenance. This measurement and assessment activity will require collaboration between hospitals and their affiliated OPOs.



These performance assessment and improvement efforts would be enhanced by the ability to compare performance across hospitals. However, this capability awaits the development and National Quality Forum endorsement of a set of standardized consensus measures for organ donation and transplantation.

Meanwhile, there are significant financial disincentives for hospitals to promote organ donation. Maintaining organ donors in ICUs is expensive. And today, like solid organs, the relatively short supply of ICU beds is in high demand across the country. An organ donor may spend as much as two days occupying a much-needed ICU bed. Currently, CMS only reimburses hospitals for costs related to maintenance of potential donors following the declaration of brain death. To encourage hospitals to notify OPOs of all imminent deaths, CMS is considering a change in policy that would allow payment under certain circumstances prior to the declaration of brain death. This change could remove a major barrier to organ donation in hospitals. Nevertheless, whatever the eventual disposition of this issue, affiliated OPO and hospital staffs should work cooperatively to establish agreed upon “clinical triggers” for identifying potential candidates for organ donation as early as possible.

Perhaps where carrots and sticks converge – the nascent public and private sector “pay for performance” initiatives – will provide a new opportunity to instill even greater hospital accountability for organ donation while also rewarding hospitals for higher donation rates. In 2003, CMS began a demonstration project, in partnership with Premier Inc., to test the effectiveness of paying more for better performance according to selected measures. Small but symbolically significant bonuses will be based on results in the management of specific clinical conditions and procedures, i.e., heart attack, heart failure, hip and knee replacement, pneumonia, and coronary artery bypass graft.

Other than the CMS demonstration project, hospitals have generally been paid the same federal dollar whether the level of care, however defined, is truly exemplary or clearly substandard. This obviously offers little incentive for what many consider to be much needed improvements in the safety and quality of health care that is being delivered today. The pay for performance concept essentially envisions rewards for desired behaviors and outcomes. This could at the least provide an additional new stimulus for increasing organ donation rates.



WHERE ALTRUISM MAY NOT BE A SUFFICIENT DRIVER, REGULATORY, ACCOUNTABILITY AND FINANCIAL ALIGNMENT MECHANISMS NEED TO BE MOBILIZED TO HELP CLOSE THE DONATION GAP.



## RECOMMENDATIONS TO CREATE A CULTURE IN WHICH ORGAN DONATION IS A PRIORITY:

TACTICS	ACCOUNTABILITY
<ul style="list-style-type: none"> <li>• Focus resources for improving organ donation rates on the hospitals with the greatest potential to yield organ donors.</li> </ul>	<ul style="list-style-type: none"> <li>➔ OPOs, DHHS, Joint Commission, UNOS, professional societies and associations</li> </ul>
<ul style="list-style-type: none"> <li>• Encourage physicians and hospital staff to work in partnership with OPOs to optimize the rate of organ donation.</li> </ul>	<ul style="list-style-type: none"> <li>➔ CMS, Joint Commission, hospital management, professional societies</li> </ul>
<ul style="list-style-type: none"> <li>• Follow the Leaders – implement the HRSA/Organ Donation Breakthrough Collaborative’s Best Practices.</li> </ul>	<ul style="list-style-type: none"> <li>➔ donor hospitals, OPOs</li> </ul>
<ul style="list-style-type: none"> <li>• Place in-hospital coordinators in Level I Trauma Centers wherever it is economically and logistically feasible.</li> </ul>	<ul style="list-style-type: none"> <li>➔ OPOs and donor hospitals</li> </ul>
<ul style="list-style-type: none"> <li>• Use ethnically “like requestors” whenever possible, and foster the cultural competency among other requestors.</li> </ul>	<ul style="list-style-type: none"> <li>➔ OPOs and donor hospitals</li> </ul>
<ul style="list-style-type: none"> <li>• Make organ donation a priority – from the top of health care organizations on down.</li> </ul>	<ul style="list-style-type: none"> <li>➔ donor hospital leaders, CMS and Joint Commission</li> </ul>
<ul style="list-style-type: none"> <li>• Educate all hospital leaders and staff on organ donation practices to dispel myths and inspire enthusiasm.</li> </ul>	<ul style="list-style-type: none"> <li>➔ hospital leaders and managers, OPO staff</li> </ul>
<ul style="list-style-type: none"> <li>• Change CMS policy to provide for the reimbursement of costs related to maintaining potential organ donors prior to declaration of death.</li> </ul>	<ul style="list-style-type: none"> <li>➔ CMS</li> </ul>
<ul style="list-style-type: none"> <li>• Make organ donation a criterion in public sector pay-for-performance models.</li> </ul>	<ul style="list-style-type: none"> <li>➔ CMS</li> </ul>
<ul style="list-style-type: none"> <li>• Develop and implement new requirements for the periodic assessment and improvement of organ donation conversion rates.</li> </ul>	<ul style="list-style-type: none"> <li>➔ CMS, Joint Commission</li> </ul>
<ul style="list-style-type: none"> <li>• Develop standardized consensus measures respecting organ donation performance</li> </ul>	<ul style="list-style-type: none"> <li>➔ AHRQ, Joint Commission, CMS, NQF</li> </ul>



## II. BRING EQUITY, FAIRNESS AND SAFETY TO THE TRANSPLANTATION PROCESS

### THE POWER OF CONTEXT<sup>49</sup>

There are indisputably substantial disparities between the experiences of white Americans and those of other minority groups when it comes to organ transplantation. African Americans in need of a kidney transplant are less than half as likely to receive one than their white counterparts.<sup>50,51</sup> Black patients receive fewer, and later, referrals for transplantation than white patients.<sup>52</sup> And once placed on the waiting list for transplantation, blacks wait more than twice as long for an organ; have five-year graft survival rates 10 to 20 percent lower than other racial/ethnic groups; and receive far fewer (14 percent) living donations than whites (78 percent).<sup>53</sup> There are contextual factors – social, economic, health, and policy – that impede minority group access to organ transplantation and affect the success of transplants once made.

What was widely evident – though less widely acknowledged – the recent IOM report, *Unequal Treatment*, made clear: Distinct disparities exist both with respect to access and to the quality of health care for racial and ethnic minorities, regardless of their insurance status or ability to pay.<sup>54</sup> The IOM report points to personal bias on the part of caregivers as one obvious contributor to these disparities, although such bias may be subconscious in many instances. Subconscious bias allows for the flourishing of “institutional racism,”<sup>55</sup> in which unequal treatment exists de facto without acknowledgment or abatement. African Americans, as well as Native

Americans and Hispanics, are at a much higher risk of end-stage renal disease (ESRD) than any other ethnicity because of their predilection to diabetes, and for African Americans, hypertension, as well. Representing 12 percent of the overall U.S. population, African Americans account for more than 35 percent of patients awaiting a kidney donation.<sup>56</sup> Whereas white ESRD patients wait an average of 675 days to receive a suitable kidney, black patients wait an average of 1603 days.<sup>57</sup> This delay is due in large part to current protocols for HLA (human leukocyte antigen) matching.

The current schemata for organ allocation give zero HLA-mismatched kidney candidates national priority regardless of geographic region or points accrued through other measures of the allocation algorithm.<sup>58</sup> The donor pool predominantly comprises Caucasians; thus, transplant candidates with the greatest genetic similarities to the donor pool are much more likely to be matched.<sup>59</sup> Patients with optimally matched kidneys receive transplants within the shortest timeframes. Conversely, those difficult to match wait longer, and are ultimately more likely to receive a poorly matched kidney.<sup>60</sup>

Diversifying the donor pool by increasing the rate of donation among ethnic and minority Americans is one way to help equalize the opportunity for timely transplantation and good outcomes. Changes in allocation policies present other potential solutions.





A recent change in the kidney allocation algorithm that eliminates the priority for the HLA-B locus has the potential to raise transplantation rates among minorities, without having a significant adverse impact on graft survival.<sup>61</sup> This reprioritization of HLA matching could potentially increase the rate of transplantation among non-whites by 6.3 percent, while decreasing the number of transplantations among whites by 4.0 percent.<sup>62</sup>

Time on the waiting list is another priority in the kidney allocation algorithm. Since African-Americans wait longer on dialysis before being put on the transplant waiting list than their majority counterparts, proposals for beginning the “wait-time” for an organ at the time a patient is placed on maintenance dialysis could also help to equalize access to transplantation.<sup>63</sup> Periodic re-evaluation of the allocation algorithm is warranted as the waiting list continues to expand, and new information becomes available regarding its impact on access to transplantation.<sup>64</sup>

Some of the reasons for transplant-related disparities are better understood than others, and targeted research efforts are therefore warranted. At the same time, greater understanding of the causes of disparate results must be

accompanied by the will for social change. As the IOM report makes clear, greater diversification of the health care workforce; improved cultural competency among clinicians and in provider organizations; public education aimed at raising health literacy; and improved access to health care for racial and ethnic minorities are among the highest priorities for achieving equal care in this country.

Today, perhaps the most difficult hurdle to overcome in providing for equal access to transplantation is the “green screen”<sup>65</sup> – the barrier to transplantation for people without the health insurance or material wealth to pay for the surgery and subsequent drug therapy. Regardless of race or ethnicity, an individual’s ability to pay is among the first screening, or screening out, criteria. To some extent, this screening serves a practical purpose in protecting the utilization and longevity of a valuable commodity – the procured organ. Experience has shown that once insurance coverage for immunosuppressive therapy ends, some transplant patients became non-compliant because they cannot afford the expensive drug therapy on their own. Ultimately, transplanted organs in these patients are rejected, and they end up back on the waiting list.



**THERE ARE CONTEXTUAL FACTORS — SOCIAL, ECONOMIC, HEALTH, AND POLICY — THAT IMPEDE MINORITY GROUP ACCESS TO ORGAN TRANSPLANTATION AND AFFECT THE SUCCESS OF TRANSPLANTS ONCE MADE.**





The logic in support of a life-time immunosuppressive drug benefit is compelling in light of the costs of retransplantation and, for kidney patients, maintenance dialysis during the intervening period. Medicare has extended such coverage for Medicare beneficiaries, but gaps in coverage remain. For those who are eligible for Medicare solely on the basis of their end-stage renal disease (ESRD), coverage ends after three years. And those who were not Medicare-eligible at the time of transplant, but become eligible because of age or disability, do not receive any immunosuppressive drug coverage. Without universal coverage, transplantation remains an option for some, but not all.

## REACHING OUT

The national Minority Organ and Tissue Transplant Education Program (MOTTEP) is reaching out to minority communities to increase their awareness and acceptance of organ donation, and to provide health education to prevent the onset of diseases that eventually drive the need for transplantation. Stemming from the successful initial efforts of its founders to increase organ donation among black Americans, MOTTEP has expanded the scope of its efforts to encompass all minority populations, including Latinos, Native Americans, Alaskan Natives, Asians and Pacific Islanders.

MOTTEP uses grassroot efforts to reach minority communities. Through the creation of volunteer community programs and engagement of local churches and other community groups, MOTTEP has been able to dispel myths and concerns that people have

about organ donation. Today, the minority donation rate has nearly doubled – to 28.5 percent from 15 percent – in the last 15 years.<sup>66</sup> In 2003, minority donation rates showed even more substantial growth – up 13 percent for Hispanics and 11 percent for African Americans in just one year.<sup>67</sup>

With the same grassroots approach, MOTTEP is also working to prevent the need for transplantation by encouraging individuals in minority communities to adopt healthy behaviors, such as eating well and exercising, and avoiding drugs and alcohol.

## DISABLED AND DISENFRANCHISED

The world of organ transplantation is also a harsh environment for people with mental and physical disabilities. When this new treatment option was first introduced, individuals with disabilities were automatically excluded from consideration for transplantation.<sup>68</sup> The basis for this exclusion was the perception of worthiness against the reality of scarcity – “a valuable organ for an unvalued life.”

Since passage of the Americans with Disabilities Act and the establishment of related federal regulations, discrimination against persons with disabilities in medical treatment is prohibited. But, despite the legal protections offered to persons with disabilities, many still face significant hurdles to being assessed for, wait-listed, and eventually receiving donor organs.



The first earnest – and very public – fight for transplantation for persons with mental disabilities began in 1995. Sandra Jensen, a 34 year-old woman with Down’s Syndrome and a terminal cardiac condition, was recommended for a heart/lung transplant by her attending physician as the only means to save her life.<sup>69</sup> Her insurer, MediCal, approved the request with the requirement that it be performed at one of its two designated California transplant centers.<sup>70</sup> Both centers refused Sandra.<sup>71</sup> One of the hospitals denied Sandra’s request without ever having met or examined her.<sup>72</sup> The position of this hospital was that people with Down’s Syndrome were not appropriate candidates for heart/lung transplants.<sup>73</sup> The other hospital did consider Sandra’s case; however, while finding no medical basis for excluding her, it determined that she would be unable to understand the procedures and to follow complex medical regimens.<sup>74</sup>

The inability to follow medical regimens and the lack of support systems are the two criteria commonly used to screen out patients with disabilities from transplant waiting lists.<sup>75</sup> In Sandra’s case, they picked on the wrong patient. According to Dr. William Bronston, who worked alongside Sandra to defend her cause, Sandra was highly accomplished, working on behalf of disability rights causes and

living independently all of her adult life. She had a close-knit family and a large network of friends and colleagues. In fact, with the help of these friends and colleagues, and her own determination, Sandra’s fight became national news. The pressure of the publicity eventually drove one of the hospitals into submission. Sandra received her heart and lung transplant – the first of its kind in the world – and opened a window for the disability community.

There are, of course, patients for whom a denial of transplantation may be justified – perhaps if only temporarily – if they cannot follow the necessary post-transplant regimens and lack necessary support systems. The legacy of Sandra’s case is that, in the words of her transplant surgeon, “We should never judge who is worthy by a generalization. Each person deserves to be evaluated as an individual.”<sup>76</sup>

Since Sandra, others with disabilities have received life-saving or enhancing transplants. The exact number is not known; however, what is known is that many people with disabilities are still denied evaluation and referral for transplantation at the primary care level.<sup>77</sup>



...DESPITE THE LEGAL PROTECTIONS OFFERED TO PERSONS WITH DISABILITIES, MANY STILL FACE SIGNIFICANT HURDLES TO BEING ASSESSED FOR, WAIT-LISTED, AND EVENTUALLY RECEIVING DONOR ORGANS.



Even if that hurdle is cleared, these individuals may still be excluded from transplantation by transplant professionals who lack specific expertise in evaluating and determining the capabilities of disabled persons to comply with post-surgical regimens.<sup>78</sup>

In 2003, The National Work Group on Disability and Transplantation was formed to address issues of access, equity and training in order to – in part – promote better understanding and treatment for persons with mental and physical disabilities. The Work Group is also pursuing a national research agenda to determine the level of access persons with disabilities have to transplantation in relation to their needs.

An initial Web-based survey of persons with disabilities and/or their family members, which was administered by the Work Group, found that 80 percent of the 205 respondents believe that people with disabilities are denied access in obtaining organ and tissue transplants because of stereotypes and negative attitudes toward the physically and mentally disabled populations.<sup>79</sup> For these respondents, there is both good news and bad news. Of the 139 respondents that were referred to a transplant center for evaluation, 55 percent were told transplantation was an option; while 45 percent were told it was not an option.<sup>80</sup> For the latter group, some of the reasons given were, “...because she has Down’s Syndrome.” And, “...if he were normal like us, he’d be a great candidate...”<sup>81</sup> One respondent – after their son was denied a liver transplant despite a determination of medical suitability – enlisted the Justice Department’s help and was able to get the denial reversed.<sup>82</sup>

Perceptions of “worthiness” are not simply an issue for the medical community and transplant system gatekeepers; it is an issue for families of disabled persons as well. Among the survey respondents, 44 percent of families did not pursue seeking a referral to a specialist or transplant center from their primary care physician.<sup>83</sup> Perceptions relating to quality of life and the value of that life color the expectations and decisions of many family members and caregivers of disabled persons, and buttress the existing biases in society at-large. Disincentives created by financial barriers loom large as well – 58 percent of survey respondents reported having no coverage, or only partial coverage for transplantation care.<sup>84</sup>

With the proper recognition and support of the health care community, people with disabilities, as well as their families and advocates, can improve access to transplantation by becoming organ donors themselves. Increasing organ donation ultimately means there will be more organs available for everyone.

## AMONG THE LIVING

Since 2001, the number of living donors has surpassed deceased donors (6,618 vs. 6,182), almost entirely due to living kidney donation (94%), although the rate of growth in living donation has dramatically slowed.<sup>85</sup> Deceased donors still provide the greatest number of donated organs, but for kidneys in particular, living donation has provided a much needed increase in the supply, particularly of high quality organs. However, from 2001 to 2002, the number of living liver donations markedly decreased – falling from 518 to 358 (-30%).<sup>86</sup>



Following the highly publicized deaths of two living liver donors, concerns have been raised about the safety of living donation for the donor. Although data on complication and mortality rates for living donors have not been regularly collected, aggregated and tracked, estimates of adult-to-adult living liver donor mortality are as high as one percent.<sup>87</sup> Researchers have estimated that one in three liver donors suffers a medical complication, and half of those are serious complications.<sup>88</sup> Another study discovered that 30 percent of liver donors had to be rehospitalized.<sup>89</sup> This same study also found that the typical living liver donor is hospitalized for about 10 days, takes 2.5 months off from work, and needs another month for full recovery.<sup>90</sup> A definitive study by the National Institutes of Health has been initiated to determine the outcomes of living liver donations for both donors and recipients. The study – which will run for seven years at a cost of over \$2 million per year – will provide information upon which to base the creation of guidelines for screening potential donors and for the performance of these transplant surgeries.

Living kidney donation, though considered a safe procedure at the time of donation, may also have impacts on the donors later in life. As of 2002, 56 kidney donors have themselves later needed kidney transplantation.<sup>91</sup>

The causes of renal failure among these donors are not yet fully understood.

Most living donors do not regret their decisions, but some indicate that the full risks respecting their surgeries were not revealed to them.<sup>92</sup> To begin to understand the full ramifications of living donation, many in the transplant community, as well as other authorities such as the ACOT, have suggested that a national registry of living donors be established. This, it is suggested, would expand knowledge about complication rates and other health outcomes. Armed with this information, health care practitioners could more accurately portray the risks, both long and short term, to potential living donors.

The recent donor deaths have also raised concerns about the processes through which living donors consent to donation. A potential living donor may be subject to the implicit coercion of the patient, the patient's family members, and the transplant team, all of whom are highly motivated to secure the donation. In New York, the State Health Department has created new rules for living donors, including a requirement that each living donor be assigned a team of advisors, independent of the transplant team, to help the donor reach an informed decision about donation.



**MOST LIVING DONORS DO NOT REGRET THEIR DECISIONS, BUT SOME INDICATE THAT THE FULL RISKS RESPECTING THEIR SURGERIES WERE NOT REVEALED TO THEM.**



Under the Health Department's rules, the living donor's team of advisors – which must include a physician, a nurse, a social worker and a psychiatrist – does not have the authority to overrule the donor's decision.

Truly obtaining informed consent requires independent advocacy to protect the best interests of the donor. It also requires the complete divulgence of risks. Through the creation of donor registries, or alternatively, through the conduct of cohort studies such as that being embarked upon by the NIH, the needed information for understanding the full risks to living donors can be secured.

## PLAYING FAIR

Living donors are patients. As such, they should receive the same attentive, high-quality care that transplant patients receive.<sup>93</sup> As the New York safeguards illustrate, advocacy for the living donor should extend beyond the consent process. These safeguards require minimum staffing requirements for transplant units, frequent donor-patient assessments by competent physicians, and lifetime follow-up care for donors.

As a means to encourage safe living donation, the Joint Commission recently expanded its patient safety consumer awareness campaign – entitled *Speak Up* – to help potential living organ donors make the process as safe as possible by becoming informed, active, and involved participants in their care. The new *Speak Up* brochure outlines basic facts about living organ donation, provides advice as to what the potential donor should ask his or her

doctor, and describes where to learn more about living donation. *Speak Up* brochures are available on the Joint Commission's website, [www.jcaho.org](http://www.jcaho.org).

In addition to the risks of grave harm, there are other disincentives to becoming a living donor. A living donor may be off work for weeks or months, thereby putting his or her job and income at risk. Following the example set by the Federal Organ Donor Leave Act, which provides Federal employees with 30 days of paid leave to be organ donors, America's other private and public employers need to adopt similar paid leave policies.

Actions are being taken to eliminate disincentives to organ donation. Groundbreaking legislation recently enacted in the state of Wisconsin provides living organ donors with a one-time state income tax deduction of up to \$10,000 to cover expenses for travel and lodging, as well as lost wages incurred in relation to donating an organ. This benefit necessarily is only available to those who pay state income taxes.

In March 2004, Congress passed, and the President subsequently signed into law, the Organ Donation and Recovery Improvement Act. This Act authorizes the DHHS to spend up to \$5 million per year to reimburse living donors for donation-related expenses. Beginning in 2005, the Act provides for an additional \$15 million in grants to support hospital and OPO activities that encourage organ donation.





Also at risk are living donors' future access to health and life insurance. Anecdotal experiences of living donors have described situations in which insurance companies have considered living donation a pre-existing condition, which can warrant insurance denials or significant premium surcharges.<sup>94</sup> Extension of recipients' insurance plans to cover donors should be a standard *quid pro quo* for donation. In the absence of private coverage, Federal insurance plans should be extended to living donors who can no longer qualify for insurance at reasonable rates on the open insurance market. In either case, these life-giving patients should be made whole following donation.

### SAFE AND SYSTEMS-BASED

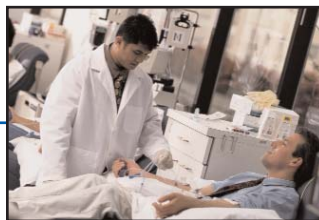
Medical error and patient safety issues are, unfortunately, ubiquitous in health care delivery environments. Highly publicized cases of disastrous error – such as the death of Jessica Santillan after being transplanted with improperly matched organs – have shown that organ donation and transplantation are as vulnerable to human error and failed systems as every other facet of health care.

Jesica's death was a clarion call to all transplant centers and their affiliated OPOs to

ensure that the proper checks and balances are in place to reduce the risk of medical error and assure patient safety.<sup>95</sup>

The system of organ placement between OPOs and hospitals is typically a verbal transaction – a phone call by the OPO that ends up with the acceptance or rejection of a matched organ. Systems based solely on “human perfection” are bound to fail.<sup>96</sup> Since Jesica's death, Duke University Hospital has designed a new system of multiple checks for compatibility. The Organ Procurement and Transplantation Network/United Network for Organ Sharing (OPTN/UNOS) has also updated its policies to require that two transplant center staff members independently verify blood type information.<sup>97</sup> Blood type data for donor and recipient must also be entered into the national database, verified by two individuals, and communicated to transplant teams.<sup>98</sup> Further, organ offers can only be made from the computer-generated “match run.”<sup>99</sup>

The use of information technology systems that support electronic sharing of information between OPOs and transplant centers should not only help to eliminate errors, but also accelerate the entire process of organ recovery and placement.



**LIVING DONORS ARE PATIENTS. AS SUCH, THEY SHOULD RECEIVE THE SAME ATTENTIVE, HIGH-QUALITY CARE THAT TRANSPLANT PATIENTS RECEIVE.**



Using such a system, One Legacy, the OPO based in Southern California, has been able to increase the number of organs recovered per donor by 12 percent.<sup>100</sup> The One Legacy system connects organ procurement coordinators equipped with portable technology in the field, with transplant coordinators and surgeons at transplant centers via a secure Internet portal. Through this connection, the OPO coordinators can electronically post for transplant center viewing donor-related information, including ABO confirmation and serology results, and digital images of donor organs. Automation of these processes speeds the recovery and placement of organs, which ultimately extends organ viability for transplantation. Along with increased donor yield, One Legacy's return on investment in this technology includes the realization of \$2.1 million in incremental revenues within the first year following implementation.<sup>101</sup>

One Legacy's use of information technology has led to an increase in its organ recovery rate from an average of 3.24 organs per donor to 3.63 per donor. The national average for organ yield per donor is 3.6, out of a possible eight transplantable organs.<sup>102</sup> In 2002, consent was obtained for 41,273 organs, but only 22,460 were recovered.<sup>103</sup> The most common reason given for non-recovered organs is "poor quality."<sup>104</sup>

Increasing the average number of organs recovered per donor could have a profound impact on the supply of available organs. Information technology is only part of the solution. As the underlying science has evolved, evidence-based practices for organ recovery and for

determination of organ suitability for transplantation could be further developed, standardized and disseminated. Today, these practices are subjective and variable.<sup>105</sup>

This variability extends to the rate of transplantation once organs are recovered. In 2002, 1,275 kidneys and 333 pancreases were recovered but not used.<sup>107</sup> This wastage is in part a function of logistics – organs that were recovered before they were matched to a recipient, or the elapse of too much time between recovery and disposition. However, there is much variation in transplant practices, particularly with regard to the use of organs from extended criteria donors – older donors or those with health issues that would have previously excluded them from donation. This makes the rates of non-utilized organs highly variable by region. For instance, 78 percent of all consented donors led to actual liver transplants, whereas in New York, livers were transplanted from 88 percent of consented donors.<sup>107</sup>

According to the OPTN/SRTR 2003 report, if New York's rate were replicated nationally, an additional 582 liver transplants would result.

Finally, transplanted organs and tissues can be life-enders rather than life-savers. Tissues containing hepatitis C and other deadly infectious agents have been transplanted, causing infection to many and death to some. Of 125,000 organ transplants performed between 1994 and 2001, there were 24 cases of donor-related cancer, 10 of which resulted in patient death.<sup>108</sup> Efforts to ascertain the integrity of procured organs must be given a much higher priority in the future, particularly in light of the increasing use of extended criteria donors.





## RECOMMENDATIONS TO BRING EQUITY, FAIRNESS AND SAFETY TO THE TRANSPLANTATION PROCESS

TACTICS	ACCOUNTABILITY
<ul style="list-style-type: none"> <li>• Employ grassroots efforts such as those used by MOTTEP to raise awareness, change behavior and increase the rate of donation among ethnic and minority groups, and among persons with disabilities and their families.</li> <li>• Periodically re-evaluate the priorities for organ allocation to identify opportunities to equalize access to transplantation.</li> <li>• Conduct further studies to enhance knowledge about the underlying causes of transplantation disparities and to create a basis for problem-solving.</li> <li>• Undertake initiatives (e.g. diversifying the health care workforce, improving health literacy) to reduce racial and ethnic disparities in access to transplantation.</li> <li>• Establish life-time immunosuppressive drug benefits for patients who have undergone successful organ transplantation.</li> <li>• Develop American with Disabilities Act compliance and clinical training materials and certification mechanisms to enhance health care professional knowledge and abilities to serve persons with disabilities.</li> <li>• Establish protocols for assessing the ability of disabled patients to comply with post-transplant regimens.</li> <li>• Establish a national living donor registry to track complications and outcomes, and to increase knowledge about the risks of such donations to donors.</li> </ul>	<ul style="list-style-type: none"> <li>➔ donation and transplantation professionals, health care professional societies, churches, schools, community-based organizations</li> <li>➔ UNOS, transplant community</li> <li>➔ IOM, AHRQ, foundations, academic health centers, health services research entities</li> <li>➔ federal and state governments, foundations, educational institutions, regulatory bodies, payers</li> <li>➔ Congress, CMS</li> <li>➔ American University Coalition on Disability, disability advocates, and professional organizations</li> <li>➔ American University Coalition on Disability, disability advocates, and professional organizations</li> <li>➔ NIH</li> </ul>



## RECOMMENDATIONS TO BRING EQUITY, FAIRNESS AND SAFETY TO THE TRANSPLANTATION PROCESS

TACTICS	ACCOUNTABILITY
<ul style="list-style-type: none"><li>• Establish requirements for living donor advocacy and protection that are independent of the transplant team.</li><li>• Provide employee leave policies for living donors.</li><li>• Extend recipients' private and/or federal life and health insurance plans to living donors.</li><li>• Adopt safe practices and systems for protecting the safety of patients and the integrity of procured organs.</li><li>• Develop and apply standardized IT systems and evidence-based practices that support determinations of organ suitability for transplantation and improve the rate and quality of organ recovery.</li></ul>	<ul style="list-style-type: none"><li>➔ federal and state regulatory agencies, Joint Commission</li><li>➔ all employers</li><li>➔ CMS, private sector health and life insurers</li><li>➔ OPOs, donor hospitals, transplant centers</li><li>➔ HRSA, NIH, AHRQ, OPOs</li></ul>



### III. TAKE ALTERNATIVE PATHS TO MEET THE DEMAND FOR ORGAN DONATION

#### THE STICKINESS FACTOR<sup>109</sup>

The Uniform Anatomical Gift Act was first enacted in 1968 to allow for the gifting of body parts. It was amended in 1987 to specifically encourage organ donation by making the gift of donation irrevocable, unless revoked by the donor before death. The amended Act further provides that the gift of donation does not require the consent or concurrence of any person after the donor's death. The intent of the revisions to the Act has been to make organ donation "stick." Yet, despite its enactment in 39 states, consent for organ donation is typically sought from family members following the potential donor's death, both in these states and elsewhere.

Why this right of "donor designation" is not always upheld seems to be a function of overzealous risk management and the endemic tradition of "honoring the wishes of the family." Fear of bad publicity and reprisals from wronged families, (i.e., "dead patients don't sue, their families do") has no apparent basis, since there is no evidence that any such suit related to organ donation has ever been successfully pursued. And, while many families consent to donation and later attest to the healing power of this life-giving act, this is, for many others, a difficult decision to make – as any decision is – at a time of such great crisis and sorrow.

Playing out the protections of the UAGA, as amended, and honoring the intentions of donors, when known, could increase the rate of organ donation. Further, enactment of the amended UAGA in the 11 states that currently have no such provisions, would nationalize "donor designation."

Upholding a donor's designated wishes is dependent on knowing those wishes in the first place. Donor cards and drivers' licenses may not be accessible at the time they are needed. This is why donor registries – central repositories of information on donor intent<sup>110</sup> – are important sources for evidence of consent. Currently, 33 states have active donor registries.<sup>111</sup> Typically, donor designations made through drivers' license application and renewal processes are used to populate these registries. Some states offer Internet-based and direct mail sign-up options as well. Expansion of donor registries across the nation, together with targeted public education to increase enrollment, could have a major impact in boosting organ donation.

#### MODELS OF DONATION

The onus of the donation decision is often placed on the family, because the potential donor did not sign a donor card, or make his or her wishes known. To address this problem, other social models for promoting organ donation have been developed. "Presumed Consent," for example, is an opt-out system – everyone is an organ donor unless they officially opt-out of the system.



The Presumed Consent model has been adopted in several European countries, although usually not in its pure form. In many of these countries, such as Spain, families are still approached about the decision to donate organs. When Sweden adopted the Presumed Consent model a few years ago, the number of individuals who registered as opposed to donation (52%) outnumbered those in favor of donation (48%).<sup>112</sup> Yet, in a survey of Swedish attitudes toward donation, 61 percent were in favor of donation; 18 percent were opposed.<sup>113</sup> Since the Swedish registry is an “opt-out” system, it is not surprising that those opposed to donation would be over-represented in the database.<sup>114</sup> In the absence of any information in the registry, individuals are presumed to be in favor of organ donation, although families may still deny the donation.<sup>115</sup>

“Mandated Choice” is a model that requires citizens to declare their intent to donate or not to donate. Under this model, leaving the donor portion of the driver’s license blank would no longer be an option. Thus, it is possible – even likely – that individuals wishing to delay the decision to another day may default to a “no,” and their families would probably honor that decision.<sup>116</sup>

Regardless of the model, avoiding “no” as the default position, requires aggressive public education and a nationwide effort to raise social awareness and identification with organ donation.

Finally, while explicit payment for donated organs is illegal in the U.S., many have speculated about the impact of offering incentives for organ donation, such as through the reimbursement of funeral expenses. Congressman James Greenwood (R-Pa.) has introduced a bill that would allow the DHHS Secretary to authorize demonstration projects to study the impact of financial incentives on organ donation. The American Medical Association and others have endorsed the pilot testing of “non-enriching” incentive programs for organ donation;<sup>117</sup> however, still other groups are opposed to such programs. Significant ethical hurdles to offering “non-enriching” incentives remain, not the least of which is the determination as to how “non-enriching” is defined. Indeed, perspectives on “non-enriching” may vary as a function of the economic status of the persons whom the incentive is meant to influence.

Without any evidence base to support or deny alternative social models or incentive programs for organ donation, regional demonstration projects in the U.S. may be warranted. However, pursuit of such demonstrations would require amendment of the National Organ Transplant Act.



## GAME, SET, MATCH

Living donors offer those awaiting transplantation, primarily for kidneys, their best chance to avoid languishing on the wait list. For so many potential recipients, living donors have stepped forward – spouses, siblings, children, parents and friends – but sometimes there is no match. Now, with the advent of living donor exchanges, donation and transplantation can still remain an option through a “rearrangement” of the donor/recipient pairs. These exchanges involve donors who are incompatible with their intended recipients, but choose to donate to other compatible recipients. In Washington D.C., two women have received kidneys that were exchanged by their husbands.<sup>118</sup> A father, who could not donate to his daughter, gave his kidney to a teenager. In turn, the teenager’s sister provided a kidney for the father’s daughter.<sup>119</sup> These exchanges are gratifying to the donors – who are able to help save the life of their intended recipients – and of course, to the recipients whose lives are saved.

There are “rules of engagement” for such exchanges.<sup>120</sup> The medical characteristics of the exchanged donors and recipients should be in balance to ensure relatively similar prospects for success. In addition, all clinical standards and evaluative criteria apply as they would with any living donation.<sup>121</sup> Both the

donors and recipients should be informed of all risks, including the prospect that one or both of the transplants may not succeed.<sup>122</sup> In New England, the donor and transplant surgeries of each exchanged pair occur simultaneously, even when at different transplant centers, to avoid the potential of one donor withdrawing after the other donor has already had his or her kidney removed.<sup>123</sup>

Regional databases, typically administered by OPOs, in which the unmatched donors and recipients are entered in as a pair, help to facilitate the identification of matched, living donor exchanges.<sup>124</sup>

## ALTERNATIVE SOURCES

In this country, organs are predominantly procured from patients who have been declared brain dead. With a long-term trend in reduced trauma-related deaths, and increased sensitivity to the delivery of futile care and the attendant early removal of ventilation support, the pool of potential organ donors among the brain-dead is dwindling. This has rekindled interest in donors after cardiac death (DCD, previously referred to as non-heart-beating donors) as a potentially significant alternative source of donor organs. Providing the option of donation to these patients and their families could also be a gratifying step in their end-of-life care.



UPHOLDING A DONOR’S DESIGNATED WISHES IS DEPENDENT ON KNOWING  
THOSE WISHES IN THE FIRST PLACE.



Organ donation from DCDs was the standard when organ transplantation was first introduced. With the advent of the ability to definitively determine brain death and to technologically sustain all other organs, organ donation after cardiac death has been rare, averaging approximately one percent of donations through the 1990s.<sup>125</sup> Negative publicity stemming from hospital failures to decouple the management of cardiac death and withdrawal of life-sustaining treatment from the process of organ donation, has also raised ethical concerns that adversely impact the potential recovery of organs from such donors.

In 1997, and again in 2000, the IOM issued reports endorsing the use of donors after cardiac death.<sup>126</sup> Recognizing that there are complex ethical and medical issues inherent in managing the DCD, the IOM, in its 2000 report, made recommendations that specifically address transplantation practices and protocols respecting such donors. Among these, the IOM recommends that local protocols, devised by OPOs and hospitals, be established before such donations are considered; that the decision to withdraw life-sustaining treatment be made prior to initiating any discussion of donation; that adequate resources be provided to cover the costs associated with sustaining donation after cardiac death; and that funding be provided for relevant clinical and public education.

Recovery of organs from DCDs has recently grown – doubling in 2002 to 3.1 percent from 1.5 percent of donors in 1999.<sup>127</sup> Routine reliance on DCDs could increase the donor pool by as many as 2500-3000 donors.<sup>128</sup>

Bearing in mind the strong consensus in the expert community, hospitals should work with their affiliated OPOs to develop and implement policies that will facilitate expansion of organ recovery from DCDs.

## **CURBING DEMAND**

Increasing the pool of donors and the rate of donation even to optimal levels may still not be enough to meet the growing demand for organ transplantation. The prevalence of some of the conditions that lead to the need for transplantation – morbid obesity, hypertension and diabetes – continues to escalate across America. Unless more resources are invested in curbing these epidemics, the demand for organs will continue to spiral. Primary care interventions and disease management programs that cure, slow or contain the progression of diseases to organ failure need to be vigorously pursued.

Preventive screening is especially important in the early detection and treatment of conditions and diseases that culminate in organ failure. For instance, screening for high blood pressure and high cholesterol identify individuals at risk for hypertension and heart disease. The Department of Health and Human Services reports that of the estimated 17 million people with diabetes in this country, about 5.9 million are undiagnosed. Without diagnosis and treatment, diabetes can rapidly progress to kidney failure, blindness, heart disease and stroke. Aggressive management of tobacco, alcohol and drug addictions could also contribute to reducing the need for transplantation.





Beyond their roles in preventive screening and addiction management, managed care plans are the primary providers of, or access points to, disease management programs. Currently, 92 percent of private health plans and 81 percent of Medicaid-only plans operate two or more disease management programs.<sup>129</sup> Most commonly, disease management programs provide support to patients with diabetes, asthma, coronary artery disease, congestive heart failure and high-risk pregnancy.<sup>130</sup> In addition, Medicare is in the process of initiating disease management demonstration projects for congestive heart failure, diabetes, arthritis, hypertension, cancer, stroke, chronic obstructive pulmonary disease, hyperlipidemia, end-stage renal disease, and liver failure.<sup>131</sup>

Finally, while modern medicine has made great strides in preventing, treating and containing the dire consequences of many diseases, access to such health care interventions and even the most basic of primary care, is a continuing challenge for the 43 million currently uninsured individuals and the millions of others expected to join their ranks in the coming years.<sup>132</sup>

## INTO THE FUTURE

Once patients receive their life-saving transplants they often face new health risks. Immunosuppressive drug therapy is hard on the body. In fact, from seven to 20 percent of non-renal transplant patients experience chronic renal failure within five years of their transplants.<sup>133</sup> Studies have also shown a higher risk of post-transplant malignancy related to immunosuppression.<sup>134</sup> Continued efforts to improve immunosuppressive drugs in the short term to reduce undesirable side effects and adverse outcomes are warranted. Over the long term, new and emerging science and technologies offer the potential to alleviate the problems of graft rejection and failure, eliminate the risks born from immunosuppressive therapy, and even create alternative approaches to closing the organ donation gap.



PRIMARY CARE INTERVENTIONS AND DISEASE MANAGEMENT PROGRAMS THAT CURE, SLOW OR CONTAIN THE PROGRESSION OF DISEASES TO ORGAN FAILURE NEED TO BE VIGOROUSLY PURSUED.



Xenotransplantation – transplantation of animal organs into humans – is still highly experimental. Scientists – who have narrowed their current focus to the use of pig organs – continue to grapple with microbiologic safety and immunological barriers to xenotransplantation.<sup>135</sup> In addition, beyond immunological tolerance, the long-term viability of pig organs in the human body remains to be determined. Nevertheless, the ultimate success of xenotransplantation could provide a nearly limitless supply of donor organs.

Stem cell therapy also holds promise for the treatment of diseases that culminate in organ failure and for the regeneration of organs that now can only be replaced through transplantation. Such regeneration would also overcome the problems of chronic graft rejection and the need for potent immunosuppressive therapy and its side-effects. Through stem cell therapy, scientists have already been able to grow skin from a patient's strand of hair. By producing the equivalent of the patient's own skin, a burn patient is able to receive an

autologous graft that bypasses the rejection response.<sup>136</sup> Scientists have also regenerated corneas for the sight-impaired.<sup>137</sup> Further, progress is being made in experimental efforts to regenerate pancreatic function in diabetic patients, and similar work is being directed to regeneration of liver function.<sup>138</sup>



OVER THE LONG TERM, NEW AND EMERGING SCIENCE AND TECHNOLOGIES OFFER THE POTENTIAL TO ALLEVIATE THE PROBLEMS OF GRAFT REJECTION AND FAILURE, ELIMINATE THE RISKS BORN FROM IMMUNOSUPPRESSIVE THERAPY, AND EVEN CREATE ALTERNATIVE APPROACHES TO CLOSING THE ORGAN DONATION GAP.



## RECOMMENDATIONS TO TAKE ALTERNATIVE PATHS TO MEET THE DEMAND FOR ORGAN DONATION

TACTICS	ACCOUNTABILITY
<ul style="list-style-type: none"> <li>• Enforce the provisions of the amended UAGA that protect the intent of the organ donor without the concurrence or consent of the donor’s family.</li> <li>• Enact the amended UAGA in the 11 states that have not done so.</li> <li>• Implement donor registries in states currently without them and educate the public to increase enrollment.</li> <li>• Conduct demonstration projects, funded by federal and state governments, to test the impacts of alternative social programs on increasing donation rates and make public education a fundamental component of these demonstration projects.</li> <li>• Implement protocols for the recovery of organs from donors after cardiac death.</li> <li>• Provide enhanced resources for and focus on preventive and health promotion programs aimed at preventing organ failure and reducing the demand for organ transplantation.</li> <li>• Promote the expansion and use of living donor exchanges.</li> <li>• Support the progression of new sciences and technologies that have the potential to narrow the donation gap and decrease the risk of organ rejection.</li> <li>• Continue efforts to improve immunosuppressive therapy to reduce undesirable side-effects and adverse outcomes.</li> </ul>	<ul style="list-style-type: none"> <li>➔ state regulatory agencies, hospital clinical staff and risk management staff, OPO staff</li> <li>➔ state legislatures, organ donation and transplantation advocates</li> <li>➔ state legislatures, public health agencies, OPOs, organ donation and transplantation advocates</li> <li>➔ federal and state governments, health care professional societies, OPOs</li> <li>➔ hospitals, OPOs</li> <li>➔ DHHS, managed care plans, health care organizations, professional societies</li> <li>➔ OPOs, hospital staff, transplant community</li> <li>➔ NIH, foundations, private enterprise</li> <li>➔ NIH, pharmaceutical industry</li> </ul>



## CONCLUSION

No one, it is said, lives forever. But, we are living ever longer than we did before, and much, much longer than we did even a century ago. The most fundamental reason for this remarkable achievement is that we as a society place a high value on human life.

Today, there are 85,000 individuals in this country awaiting organ transplants. That is, to be sure, an imposing number, and it is a particularly worrisome number because it is growing. We are falling further behind this power curve. But 85,000 is a small number compared to what it might be in the future. Some might see the current problem – the unavailability of sufficient organs to meet present transplantation needs – as their problem. However, tomorrow – as current demographic trends suggest – this will be our problem.

In this paper, we describe a series of barriers that must be overcome to resolve the current organ availability crisis and permit this society to meet its obligations to all of its members. These include the insufficiency of educational outreach to caregivers and to the public; the processes for setting health care priorities and allocating scarce resources; ethnic and racial disparities in the way care is (and is not) delivered; acknowledgement of persons with disabilities as productive members of society; the need for greater attention to standardization of care processes and other patient safety issues; deficiencies in health literacy among the public and cultural competency among caregivers;

payment system disincentives to do the right thing; and the urgent need for further research and scientific advances. These problem areas are not peculiar to the world of organ donation and transplantation, but they stand in striking relief against this backdrop. If and when these needs are successfully addressed, the benefits for society will extend well beyond this particular arena.

With progress will, of course, come new challenges. The donation of an organ is a gift of life, not an entitlement. Each individual in this society has an obligation to maintain and preserve his or her health to the fullest extent possible – an obligation to that individual and to this society – in order to forestall that time in life when an organ may be needed. In a country that largely gives lip service to the concepts of health promotion and disease prevention, the need for change will become urgently apparent all too soon.

In the maelstrom of everyday life, it is easy to forget how far we have come and how fast we have gotten there. Much of that progress has happened because we willed it to be so – we have made it happen. Now, as we begin to approach the next frontier of human longevity, we need to will ourselves beyond the current barriers to organ transplantation for all Americans in such need.



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# HEALTH CARE AT THE CROSSROADS:

Strategies for Narrowing the Organ Donation Gap and Protecting Patients



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