

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

Organ Donor Registries

A Useful, but Limited, Tool



**JANET REHNQUIST
Inspector General**

**FEBRUARY 2002
OEI-01-01-00350**

OFFICE OF INSPECTOR GENERAL

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, is to protect the integrity of the Department of Health and Human Services programs as well as the health and welfare of beneficiaries served by them. This statutory mission is carried out through a nationwide program of audits, investigations, inspections, sanctions, and fraud alerts. The Inspector General informs the Secretary of program and management problems and recommends legislative, regulatory, and operational approaches to correct them.

Office of Evaluation and Inspections

The Office of Evaluation and Inspections (OEI) is one of several components of the Office of Inspector General. It conducts short-term management and program evaluations (called inspections) that focus on issues of concern to the Department, the Congress, and the public. The inspection reports provide findings and recommendations on the efficiency, vulnerability, and effectiveness of departmental programs.

OEI's Boston Regional Office prepared this report under the direction of Mark R Yessian, Ph.D., Regional Inspector General, and Joyce M. Greenleaf, M.B.A., Assistant Regional Inspector General. Principal OEI staff included:

Boston Region

Russell W. Hereford, Ph.D., *Project Leader*
Norman Han, M.P.A., *Program Analyst*
Julia Green, B.A., *Program Analyst*

Headquarters

Alan Levine, *Program Specialist*

To obtain copies of this report, please call the Boston Regional Office at 617-565-1050.

Reports are also available on the World Wide Web at our home page address:

<http://oig.hhs.gov/oei>

EXECUTIVE SUMMARY

PURPOSE

To assess the value of donor registries as a strategy for increasing organ donation

BACKGROUND

Almost 80,000 Americans are waiting for organ transplants, yet fewer than 23,000 received a transplant in the year 2000. About 5,600 people died while awaiting an organ transplant. An estimated 12,000 to 15,000 deaths a year could yield suitable donor organs, but fewer than half of those deaths resulted in organ donation.

The Department of Health and Human Services has taken actions to increase donation. These steps include grants and technical assistance to organ procurement organizations (OPOs) and other transplant entities. Medicare requires hospitals to notify their OPO about all individuals whose death is imminent or who die in the hospital, thus ensuring that virtually all potential donors are referred for consideration.

In many States a person who obtains or renews a driver's license may indicate an intent to be a donor. In some—but not all—States, this intent is recorded in a “donor registry,” a central repository of information on that intent. When an OPO identifies a potential donor, it can contact the registry to determine whether the person indicated a wish to donate.

Despite these efforts, the gap between the need for organs and their availability continues to grow. In April 2001, Secretary Thompson announced an initiative to encourage donation. Among other actions, the Secretary asked the Office of Inspector General to examine lessons that could be learned from existing donor registries. This report responds to that request.

We base this report on a survey of all OPOs, review of State legislation, analysis of OPO and State web-sites, and interviews with more than 50 knowledgeable individuals from OPOs, State agencies, and other organizations.

FINDINGS

Organ donor registries are emerging as a useful tool. But the contribution that registries can make to increasing the number of organ donors is limited.

Organ procurement organizations and States are turning to donor registries as a strategy for increasing organ donation.

- Fourteen States operate registries; 22 of the nation’s 59 OPOs operate in these States. These States contain 39 percent of the nation’s population and 42 percent of donors.
- OPOs in two additional States operate their own registries. These OPOs operate in States with 5 percent of the country’s population and 5 percent of donors.
- Six other States, with 13 OPOs, have recently passed laws establishing registries. These States contain 21 percent of the country’s population and 19 percent of donors. In two of these States, however, the registries have not received start-up funding.

Donor registries have assisted OPOs’ organ procurement activities.

- Registries have led to increased effectiveness and efficiency in OPO operations. In both our survey and in interviews, OPO directors told us the registry improves their ability to identify a decedent’s wishes about donation. They also told us the registry information is convincing for the decedent’s next-of-kin and for hospital staff.
- OPOs have used data from the registry to focus public education and outreach about donation. OPO staff told us they analyze data on enrollment as a tool to help develop educational programs and to monitor the impact of these efforts geographically and on specific population groups.

However, there are limits to the contribution registries can make to increasing the number of donors.

- Registries’ measurable impact on increasing the number of organ donors has been marginal. Our analysis of data found that families of registry enrollees give consent for donation at a much higher rate than do families of non-enrollees; however, enrollees are a relatively small portion of all donors at those OPOs.
- At present, enrollment in registries is limited. Even though the number of registrants is growing, only one-quarter of the adult population has enrolled.
- While registries can foster interstate sharing of information about potential donors from other States, the number of such donors is small. Nationally, fewer than 20 percent of all donors--an average of three donors per day--are from out-of-State.

We identified a number of practices that could enable OPOs to take fuller advantage of the opportunities that registries offer.

Our interviews with knowledgeable individuals, both in the OPO community and elsewhere, identified innovations that can help maximize registries’ contributions.

- Registration. In addition to the usual drivers’ licensing process, some OPOs use prepaid mailings, Internet sign-up, and free-standing kiosks.
- Storage. Some motor vehicle agencies download relevant data to the OPOs, which maintain

the registry database. This permits faster access, while protecting other sensitive information in the drivers' license records.

- Retrieval. Some OPOs' referral systems conduct automated queries of the registry whenever a potential donor is identified.
- Using information. Some OPOs use the registry indication as primary evidence of consent and do not require additional consent from next-of-kin.

RECOMMENDATIONS

We conclude from our review that caution should be exercised to avoid over-promising on the contributions that donor registries, by themselves, can make to increasing donation. We believe that the most appropriate use of Department resources with respect to donor registries is to foster ways of enhancing their effectiveness.

HRSA should establish a mechanism to provide for dissemination of information on donor registries.

A clearinghouse could enhance the effectiveness of donor registries. The clearinghouse could support information sharing and provide technical assistance. We would urge that it pay particular attention to three areas:

- Automation to take advantage of technology to overcome technical difficulties, particularly those related to retrieval of information;
- Innovation in identifying and developing new avenues for enrolling people, for example, through websites or using the Internet at community events; and
- Education on effective ways of informing the public about the registry, its benefits, and the need for organs.

To the extent that funding is available, HRSA could support research projects that seek to maximize the impact that donor registries can have.

Two areas merit particular consideration:

- What more can be done to tap registries' potential? Even those registries in place for many years contain a minority of the State's population. Are there better ways to educate people about donation and joining the registry? What are alternatives to the driver's licensing process for registering people? If people are reluctant to be listed in a large database, what can be done to allay those fears?
- How widespread are concerns about using the registry as primary consent for donation? More OPOs are using information from the registry as evidence of consent, rather than relying on the family. How informed are people when they join a registry? Do they view enrollment as providing consent for donation? What are family expectations and understandings?

COMMENTS ON THE DRAFT REPORT

We received comments on the draft report from the Health Services and Research Administration (HRSA). HRSA concurs with our report and recommendation.

The Association of Organ Procurement Organizations also provided comments. The association is concerned that we may understate the potential future value of registries, particularly if more OPOs begin to view enrollment in a registry as consent for donation. *We base our report on the experiences of those who have worked with donor registries, and on a review of available data about registries. This review leads us to conclude that registries can be a useful tool in organ procurement. But we urge caution in assuming that establishing a registry will lead directly to a dramatic increase in the number of donors. At the same time, however, given the critical need for donors, even a moderate increase in their number can be beneficial. We certainly would encourage ongoing evaluation of new registries and other initiatives intended to increase donation.*

We present the full text of the written comments in Appendix C.

TABLE OF CONTENTS

EXECUTIVE SUMMARY	i
INTRODUCTION	1
FINDINGS	
Registries operate in many States	5
Registries can provide assistance to OPOs	6
Registries' contributions are limited	8
Taking advantage of registries' potential	11
RECOMMENDATIONS	16
COMMENTS ON THE DRAFT REPORT	18
APPENDICES	
A: Registry descriptions	19
B: Survey responses	21
C: Comments on the draft report	25
D: Endnotes	31

INTRODUCTION

PURPOSE

To assess the value of donor registries as a strategy for increasing organ donation.

BACKGROUND

Almost 80,000 Americans are waiting for organ transplants, yet fewer than 23,000 received a transplant in the year 2000. In that same year, about 5,600 people died while awaiting an organ transplant.¹ An estimated 12,000 to 15,000 deaths occurring in the United States every year could yield suitable donor organs.² However, only 6,000 of those deaths resulted in organ donation in the year 2000. Between 1995 and 2000, the number of patients awaiting a transplant grew by 80 percent, while the number of donors grew by only 12 percent.³

The Department's Role in Organ Donation

Health Resources and Services Administration (HRSA). HRSA's Division of Transplantation provides Federal oversight and support for the organ procurement, allocation, and transplantation system. HRSA is responsible for national coordination of organ donation activities, the funding of grants and special initiatives to learn more about what works to increase donation, and technical assistance to organ procurement organizations (OPOs) and other transplant-related entities. For example, HRSA recently funded 12 projects that examine strategies to increase organ and tissue donation, including one to assist with the development of a donor registry.

HRSA also funds the Organ Procurement and Transplantation Network (OPTN) and the Scientific Registry of Transplant Recipients (SRTR). The OPTN is charged with operating and monitoring an equitable system for allocating organs, maintaining a waiting list of potential recipients, matching potential recipients with donors, and increasing organ donation. The SRTR supports the ongoing evaluation of the scientific and clinical status of solid organ transplantation in the United States.⁴

Centers for Medicare & Medicaid Services (CMS). CMS specifies organ procurement service areas and certifies OPOs for participation in Medicare. Medicare provides coverage for End Stage Renal Disease. This coverage is unique, in that it is the only disease-specific condition that qualifies someone for Medicare, regardless of age. That coverage includes kidney transplantation.

Since 1998, CMS has required that every hospital contact its OPO in a timely manner about individuals whose death is imminent or who die in the hospital. The OPO then determines

the individual's medical suitability for organ donation. Because the hospital notifies the OPO of each death or imminent death, the rule is intended to ensure that the family of every potential donor is informed of the option to donate organs, tissues, or eyes.

Organ Procurement Organizations

OPOs provide the services necessary to coordinate the identification of potential organ donors, requests for donation, and recovery and transport of organs. OPOs work with medical professionals and the public to encourage organ donation. Every hospital has an agreement with one OPO.

There are 59 OPOs in operation. Each OPO serves a defined geographic area. OPOs' service areas contain populations ranging from just over 1 million people to more than 11 million people. CMS certifies OPOs for participation in Medicare and provides funding through the Medicare program.

Secretary's Organ Donor Initiative

Despite ongoing efforts, the gap between the need for organs and their availability continues to grow. In April 2001, Secretary Thompson announced an initiative to encourage donation. This initiative includes the following:

- Workplace partnerships,
- Development of a model donor card,
- Support of a national "Gift of Life" medal,
- Development of a model curriculum for driver's education classes, and
- A national forum on organ donor registries.

As part of this initiative, the Secretary asked the Office of Inspector General to examine existing organ donor registries throughout the country. This report responds to that request.

Congressional Proposals

Two bills have been introduced in the U.S. Senate to address the issue of donor registries. S. 788 would establish a national donor registry that would work in conjunction with State registries.⁵ S. 1062 would encourage development of and improve linkage among State donor registries.⁶

Donor Registries

Donor registry is a catch-all term that describes a centralized repository of information indicating a person's intent to donate organs and tissues. In many States people obtaining or renewing a driver's license are able to indicate if they wish to be an organ donor. In some--but not all--of these States, this intention is recorded in a centralized data base--the registry.

When an OPO identifies a potential donor, it can contact the registry to determine whether the person indicated intent to donate. Registries can offer numerous advantages compared to traditional methods for increasing donations including:

- Greater efficiency: Registries allow OPOs to more easily identify interested donors. The information in registries can be accessed 24 hours a day. It does not rely on the physical presence of a driver's license or donor card.
- More explicit expression of intent: Registries give the opportunity for donors to specify which organs they want to donate, and for what purposes (*e.g.*, transplantation, research).
- More persuasive evidence of intent: Registry listings provide immediate documentation of an individual's wish to donate. They also allow OPO staff to prepare themselves with information about the potential donor's intent before contacting donor families.
- Larger pool of donors: Increased publicity and expanded avenues for enrollment (*e.g.*, Internet-based enrollment, as well as the traditional driver's license) allow more people to learn about donation and record their intent to donate.
- Better informed donor pool: Registries allow OPOs to contact enrollees with continuing education about donation. Contact could lead to more committed donors and raise awareness about donation among the public at large.
- More up-to-date records: Information in the registry can be revised easily for enrollees who change their name or address, or who change their mind about donation.

METHODOLOGY

We surveyed the executive directors of the nation's 59 OPOs in August, 2001. We distributed the survey as an attachment to an e-mail, asking the OPO directors to return their responses by fax. We received responses from 55 of them (93 percent); 27 of these individuals reported that they had experience working with a donor registry.

Our analysis of the role that registries play is based upon the responses of 22 OPO directors. We excluded from our review five of the 27 respondents based on our analysis and discussions with them. In one case, an individual who was serving as director of two OPOs responded separately for each of them, so we used only one response. In other cases, two respondents indicated that they had not really worked with a registry in recent years. Two other respondents were from States that are in the process of establishing a new registry, rather than operating an existing one.

Appendix B provides the distribution of these 22 responses to the survey.

We interviewed more than 50 knowledgeable individuals from OPOs, State agencies, and other organizations with involvement in organ procurement. We visited OPOs in five States where we interviewed key staff, procurement coordinators, and State officials. We

focused these discussions on OPOs and States that had experience with operating a registry, as well as on those that were in the process of establishing a registry.

We reviewed the Internet websites of the OPOs and States to determine what materials were available about donor registries and whether it was possible to enroll on-line. We also reviewed State laws governing donor registries.

Throughout this report, we use the term Department of Motor Vehicles (DMV) to describe the State agency responsible for issuing driver's licenses.⁷ Likewise, we use the term Department of Health to refer to the State agency responsible for health services.

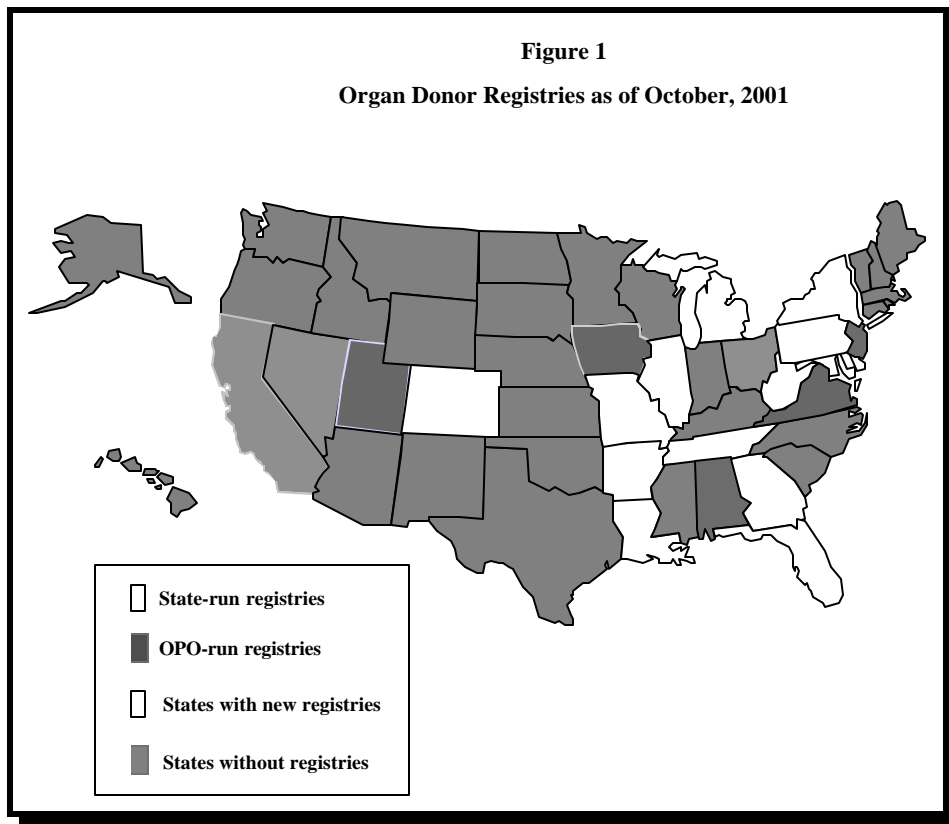
We conducted this inspection in accordance with the *Quality Standards for Inspections* issued by the President's Council on Integrity and Efficiency.

FINDINGS

Organ procurement organizations and States are turning to donor registries as a strategy for increasing organ donation.

Fourteen States operate registries; 22 of the nation's 59 OPOs operate in these States.

These 14 States contain 39 percent of the nation's population and 42 percent of the total number of organ donors recovered in the Year 2000.⁸ Figure 1 shows the distribution of donor registries.



In all of these States, the driver's licensing and renewal process is the primary entrance point to the registry. In seven States, the Department of Motor Vehicles (DMV) maintains the data base of enrollees. In four States, the DMV transfers that data to the OPO, which manages the registry. In three States, the DMV transfers the data to the State Department of Health, which manages the registry. In addition to the driver's license, many DMVs issue identification cards to people who do not drive. Obtaining an identification card also

provides the opportunity for someone to enroll in the registry.

Appendix A contains State-specific information on these registries.

OPOs in two other States operate their own registries.

OPOs operate registries in Alabama and New Jersey.⁹ These States contain 5 percent of the country's population and 5 percent of donors recovered in 2000. Each of these OPOs enrolls the registrants and maintains the data in the registry. In Alabama, the OPO's service area is the entire State; in New Jersey, the OPO (the Sharing Network) shares information with Gift of Life, which is based in Philadelphia and covers seven counties in the southern part of the State.

Appendix A contains State-specific information on these registries.

Six additional States, with 13 OPOs, have recently passed laws establishing registries.

These States are now in the implementation process. These States contain 21 percent of the country's population and 19 percent of the total number of organ donors recovered in 2000. In each State, the driver's license will serve as the primary point for enrollment. Day-to-day registry management, however, will vary.

- In Ohio, the DMV will continue to maintain the data and manage the registry.
- In Nevada, the data will be transferred to a private donor registry, The Living Bank, based in Houston, Texas.
- In Utah, the DMV will transfer the data to the OPO.¹⁰
- In Virginia, the DMV will transfer the data to the Virginia Transplant Council, an agency in the Department of Health, which will manage the registry.
- In Iowa, the Department of Public Health is authorized to contract for the establishment of a statewide organ and tissue donor registry. Start-up funding has not yet been appropriated.
- In California, which enacted a registry law in October, 2001, the DMV will provide a standard form when people receive a driver's license; the completed form would be mailed to the Department of Health, which will maintain the registry. Start-up funding has not yet been appropriated.

Appendix A contains State-specific information on these new registries.

Donor registries have provided assistance to OPOs' organ procurement activities.

Registries have led to increased effectiveness and efficiency in OPO operations.

Identifying donors. Nineteen of 22 respondents to our survey said the registry improved

their ability to identify a potential donor's intent; 17 respondents said it improved the timeliness of identification.

Working with next-of-kin. Even if an individual has indicated willingness to donate, it is practice in this country for an OPO to obtain consent from the next-of-kin. Twelve of 22 respondents said the registry helped gain consent from next-of-kin in a timely manner. Thirteen respondents said that the registry information was more convincing than other methods for indicating intent, such as a driver's license, donor card, or living will.

Most OPOs do not consider a decision to enroll in the registry equivalent to consent for donation. Thirteen OPO directors responded they never accept that indication as primary evidence of consent, and four said they rarely accept it. Instead, they use enrollment as supporting information in their discussion with family members. Only one OPO director responded that the OPO always accepts the registry indication as primary evidence of consent if the family disagrees, and two OPOs said they occasionally accept this indication.

Working with hospital staff. Research shows a collaborative approach between OPO staff and hospital staff yields the highest consent rates.¹¹ It is reasonable to speculate that a registry can help to encourage a collaborative approach. Typical of this improvement are the comments of two procurement coordinators. One told us, "When a potential donor is listed in the registry, hospital staff are more willing to let us have full access to the family." A coordinator at another OPO said, "If there is no registry indication, the staff may feel that they are wasting hospital resources since the person might not be a donor. If the indication is on the license, though, they feel that the person will be a donor, so it is worth tying up those resources."

Responses to our survey support this view. Thirteen OPO directors responded that the information in the registry is more convincing for hospital staff than other methods for indicating intent. Nine OPO directors responded that information in the registry improves their interaction with the hospital staff when a donor is identified.

Limited impact on efficiency. Only half of the 22 OPO directors responding to our survey said that the registry had improved the overall efficiency of their OPO's operations. Ten directors said that there had been no change, and only one director reported that it had hindered operations.

OPOs have used data from the registry to focus public education and outreach about donation.

In our interviews and site visits, OPO and DMV staff showed us how they use data from the registry to focus their educational efforts. Some OPOs routinely receive data from the DMV at a county-specific level, as well as breakdowns by age and gender. OPOs can use these data both to assess the impact of advertising campaigns and to identify geographic areas and populations that need additional education. Staff with the Illinois registry, which

operates an extensive educational campaign, told us that they routinely assess the effects of their targeted initiatives by monitoring changes in enrollment. The staff reported that they can determine the impact of their targeted educational initiatives by monitoring changes in enrollment and donation over time.

Fourteen OPO directors said the registry has led to a more informed donor pool. The majority of OPOs responded that the registry has led them to expand public education activities. These activities include:

- Creating new advertisements and public service announcements;
- Developing materials for educating people when they enroll in the registry;
- Providing training curriculum for DMV personnel;
- Designing educational programs for other agencies and organizations; and
- Enhancing the OPO's web site.

Seven OPO directors responded that the registry has led them to expand all five of these activities; five OPOs responded that the registry has led them to expand their work in four of these activities.

However, only one OPO director reported that his organization maintained ongoing communications with registry enrollees. This number may reflect the cost of ongoing communication--postage and staff time are direct costs, and the OPOs may feel that funds could be put to better use for other initiatives. Alternatively, this response may indicate that OPOs believe that the critical activity is convincing people to join the registry in the first place. They may consider reinforcement of that decision to be less important.

There are limits to the contribution registries can make to increasing the number of donors.

Registries' measurable impact on increasing the number of organ donors has been marginal.

In responses to our surveys and in our interviews, OPO directors credited the registry with only a modest impact on the number of people willing to donate, donors recovered, and the consent rate for donation.

Out of 21 responses to the survey, 14 OPO directors said that the number of people in their States willing to donate organs had increased, while seven said that there had been no change.

Twelve OPO directors said the actual number of organ donors had increased, and 13 responded that families' rate of consent had increased. However, only one director reported a large increase in donors, and only two reported a large increase in the consent rate.

We reviewed data from two OPOs with several years experience in using registries. These data show that families of people who have enrolled in the registry provide consent for donation at a higher rate than do families of those who have not enrolled. However, at both OPOs, registry enrollees account for a relatively small proportion of all donors.

Table 1 shows the results of this analysis. When asked to join the registry for OPO-A, “Yes” is recorded to indicate enrollment; if the person does not wish to join, there simply is no designation. At OPO-B, people are asked if they wish to join the registry, and the response can be “Yes, I want to enroll,” “No, I do not want to enroll,” or “No decision.”

Both OPOs had a higher consent rate from families of people who had joined the registry. At OPO-A 100 percent of the families of enrollees consented; at OPO-B 76 percent of families gave consent. About 40 percent of the population in both States had enrolled in the registry. However, only one-quarter of those who actually donated had enrolled.¹²

Table 1 Comparison of Consent for Registry Enrollees and Non-Enrollees at Two OPOs			
OPO	Registry Status	Family Consent Rate	Percent of All Donors for the OPO
A	Enrolled	100 %	23 %
	No Designation	49 %	77 %
B	Enrolled	76 %	25 %
	Rejected Enrollment	44 %	22 %
	No Decision	60 %	53 %

Data provided by two OPOs for January - August, 2001.

Registries contain only a limited number of donor indications.

We estimate, based on data provided by the OPOs, that about 27 percent of the aggregate population over the age of 18 in the 14 States with registries have actually enrolled in the registry.¹³ There is wide variation in these percentages. Only two States, Georgia and Colorado, indicated that more than 50 percent of the over-18 population have enrolled.¹⁴ Three other States have enrolled between 40 and 50 percent. At the other end of the spectrum in two States, less than five percent had enrolled. We provide our estimates of State by State enrollment in Appendix A.

It is difficult to obtain accurate data on the number of registrants. In some States, there are duplicate enrollments, the exact number of which are not known. For example, DMV staff

in one State estimated that as many as 20 percent of those listed in the registry may be duplicates; in another State, an OPO official told us that duplicates account for between 15 and 20 percent of enrollees. These officials indicated that deleting duplicate enrollments would be expensive, while yielding little benefit: if someone's name appeared twice in the registry, it still would result in only one potential donor.

Despite the uncertainty in the data, there appears to be potential for increasing the number of people enrolled. It is not clear what is a realistic expectation for enrollment. One OPO director told us that enrollment had grown steadily in his State until recent months, when it has stagnated at 40 percent; he was unsure if this level was temporary or if enrollment had reached an upper limit pending more aggressive educational campaigns and interventions.

While registries can foster interstate sharing of information about potential donors from other States, the number of such cases is small.

One purported advantage of registries is their use to link OPOs in different States. By contacting the registry in the decedent's home State, an OPO could determine if that individual had enrolled.

As Table 2 shows, out-of-State organ donors account for almost 20 percent of all donors, an average of 3 donors per day across the country.¹⁵ It is possible that finding the family of a potential donor from another State may take extra work on behalf of the OPO. It also is possible that more out-of-State donors could be identified if registries operated in more States, or even nationally. At present, however, the actual number of out-of-State donors does not appear to constitute a consistently heavy workload.

Table 2 Out-of-State Organ Donors, 1999 and 2000				
Year	Total Donors	In-State Donors (% of Total)	Out-of-State Donors (% of Total)	Average Out-of-State Donors per Day
2000	5,984	4,922 (82.3 %)	1,062 (17.7 %)	2.9
1999	5,810	4,710 (81.1 %)	1,100 (19.9 %)	3.0
Source: Division on Transplantation, Health Resources and Services Administration				

In our interviews with OPO officials, they indicated that when a potential donor from another State is identified, the procurement coordinator contacts the OPO in the home State to determine how to proceed. If there is a registry in that State, the coordinator would ask the OPO to contact it. The home-State OPO, if it were able to obtain useful information, would then provide it to the OPO that initiated the request.

We identified a number of practices that could enable OPOs to take fuller advantage of the opportunities that registries offer.

In our interviews with knowledgeable individuals, both in the OPO community and elsewhere, we identified a number of innovations that OPOs and donor registries are using. We have not evaluated the success of any of these innovations. We do not claim that these approaches are the full range of possibilities, or are indicative of all actions currently underway. Nevertheless, we believe they are illustrative of the types of innovations that can maximize registries' contribution to increasing donation.

Registration

One OPO director told us, "The most critical component of a registry is an easy way to designate intent. No matter how well informed and educated a potential donor is, there has to be an easy way to take action on their decision." Here we describe four approaches that make it easy to enroll in the donor registry.

Preprinted postage. In Michigan, the DMV has begun to include a separate preprinted, postage-paid form with every driver's license renewal application. On the back of the form is a donor card, with the person's name already filled in. In order to register, the person simply has to check the box on the card, sign it, and drop it in the mail. When the DMV receives the card, it scans it into a computer in a digitized format, including the individual's signature.

Electronic kiosks. Louisiana Organ Procurement Agency (LOPA) allows people to enroll at electronic kiosks that also provide public service announcements. These kiosks are located at the Superdome, at transplant centers, in hospital emergency rooms, and at colleges and universities. LOPA can tailor the individual kiosks to provide a relevant message. For example, the kiosks at the Superdome provide information on NFL scores and statistics; according to the OPO staff, "First they have to listen to a 30 second commercial on organ donation." The kiosks at the universities provide students with access to their e-mail accounts. LOPA estimates that each kiosk costs about \$5,000 to set up and operate, but the OPO is sharing the costs and ad revenues with sponsors. For example, medical supply companies co-sponsor the kiosks in some hospitals.¹⁶

Computerized data base of donor cards. The Center for Organ Recovery and Education (CORE), based in western Pennsylvania and West Virginia, maintains its own separate internal registry, in addition to the DMV registry. This registry contains about 45,000 enrollees. The organization enrolled these individuals prior to the start of the DMV registry; it continues to add new enrollees through health fairs, educational programs, and phone-ins. CORE keeps these names on its own computer system, and the original signed document is kept at the CORE offices. This registry is an important source of enrollees since about one-third of the adult population in the CORE service area do not drive and, thus, do not participate in the DMV registry.

Internet enrollment. OPOs from seven States told us that they use the Internet for enrollment into the registry. These include the OPOs in New York, Illinois, Louisiana, Michigan, and Colorado. In addition, the two OPO-run registries--the Sharing Network in New Jersey, and the Alabama Organ Center--use Internet enrollment.

Storage

Ready access to the registry is critical if the OPO is to use that information as it approaches donor families. One way of improving that access is to maintain the data at the OPO, rather than at the DMV. Efforts to achieve this include:

Automatic downloads of registry data to the OPO. In Michigan, the DMV downloads the file with the scanned cards onto a compact disc and sends it to the OPO weekly. The DMV then deletes the file with those scanned cards, because it does not want to maintain personal medical information. In essence, the DMV acts as a conduit to get the information to the OPO, which then controls access to the registry information.

Colorado has a similar arrangement. The legislation creating the registry requires the DMV to transfer the relevant information from the driver's license to the OPO. (In practice, the data are downloaded to the contractor that Donor Alliance uses to receive referral calls about potential donors.) The DMV collects the basic information at driver's license issuance/renewal and sends this electronically to Donor Alliance.

Health Department maintenance of registry data. As Virginia implements its registry, the DMV will continue to collect information as part of the licensing process. The DMV will download the names of enrollees to the Virginia Transplant Council, which is part of the Department of Health. The Council will then manage the registry, which is accessible to both of the State's OPOs and other procurement organizations. The Council has contracted with a vendor to buy space on the vendor's computer system; the vendor has a toll free hotline available to deal with any problems that arise.

Retrieval

Traditionally, OPOs have accessed information by a telephone call either to the State police or the DMV, which then accesses its data base to determine if someone has enrolled. The disadvantages of this approach include busy signals, no answers, a lengthy period between the initial request and response, and the use of the system for other tasks and users. Efforts to address these problems include the following:

Automated queries of the data. The OPOs in Colorado, Michigan, and Louisiana access the registry information automatically. When Colorado's Donor Alliance receives a referral call, an automated query of the registry is made as part of the referral process. In Michigan calls are logged into the OPO computer system; before staff can close the computer screen,

they must hit a function key that automatically queries the Registry. The Louisiana OPO uses an ambulance service that receives 911 calls. The referral software includes a query to get the name, Social Security Number, and date of birth of the potential donor. The computer then automatically checks the registry.

Direct computer access to the registry. As a general rule, DMVs want to limit access to registries, because the information contained in their data bases goes well beyond donor information.¹⁷ However, in Delaware, the OPO uses a modem to dial into the registry; staff can then see and obtain the licensing information on the screen, with the necessary information about the organ donor. In Ohio, plans call for the DMV to provide the OPOs with inquiry terminals, through which the OPO staff can retrieve information about an individual who has joined the registry.

Copy of registry information. In some states, the DMV provide verbal acknowledgment of the donor status. Elsewhere, the police are able to access the original license application and fax it to the OPO. The OPO then can determine the person's intent and share a hard copy with the family. OPOs in Tennessee and Colorado told us they receive a hard copy of the information.

Using information

Responses to our survey showed that most OPOs do not use the indication in the registry as primary evidence of consent. This practice, however, appears to be changing.

Complete evidence of consent. OPOs in two States--CORE, based in Pittsburgh, and Tennessee Donor Services, based in Nashville--reported they are using information from the donor registry as primary evidence of donor consent. They believe the indication in the registry provides a sufficient basis on which to proceed to recover organs without the need for formal consent from the next-of-kin.

OPOs in other States are starting to use this indication for primary consent, as changes and clarifications in their State Uniform Anatomical Gift Acts have reinforced the primacy of these wishes. OPOs in Virginia, Colorado, Ohio, and Utah told us they are moving or have moved recently towards using the donor indication in the registry as sufficient for recovery without the need for further consent.¹⁸

These OPO staff and directors told us they need physical evidence of the donor's intent prior to proceeding. They will not go forward with recovery solely on the basis of a telephone message. One director told us his OPO staff needs the original signed donor card or driver's license. Others told us that a facsimile copy or electronic copy suffices. A copy of the document is placed in the hospital record and the OPO recovery record.

It is important to recognize in these cases that the OPO does not merely procure organs without any discussion with the family. Rather, OPO staff approach the family with words

along the lines of, “Your loved one made a decision to donate, and this is what needs to be done to carry out those wishes.”

We identified four reasons that OPO staff and directors gave for proceeding with procurement on the basis of the driver’s document alone:

- Most people who have signed a driver’s license or donor card assume they have signed up to be a donor, not that they merely are having their name entered into a registry.
- OPO procurement staff and requestors told us that using the document as evidence of donation “makes it easier on the family. They already are dealing with a tragic situation, and anything we can do to make it easier is worthwhile.”
- A registry serves little purpose if it is not used for consent. One OPO director summarized this concern when she told us, “This is the only thing that makes sense with a Registry. If you don’t act on the individual’s wishes stated there, then why bother to do it.” Another OPO director told us, “The government and OPOs spend millions of dollars on donor cards, but they never use them. Why are we spending this money if they don’t mean something?”
- Families rarely override the registry information. One director told us that, “We have procured over 4,000 organ and tissue donors on the basis of the registry. In that time, we have had only three families object to our going ahead. We’ve continued to work with those families, and two of them are now very active supporters in our organization.”

Other OPOs, however, have chosen to not proceed with donation on the basis of the registry indication alone. The ways in which these OPOs use the registry information vary widely. In some OPOs, the staff do not share this information with the family unless a member of the family asks specifically if the OPO knows what the person wanted.

Elsewhere, OPO staff use the information more aggressively. Rather than simply approach the family and request consent, the conversation takes on a different tone, so that “it is an affirmation of his wishes,” rather than requesting consent. While these OPOs do not proceed with procurement if the family objects, this approach does make a basic assumption that the decedent’s wishes will be carried out.

One director who does not use the card as primary consent typified concerns of others when he cited “philosophical difference with others” on the extent to which his OPO will use the information. He cited four reasons for not using the card as primary consent:

- He has concerns about the accuracy of the registry data base. For example, the address in the registry may differ from the address on a decedent’s driver’s license.
- Members of the OPO board of directors are “nervous about the front page image of overriding a family decision.” Most families go along with the indication, but the OPO

staff do not want to force the issue if the family is opposed.

- Even if the donor card is legal consent, the OPO still must get the medical-social history from the family. If the family does not cooperate in providing that information, the organs and tissues might not be able to be used.
- He is skeptical of claims that productivity will be increased by using only the donor card. “The registry and that information is only one part of the process of obtaining consent.” The OPO staff feel more comfortable presenting the information about enrollment to the family during the discussion about donation, rather than making an assumption based on what was contained in the data base.

RECOMMENDATIONS

We conclude from our review that caution should be exercised to avoid over-promising on the contributions that donor registries, by themselves, can make toward increasing donation. Registries are one tool available to OPOs, and they add value to OPOs' efforts.

But we also found that registries' impact on increasing the number of organs available has been marginal. However, with almost 80,000 seriously ill Americans waiting for an organ transplant, even marginal improvements are important.

Our review also found that the majority of the population in this country reside in states that currently have a registry or are in the process of implementing legislation to establish a registry. In addition, most other States are considering establishing registries.

In light of this, we believe the most appropriate use of Department resources with respect to donor registries is to foster ways to enhance their effectiveness. Toward that end, our recommendations focus on two strategies the Department should adopt: A clearinghouse of information on donor registries and research on maximizing their potential impact.

HRSA should establish a mechanism to provide for dissemination of information on donor registries that can be used by the organ procurement community, State governments, and other relevant entities.

The purpose of the clearinghouse would be to enhance the effectiveness of donor registries. Through the clearinghouse, HRSA could support information sharing among the States and OPOs. This sharing might include, for example, making experts available to work on implementation issues. The clearinghouse might serve as a forum for convening conferences, with technical papers that focus on protocols, effective standards, and successful practices.

In this report we identified a number of innovative practices and approaches that appear to offer promise for enhancing effectiveness. Undoubtedly there are other approaches that the clearinghouse could share.

We would urge that the clearinghouse pay particular attention to three areas:

- **Automation.** We found limited use of automated approaches that take advantage of current technology in the operation of registries. Our survey of OPO directors revealed that technical difficulties related to retrieval of information are an important constraint on the usefulness of registries. Certainly, one focus could be on ways of making data retrieval more efficient and useful.

- **Innovation.** The driver’s licensing process continues to be the main gateway for registry enrollment. Innovations could be particularly useful in identifying and developing new avenues for enrolling in the registry. For example, consideration could be given to expanding the use of technology to enroll people through Web Sites or through the Internet at community events. Other countries also could provide lessons about approaches to enrolling people in donor registries. From a limited review of such methods, we found that other countries use many methods in addition to the licensing process to register enrollees. These methods include forms at physicians offices and pharmacies, as well as credit card solicitations.¹⁹
- **Education.** OPOs have many tools they use to educate the public about donation. A clearinghouse could provide other organizations with information about which tools have proven effective in informing the public about the registry, its benefits, and the need for organs.

To the extent that funding is available, HRSA could support research projects that seek to maximize the potential impact of donor registries.

HRSA already provides grant assistance to entities in order to improve the effectiveness of the organ donation and transplantation system. Below, we describe two useful areas of inquiry for additional research on donor registries.

What more can be done to tap the potential of registries? Even those registries in place for many years contain a minority of the State’s population. Questions that might be addressed include:

- Are there ways to provide better education about donation while people are waiting in line to get their driver’s license or before they arrive at the DMV?
- What are effective alternatives to that licensing process as a way of registering people?
- If people are reluctant to list their names in a large database, what can be done to allay those fears?
- How can donation, and consideration of joining a registry, be better incorporated into discussions about end-of-life issues?

How widespread are concerns about using the registry as primary consent for donation?

More OPOs are using or planning to use the indication in the registry as evidence of consent, rather than relying on consent from the family. This raises a number of questions, including:

- How informed are people when they join a registry?
- Do they view enrollment as providing consent for donation?
- What are family expectations and understandings about joining the registry?

COMMENTS ON THE DRAFT REPORT

We received comments on the draft report from the Department's Health Resources and Services Administration (HRSA), which houses the Division of Transplantation.

HRSA concurs with our report and recommendations, particularly our recommendation that HRSA establish a clearinghouse to promote information sharing and technical assistance. In addition, the agency made a number of technical comments. *We appreciate HRSA's concurrence in our report, as well as the agency's ongoing work in support of increasing donation. We have incorporated the agency's technical comments in this final report.*

The Association of Organ Procurement Organizations (AOPO) also provided comments. AOPO raises three broad issues. We summarize each issue and give our response in italics.

First, AOPO believes that while our report provides useful information on the current status of registries, it may understate their future value. *We base our report on the experiences of those who have worked with donor registries, and on a review of available data about registries. This review leads us to conclude that registries can be a useful tool in organ procurement. But we urge caution in assuming that establishing a registry will lead directly to a dramatic increase in the number of donors. That has not been the experience to date. At the same time, however, given the critical need for donors, even a moderate increase in their number can be beneficial. We certainly would encourage ongoing evaluation of new registries and other initiatives intended to increase donation.*

Second, AOPO urges that additional attention be paid to donor preference legislation. Such legislation would consider an individual's decision to join a registry as documentation for consent, rather than as a declaration of intent that would require familial consent. *Where we discuss how OPOs use registry information as evidence of consent, we do so to present a balanced view of this controversial issue within the context of registry operations. The discussion in our report clearly shows that there are multiple views on this issue, even within the organ procurement community.*

Third, AOPO cites the value of ongoing work with States about donation initiatives and new legislation. *We agree that State officials are key parties in developing programs to increase donation. The Secretary, HRSA, and other agencies of the Department continue to work actively with State officials on donation issues. For example, as cited in AOPO's comments, HRSA convened a conference on donor registries in November, 2001, which facilitated networking among State officials and organ procurement agencies. We also believe, however, that it is incumbent upon the local organ procurement organizations to perform ongoing education and dissemination for their elected State and local officials.*

Appendix C contains the full text of both sets of comments.

Description of Donor Registry Features

APPENDIX A

State	Number of OPOs	Primary Manager	Enrollment Methods	Primary Method of Access to Data	Who has access to Data	Estimated Enrollment*	% of adults in Registry	Cadaveric Donors in 2000	Statute
State Registries									
Arkansas	1	DMV	Driver's License, Mail-in Card	OPO via Internet	OPO	807,000	40%	35	Chapter 75 of 1997
Colorado	1	OPO	Driver's License, Internet, Mail in Card	OPO computer	OPO	1,800,000	56%	78	Senate Bill 00-054 (2000), Chapter 175 of 2000, CRS 12-34-101.5
Delaware	2	DMV	Driver's License	OPO via Internet, DMV	OPO, State Police, DMV	219,000	37%	24	DE Statutes Title 16, §2724
Florida	5	Agency Health Care Admin.	Driver's License, Mail-in card	OPO via Internet	OPO	2,800,000	23%	440	FL Statutes, §765
Georgia	1	OPO	Driver's License, Mail-in card	OPO via Internet	OPO, DMV	3,200,000	53%	170	CGA §40-5-25 (Chapter 608 of 1996)
Illinois	2	DMV	Driver's License, Internet, Mail-in card	Telephone to Secretary of State's Police	State Police, DMV	4,100,000	45%	284	625 ILCS 5/6-110
Louisiana	1	OPO	Driver's License, Internet, Mail-in card	OPO via Internet	OPO, DMV	711,000	22%	100	RS Chapter 32, §410
Maryland	2	DMV	Driver's License, Mail-in card	Telephone to State Police	State Police	1,445,000	37%	106	Chapter 1, Acts of 1998
Michigan	1	OPO	Driver's License, Internet, Mail-in card	OPO computer	OPO	310,000	4%	199	Vehicle Code §307
Missouri	2	Health Dept.	Driver's License	OPO via Internet	OPO, Health Department	1,800,000	43%	156	MoRS Chapter 194.304 (HB 178 of 1995)
New York	4	Health Dept.	Driver's License, Internet, Mail-in card	OPO via Internet	OPO, DMV	123,000	1%	334	
Pennsylvania	2	DMV	Driver's License	Telephone to DMV	OPO	3,500,000	37%	366	Act 102, 1994

Description of Donor Registry Features

APPENDIX A

State	Number of OPOs	Primary Manager	Enrollment Methods	Primary Method of Access to Data	Who has access to Data	Estimated Enrollment†*	% of adults in Registry	Cadaveric Donors in 2000	Statute
Tennessee	2	DMV	Driver's License	Telephone to DMV	OPO, State Police	650,000	15%	136	Tenn Statutes, §4-3-2011
West Virginia	1	DMV	Driver's License	OPO via Internet	OPO	270,000	19%	46	WV Code, Article 1B, §17B-1B
OPO-Run Registries									
Alabama	1	OPO	Internet, Mail-in Card	OPO computer	OPO	2,000	<1%	127	
New Jersey	2	OPO	Internet, Mail-in card	OPO computer	OPO	1,400	<1%	174	
New Registries									
California	4	Health Dept.						571	Senate Bill 108 (2001)
Iowa	1	Health Dept.						62	2000 Acts, Chapter 1052, §2
Nevada	2	Living Bank						44	Assembly Bill 497 (2001), Chapter 460 NRS
Ohio	4	DMV						254	Senate Bill 188 (2000)
Utah	1	OPO						50	Chapter 117 (2001)
Virginia	2	Health Dept.						123	Virginia Code, §32.1-292.2, Chapters 481 & 490 (2000)

†enrollment estimate for Summer, 2001. Exact date varies by State.

Responses to Survey of OPO Directors

APPENDIX B

I. Efficiency

	Improved Greatly	Improved Somewhat	No Change	Hindered Somewhat	Hindered Greatly	Missing
Overall, how has working with a donor registry affected the efficiency of your OPO's operation?	3	8	10	1	0	0
<i>More specifically, how has the registry affected your OPO's ability to:</i>						
Identify a potential donor's intent?	6	13	2	0	0	1
Get information about a decedent's intent in a timely manner?	7	10	4	0	0	1
Gain consent from next-of-kin in a timely manner?	1	11	8	0	0	2
Interact with hospital staff when a potential donor is identified?	1	8	12	0	0	1

II. Accepting Donor Intent

	Much More Convincing	Somewhat More Convincing	No Difference	Somewhat Less Convincing	Much Less Convincing	Missing
Overall, how does the registry compare with other indications of intent in its persuasiveness?	5	7	4	2	0	4
<i>More specifically, how persuasive do the following parties find intent stated in the registry:</i>						
Next-of-kin?	7	6	3	1	0	5
OPO staff?	8	3	6	0	0	5
Hospital staff?	11	2	3	1	0	5
Coroner/ medical examiner?	7	1	7	1	0	6

Responses to Survey of OPO Directors

APPENDIX B

	Always	Frequently	Occasionally	Rarely	Never	Missing
Does your OPO accept the registry's documentation of intent as consent for donation, even if the family disagrees?	1	0	2	4	13	2

III. Size of Donor Pool

<i>What effect would you say that the registry has had on:</i>	Increased Greatly	Increased Somewhat	No Change	Decreased Somewhat	Decreased Greatly	Missing
The number of people in your state willing to donate organs?	3	11	7	0	0	1
The number of organ donors that your OPO has recovered?	1	11	9	0	0	1
The consent rate for organ donation?	2	11	8	0	0	1

IV. Better Informed Donor Pool

	Much More Informed	Somewhat More Informed	No Change	Somewhat Less Informed	Much Less Informed	Missing
Overall, how would you assess the effect of the registry on the public's knowledge about donation?	3	12	6	0	0	1

More specifically, has having a registry led you to expand public education in any of the following areas:

	Yes	No
Advertising and public service announcements?	15	7
Development of materials for distribution at enrollment?	16	6
Training curriculum for State motor vehicle agency personnel?	13	9
Educational programs for other agencies/ organizations?	15	7
Establishment/ expansion of your OPO's web site?	14	8
Ongoing communication with registry enrollees?	1	21

Responses to Survey of OPO Directors

APPENDIX B

V. Reliability of Information

	Always	Usually	Rarely	Missing
Overall, would you say the information in the registry is reliable?	8	11	1	2
<i>More specifically, is the information:</i>				
Up-to-date?	5	13	2	2
Accurate?	6	12	1	3

VI. Concerns

Have you encountered problems with the registry in any of the following areas:

	Major Problems	Minor Problems	No problems	Missing
Privacy of personal information?	1	2	18	1
Start up costs?	5	4	10	3
Ongoing operational costs?	3	6	11	2
Computer problems?	5	10	6	1
Accessibility by telephone?	2	5	10	5

VII. Registry Profile

What organization has primary responsibility for administering the registry?

Your OPO 6

State motor vehicle agency 7

State department of health 3

Responses to Survey of OPO Directors

APPENDIX B

Which of these methods can people use to enroll in the registry?

	Yes	No
Driver's license application/ renewal process	14	2
Internet sign up	7	9
Mail-in card	11	5

How does your OPO get information from the registry about a potential donor?

	Yes	No
OPO staff obtain information directly from registry via Internet/ computer	12	4
OPO contacts State police, which provides information from the registry	2	14
OPO contacts motor vehicle agency, which provides information from the registry	3	13

Who has direct access to the registry for information about a potential donor's intent?

	Yes	No
OPO staff	14	2
State police	4	12
State motor vehicle agency	6	10
State department of health	2	14

Comments on the Draft Report

	Page
Health Resources and Services Administration	26
Association of Organ Procurement Organizations	29



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Rockville, Maryland 20857

JAN 23 2002

TO: Inspector General
FROM: Acting Administrator
SUBJECT: Office of the Inspector General (OIG) Draft Report, "Organ Donor Registries"
(OEI-01-01-00350)

Thank you for the opportunity to review and comment on this Draft Report. Attached please find the Health Resources and Services Administration's comments.

Staff questions may be referred to John Gallicchio on (301) 443-3099.


Betty James Duke

Attachment

Health Resources and Services Administration (HRSA) Comments on the Office of the Inspector General (OIG) Draft Report "Organ Donor Registries" (OIG-01-01-00350)

General Comments

We believe this report provides an excellent overview of the status of donor registries in the U.S. and appreciate its emphasis on registries as a vital tool to be used by organ procurement organizations.

OIG Recommendation

We conclude from our review that caution should be exercised to avoid over-promising on the contributions that donor registries, by themselves, can make to increasing donation. We believe that the most appropriate use of Department resources with respect to donor registries is to foster ways of enhancing their effectiveness.

HRSA should establish a mechanism to provide for dissemination of information on donor registries.

To the extent that funding is available, HRSA could support research projects that seek to maximize the impact that donor registries can have.

HRSA Response

We concur that HRSA can render an important service by establishing a clearinghouse to support information sharing and provide technical assistance. HRSA's Division of Transplantation is already funding three programs to enhance registry effectiveness through its *Model Interventions to Increase Donation* grant program. One program, in Louisiana, places kiosks in public areas such as shopping malls that encourage residents to join the registry. Another in Utah will support the development and evaluation of a new statewide donor registry. And, a Michigan project is evaluating the effectiveness of an Internet program in increasing registry entries.

Technical Comments

- The report refers in the Executive Summary, on page 1, and on page 16 to the number of people on the national transplant waiting list. At the time this report was drafted, that number was over 78,000, however, the number of patients waiting for transplant is now almost 80,000. The report should be revised to reflect the more accurate count.
- In the Executive Summary and on page 1 the report notes that 23,000 patients received a transplant last year. Because the final report will be issued in the year 2002 it would be most appropriate to state that 23,000 patients received transplants in the year 2000. Transplant statistics for the year 2001 are not yet available.
- Page 1 of the introduction states that the "SRTR is a database on recipients of solid organ

-2-

- ▶ transplants." We feel this description does not accurately portray the scope of the SRTR's activities and would recommend changing this sentence to: *"The SRTR supports the ongoing evaluation of the scientific and clinical status of solid organ transplantation in the United States."*
- ▶ Page 3 of the report provides information about methodology. It might be helpful to describe the methodology or criteria used to select those individuals that were interviewed and the OPOs that were visited.
- ▶ There is an extra bullet on page 3.
- ▶ The last sentence of the first paragraph on page 8 should be revised. The end of this sentence reads "...and whether the upward trends continues."
- ▶ Page 15 of the draft report discusses the importance of next-of-kin cooperation in obtaining medical-social histories on organ and tissue donors. It states that if a history is not obtained, organs and tissues cannot be used. While it is true that the lack of a medical-social history would likely preclude tissue donation, it is not certain that organ donation (particularly organs such as hearts, lungs, and livers intended for critically ill patients) would be prevented. It might be more appropriate for the last sentence in the first bullet point on page 15 to read: "If the family does not cooperate in providing that information, the organs and tissues *may not be able to be used.*"
- ▶ Page 17 discusses ways to better tap the potential of donor registries and questions whether there are better ways to educate people about donation while waiting in line to get a drivers license. We believe this question to be too limiting and should be expanded to say: *"Are there ways to provide better education about donation while people are waiting in line to get their driver's license or before they arrive at the DMV?"*
- ▶ In the endnotes the report states that URREA, based at the University of Michigan, holds the SRTR contract. It would be more accurate to state that: *"The University Renal Research and Education Association, based in Ann Arbor, in collaboration with the University of Michigan, holds the SRTR contract."*



Dennis Heinrichs, Florida
President
Lloyd Jordan, North Carolina
President-Elect
Mitchell Henry, M.D., Ohio
Medical Advisor
Martin F. Mozes, M.D. Illinois
Medical Advisor - Elect
Thomas Beyersdorf, Michigan
Secretary/Treasurer
Sue Duma, Colorado
Member - At-Large
Susan Gunderson, Minnesota
Immediate Past-President
Paul M. Schwab, Virginia
Executive Director

January 14, 2002

Department of Health and Human Services
Office of Inspector General
Room 5246 Cohen Building
330 Independence Avenue, SW
Washington, DC 20201

To the Office of the Inspector General:

The Association of Organ Procurement Organizations (AOPO) and our Donor Registry Task Force are grateful for this opportunity to comment on the draft report on the value of donor registries.

1. We believe that the report overall provides a reasoned presentation of the current status of donor registries, but possibly understates the potential future value of registries. This is particularly the case if registries are increasingly considered as documentation of consent rather than simply as declaration of intent, a point which was made in the analysis of the IG survey of OPOs.
2. With regard to the IG recommendation to HRSA to establish a mechanism to provide for dissemination of information on donor registries (i.e., a clearinghouse), this should be considered as part of an overall, ongoing HHS technical assistance strategy to States regarding opportunities and strategies for increasing organ and tissue donation. The topics of automation, innovation, and education are appropriate.
3. A third research project might be to study the effectiveness of registries in States with newly established donor preference legislation. At the very least, steps might be taken to uniformly account for registry applications in these States (i.e. are they making a difference?).
4. AOPO also believes that donor preference legislation may be useful in increasing the availability of organs and tissue transplantation. State legislators and chief executives should be educated on recent State legislative developments regarding donor designation laws, model legislation should be developed and disseminated, and opportunity should be taken to evaluate the effectiveness of such legislation for increasing organ and tissue donation.
5. A very helpful aspect of the recent DOT Conference on Donor Registries was the value achieved in networking with State officials regarding donation matters. This should be

*Share your life. Share your decision.**

One Cambridge Court • 8110 Gatehouse Road • Suite 101 West • Falls Church, VA 22042 • 703-573-AOPO • Fax 703-573-0578

January 14, 2002
Department of Health and Human Services
Office of Inspector General
Page 2

continued and strengthened, including but not limited to assistance to States regarding donor registry issues.

6. Finally, AOPO believes that it is too soon in the evolution of registries in states to make a determination that they are not effective. We encourage the Department to continue to support the development of registries in states and to study their impact on increasing organ donation.

Sincerely,



Paul M. Schwab
Executive Director

Cc: Russell Hereford
Tracy Schmidt

Endnotes

1. United Network for Organ Sharing, <http://www.unos.org>, January 4, 2002
2. Steven Gortmaker, Carol Beasley, *et al.*, “Organ Donor Potential and Performance: Size and Nature of the Organ Donor Shortfall,” *Critical Care Medicine*, 24: 432-439.
3. United Network for Organ Sharing.
4. The United Network for Organ Sharing, a nonprofit organization based in Richmond, Virginia, holds the contract to operate the OPTN. The University Renal Research and Education Association, based in Ann Arbor, in collaboration with the University of Michigan, holds the SRTR contract.
5. S. 788 was introduced by Senator Schumer. A House companion version of this bill, H.R. 2645, was introduced by Representative Boswell.
6. S. 1062 was introduced by Senator Durbin and others.
7. The agency responsible for issuing driver’s licenses is also called the Bureau of Motor Vehicles, Office of Motor Vehicles, Registry of Motor Vehicles, or the Motor Vehicle Administration.
8. Arkansas, Colorado, Delaware, Florida, Georgia, Illinois, Louisiana, Maryland, Michigan, Missouri, New York, Pennsylvania, Tennessee, and West Virginia.
9. The Alabama Organ Center and the New Jersey Organ and Tissue Sharing Network.
10. The Health Resources and Services Administration (HRSA) is supporting the development of the Utah registry through a grant that will “study the utility of a new, comprehensive, centralized statewide organ and tissue donor registry system and its impact on declarations of intent, consent rates, and organ and tissue donation. The project also will use the registry to evaluate both interest in, and actual, unrelated living donation rates within a multi-hospital system.” (HRSA press release.)
11. William DeJong *et al.*, “Requesting Organ Donation: An Interview Study of Donor and Nondonor Families,” *American Journal of Critical Care* 7 (January 1998) 1: 13-23; Michael J. Evanisko *et al.*, “Readiness of Critical Care Physicians and Nurses to Handle Requests for Organ Donation,” *American Journal of Critical Care* 7 (January 1998) 1: 4-12; Patrick McNamara and Carol Beasley, “Determinants of Familial Consent to Organ Donation in the Hospital Setting,” *Clinical Transplants* 1997, Cecka and Terasakai, Eds., (UCLA Tissue Typing Laboratory, 1998), 219-229.
12. All differences are significant at $p < .01$, using a Chi-square test.

13. We use the over-18 population both because it tends to be the age of majority, and it reflects those likely to have applied for a driver's license. About 20 percent of the total population has enrolled in those States.

14. Georgia discounts the cost of a driver's license renewal, down to \$8 from \$15, for those who enroll in the registry. The total for Colorado includes people who had signed their driver's license showing an intent to be a donor prior to the establishment of the registry..

15. We recognize that there is seasonal and daily variation in donation rates, and that some States encounter more out-of-State donors than others; yet the point remains that the burden is simply not that large.

16. The development and use of these kiosks has been supported through a grant from HRSA.

17. In some States, the DMV data base may include such information as voting registration, criminal convictions, and child support judgements.

18. Four OPOs operate in Ohio. At this point, it is not clear if all of them will use the registry indication as primary consent.

19. We looked at available literature and conducted an Internet review of enrollment in other countries. In British Columbia, Canada, for example, people may enroll in the registry at all doctors' offices, pharmacies, automobile insurers, and credit unions, in addition to the DMV.

In the United Kingdom, people can enroll when renewing their driver's license or passport, when registering with a new general practitioner, or online through the National Health Service website. In addition, many credit card application forms allow customers to sign up for the registry.

The Australian Health Insurance Commission (HIC), which administers the country's universal health insurance program, maintains the register. HIC uses a resident's health number to organize donation information. Residents can enroll by printing a form at the HIC website and mailing it in to HIC. There are also sign-up forms at every Medicare office. In addition, many states have registries connected to the driver's license renewal process and the information they collect is forwarded to the national register.