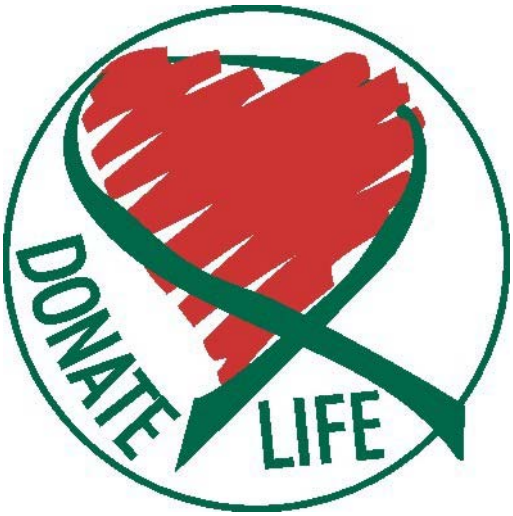

Guidelines for Donor Registry Development Conference Final Report

U.S. Department of Health and Human Services
Health Resources and Services Administration
Office of Special Programs, Division of Transplantation

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Prepared By:
The Lewin Group, Inc.

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This report was prepared by Clifford Goodman, Christina Worrall, Alycia Steinberg, Umi Chong, and Connie Liu of The Lewin Group. Other Lewin staff who participated in the conference included Marihelen Barrett, Joan DaVanzo, and Susan Green. The Project Officer was Virginia McBride of the Health Resources and Services Administration (HRSA), Office of Special Programs (OSP), Division of Transplantation (DoT), U.S. Department of Health and Human Services. HRSA also gratefully acknowledges the contributions of Secretary Tommy G. Thompson; Elizabeth James Duke, HRSA; Lynn Rothberg Wegman, HRSA, OSP, DoT; Mary Ganikos, HRSA, OSP, DoT; Coralyn Colladay, HHS Office of the Assistant Secretary for Planning and Evaluation; and BETAH Associates, Inc. In addition, HRSA appreciates the comments from the following reviewers: James Cutler, Southwest Transplant Alliance; Lori Darr, Missouri Department of Health and Senior Services; Jon J. Eiche, The Living Bank International; Jerome A. Emerson, Delaware Division of Motor Vehicles; Louise M. Jaccobi, Saturn Management Services; Antigone Klima, Transplantation Society of Michigan; Marlene Murphy, Donor Awareness Council, Tracy Schmidt, Intermountain Donor Services; and Carla Williams, The New York State Task Force to Increase Organ and Tissue Donation.

EXECUTIVE SUMMARY

A. Introduction

Organ, tissue, and eye donation has emerged over the last decade as a public health imperative in the United States. In 2001, more than 6,000 patients who were wait-listed for organ transplantation died waiting. From 1995 to 2000, the number of patients waiting for organ transplantation increased by 80 percent, while the number of cadaveric donors grew by less than 12 percent. In 2001, cadaveric donors totaled 6,081, an increase of 1.7 percent from 2000, and resulted in the recovery of 21,920 organs. So severe is the shortage that, today, more than 79,000 people remain on the national transplant waiting list for a kidney, liver, heart, lung, pancreas, or intestine. Recognizing that cadaveric donation is still the most promising source of donation, the Department of Health and Human Services (HHS) has been engaged in efforts to educate the public and raise awareness on donation in order to address the shortage of donor organs, tissue, and eyes.

One means of narrowing the gap between the demand and supply of organs, tissue, and eyes is through the use of donor registries. With 20 states already having operational donor registries, and with several organ registry bills pending in Congress, there is considerable interest on the part of both HHS and Congress to examine the potential effectiveness and practical aspects of establishing and operating donor registries. On November 29th and 30th, 2001, as part of the Secretary's Gift of Life Donation Initiative, the Health Resources and Services Administration (HRSA), Office of Special Program (OSP), Division of Transplantation (DoT) convened a national forum on donor registries, providing a timely opportunity to gather and assess information regarding donor registries from various representatives from the transplant and donation communities and from state and federal government agencies.

The conference spanned two days. On Day 1, Secretary Tommy Thompson provided opening remarks, reinforcing the conference goals, which were to develop guidelines for successful donor registries; recommend options for a federal role in facilitating effective donor registries; identify strategies to promote commitment and involvement among government entities, organ procurement agencies, and tissue and eye banks; and inform ongoing policy making regarding donation. The Secretary offered registries as a potential tool to increase donation, highlighting potentially beneficial and tangible outcomes such as ensuring that donor's wishes are carried out and providing an electronic database that is readily accessible within and across states. The rest of Day 1 focused on developing guidelines and identifying other key aspects pertaining to successful donor registries. Day 2 focused on the anticipated effectiveness and implications of pending federal donor registry legislation.

B. Day 1 Findings

Prior to six facilitated working groups to discuss various issues related to donor registries, key issues and challenges of donor registries were highlighted by Tracy Schmidt, Chairperson of the Association of Organ Procurement Organizations (AOPO) Donor Registry Task Force, Lori Darr of the Missouri Department of Health and Missouri Organ Donor Program, and Russ Hereford, Project Leader of the HHS Office of Inspector General (OIG) Office of Evaluations and Inspections. The three presenters concurred that donor registries need to be uniform, accurate, readily accessible, and

cost-effective. Mr. Schmidt and Ms. Darr were in support of registry development, citing recent technological advances, the current political interest in registries, and their role in facilitating the consent process as contributing factors.

Russ Hereford made comments based on the OIG study on donor registries. Mr. Hereford noted that there is little evidence to date for the impact of registries to yield organ donors. Further, information exchange among OPOs and bilateral agreements among states with registries might diminish the apparent need for a national registry. Mr. Hereford noted the need for more public education and stressed that registries are one of many tools that may increase donation.

The topics for each of the six working groups and their main recommendations are as follows.

1. Working Group 1: Information at Registry Enrollment

This group examined the types of information that should be collected for each participant in a registry. Points to consider in examining this topic included that effectiveness of a registry is largely dependent on the information collected, and registry data can enhance the registry's potential use for outreach and evaluation activities. The group's recommendations are as follows.

- Three main identified uses of registry data include: 1) verification of decedent's identity, 2) data collection for evaluation, awareness, and education outreach, and 3) registry maintenance.
- The minimum core data elements are: first and last name, date of birth, and Social Security or driver's license number. Time and resources permitting, additional information would include demographic and physical characteristics, contact information, and specification of what the registrant intended to donate and for what purposes.
- Due to variation in legislation, regulation, and interpretation of legally binding consent, the group did not reach consensus on what data would best ensure informed consent.
- Only posthumous donors should be included in a state donor registry. Though important, living donation and anatomical and medical research donation should be considered separately.
- Registries must allow for voluntary disenrollment of registrants and removal of those who are deceased or moved out of state.

2. Working Group 2: Portals of Entry

This group focused on portals of entry for registry enrollees. Points to consider were the role of state department of motor vehicles (DMV) as the primary portal of entry and need for coordination for multiple portals. The group's main findings and recommendations are as follows.

- Characteristics of an effective portal include: easy public access, validation of data at time of enrollment and follow-up, and ease of ongoing maintenance for the registry gatekeeper, which is the entity responsible for the operation, maintenance, and security of the registry

- Decoupling the portal role from that of the gatekeeper role might help to alleviate the numerous responsibilities that come with being responsible for both.
- Once a portal has been established, public awareness and education are essential for the registry's success.
- Due to variation among portals, linkages across states vary and hinder more formal linkage.

3. Working Group 3: Training DMV Employees and the Public

Group 3 discussed the role of the DMV in the donor registry process. Understanding that donor registration is not the primary role of the DMV or the area of expertise of DMV staff, participants acknowledged the DMV as the primary portal and provided the following recommendations to ensure that sufficient training and adequate resources are provided to better reconcile the needs of the donation community within the DMV environment.

- Expectations of DMV staff must be considered given the importance of their role in the donation process vis-a-vis their primary duties, responsibilities, and existing human resource and procedural constraints.
- Develop effective strategies for preparing DMV staff and increasing their appreciation and understanding of donation issues.

4. Working Group 4: Registry Access

This group focused on multiple issues related to registry access. Recommendations included the following.

- Access to registry information should only be provided in order to facilitate the donation process as well as for outreach and educational activities.
- Besides the gatekeeper and the necessary procurement personnel, access to the donor registry should be restricted in order to ensure privacy and the public's trust.
- Data elements that are necessary to verify the identity of the donor should be accessible at all times, across states.

5. Working Group 5: Funding and Legislative Support for Registries

Group 5 discussed registry issues related to funding and legislative support and made the following points.

- More research needs to be conducted to adequately address the costs involved with registry development, and more information needs to be shared among states on the start-up and operating costs of registries. Regardless of registry costs, the group stressed that more federal and state funding is needed to supplement funding already secured through innovative mechanisms.

- For any donor registry legislation to be successful, it must promote and facilitate communication among states, OPOs, and tissue banks as well as other stakeholders. Continued involvement is needed of HHS, states, and the donation community in promoting and educating organ donation.

6. Working Group 6: Evaluating Registries

This group focused on evaluating the effectiveness and impact of donor registries and the effect of evaluation on strengthening existing registries and increasing support for donor registries in states where they do not exist. The group made the following recommendations.

- Evaluation needs to be tailored to registry type given the variability that exists among registries.
- Structural, process, and outcome measures are required to evaluate registry effectiveness in the short-term, intermediate term, and long-term basis.
- Evaluation findings for registries can be used to support education, outreach, and marketing efforts.
- To ensure that registries' evaluation data are current and useful, various state agencies should cross reference or share data with each other as well as have access to any outcome data.

C. Day 2 Findings

Day 2 focused on the main attributes and implications of four pending bills in Congress, including: The Motor Donor Act (S. 788 and H.R. 2645), The Donate Act (S. 1062), The Organ Donor Enhancement Act (H.R. 955), and The Organ Donation Improvement Act of 2001 (H.R. 624). (A fifth bill, The Organ Donation and Recovery Improvement Act [S. 1949], was introduced following the conference.) Prior to three facilitated breakout sessions, favorable and unfavorable attributes of the four bills were discussed by three panelists representing the perspectives of private registries, OPOs, and states: John Eiche of the of the Living Bank, Louise Jacobbi of Saturn Management Systems, and Antigone Klima of the Transplantation Society of Michigan. The group concurred that merits of all the bills included their focus on registry development and enhancement, promotion of linkage, inclusion and recognition of public education and awareness, and provisions ensuring immediate access, security, and confidentiality of registries. Components of the bills identified as needing further development or refinement included: the need to involve states without registries, more details on how registries would be linked, better definition of the HHS role, additional details on funding to implement various provisions, and lack of first-person consent (i.e., where donor designation is accepted as legally binding consent).

Though conference participants lauded both The Organ Donor Enhancement Act and The Organ Donation Improvement Act of 2001 for addressing and promoting organ and tissue donation, discussion regarding the attributes and implications of legislation primarily centered on the more detailed bills, The Donate Act and The Motor Donor Act.

The Donate Act was considered by conference participants to be the most comprehensive bill of the four presented. Key favorable attributes contributing to its near unanimous support by conference participants were the bill's emphasis on the state's role in developing registries with federal support in selected functions and on an evaluation component for registries. Additional favorable aspects include its provision for uniform consensus guidelines on consent, privacy, and data exchange protocols.

Key favorable attributes noted by conference participants for The Motor Donor Act were its provisions for a federal framework for registry development, allowance for people who reside in states without registries to sign up via a website (allowing for voluntary exit and notification regarding registry participation), designation of a minimum data set, and building upon existing infrastructure through the use of DMV as the primary portal. However, the latter point was also viewed as an unfavorable attribute, as it ignores other portals that may serve to widen access.

In discussing various issues related to donor registries, including pending legislation, four issues arose repeatedly. The first issue concerns the importance of distinguishing between registries of consent and intent to donate as this affects the purpose and role of the registry. The second issue relates to the importance of registry-related education and public awareness activities so that the registry is not only an information resource, but also a functional, cost-effective tool for education and outreach. The third issue pertains to the need for greater coordination in the organ and tissue donation community so as to facilitate intra-community communication for exchange of information and experiences regarding donor registries. The last issue addresses the need for more research and evaluation.

The conference concluded with a plenary session devoted to developing eight themes and strategies for implementing successful donor registries. They are as follows.

- ***Make organ donation a public health imperative.*** Given the unacceptable gap between the availability of and the need for organs, organ donation must be elevated to the level of a public health imperative. This does not mean that all U.S. residents should be obliged to become organ donors. It does mean that every reasonable effort should be made to provide well-informed, readily accessible opportunities for people who choose to be donors to register as such, for families who choose to provide consent to do so when their consent is required to proceed with donation, and for the donation community to fulfill these designations.
- ***Clarify consent versus intent.*** The concept of consent vs. intent to donate must be clarified, not only for the public, but so that hospitals, OPOs, families, and others involved in the donation process can comply with the designation made by the donor. The absence of such clarification may limit significant improvement in public confidence in the organ donation process and in donation rates.
- ***Retain and respect state autonomy.*** Continued development and successful operation of donor registries will depend upon maintaining and promoting state-level donor registries. States will continue to build practical and diverse experience with registries, contributing to the knowledge base of what works in donor registries and enhancing information exchange and other productive linkages across states.

- ***Do not establish a national registry at this time.*** A national registry, particularly one that supersedes or interferes with state registry efforts, is not necessary at this time. However, this does not preclude national efforts or selective federal involvement in facilitating state registries, their interaction, and other aspects of registry enhancements.
- ***Define the federal role.*** There exists a need to define the national role in terms of such key aspects as public awareness and education, readily accessible portals of entry, linkages among states, research and demonstrations, and evaluation of registries.
- ***Minimize public confusion***. More education and coordinated efforts are needed to clarify consent vs. intent to donate, explain the donation process and registry participation, and dispel myths about donation. These and other aspects of public confusion pose significant barriers to donation.
- ***Provide opportunities for the public to register.*** The public must have readily accessible, informed opportunities to register as donors. The diverse means of registering among states should provide a basis for identifying effective means of access. Registration opportunities may be expanded via creation of linkages between states with and without registries, and by a national portal for accessing existing registries, as appropriate.
- ***Ongoing evaluation and accountability of registries.*** Ongoing evaluation is necessary for understanding what works and what does not for improving the effectiveness of registries. Further, evaluation is needed to ensure that registries are accountable to their purposes and to their stakeholders, including registrants, families, procurement organizations, health care providers, and the public.

D. Roles and Responsibilities

Policy makers and other stakeholders can assume certain roles and responsibilities toward successful implementation of these strategies. These include, but are not limited to, the following.

The Secretary of HHS can:

- Continue to promote donation as a public health issue;
- Help to clarify or explain existing federal laws and regulations pertaining to organ procurement (including donation) and transplantation, and the intent or implications of relevant proposed laws and regulations;
- Request an Institute of Medicine (IOM) study to explore the ethical, legal, and practical issues surrounding registries of consent and intent;
- Emphasize the need to respect and build upon, rather than supersede, the principal role of states;
- Clarify that the role of registries in strengthening donation does not require a national registry;
- With the advice of the Advisory Committee on Organ Transplantation (ACOT) and other expert sources, determine the most effective federal role in donor registries;
- Call for readily accessible, informed opportunities for registering as a donor; and

- Insist that donation-enhancing efforts, including registries, be subject to ongoing, objective evaluation and accountability.

The Congress can:

- Enact legislation and provide adequate funding to develop and support the donation initiative;
- Recognize the principal role of states in the context of future legislation and related funding regarding donation;
- Provide incentives for states to establish new registries and enhance access to existing ones;
- Enact legislation and provide adequate funding for selective federal involvement, but not a national registry; and
- Tie support for organ donation efforts, including registries, to requirements for evaluation and accountability.

State governments, including governors, legislatures, and legislative organizations, can:

- Promote donation in their state and linkages with other states;
- Promote their own state registries and facilitate relationships with states that have yet to develop registries;
- Periodically evaluate and upgrade accessibility to their registries; and
- Contribute to an appropriate federal role by providing input, communicating with relevant stakeholders, and committing to partnerships across agencies and with the federal government.

Donation and recovery organizations, including organ, tissue, and eye agencies, registries, AOPO, American Association of Tissue Banks (AATB), Eye Bank Association of America (EBAA), and others can:

- Educate the public on the importance of donation and these organizations' respective roles in donation;
- Increase public awareness of the importance of consent vs. intent to donate;
- Provide input to the IOM for a study of the issue of consent vs. intent to donate; and
- Help to delineate aspects of donation most suited to federal involvement.

Other stakeholders:

- The National Governors Association, transplant centers, and others can promote the message to retain and respect the principal role of states.
- State agencies (including DMVs and departments of health and education), voluntary health agencies, consumer organizations, and professional associations can support public awareness about how to register as a donor.

I. INTRODUCTION

Organ, tissue, and eye donation has emerged over the last decade as a public health imperative in the United States. In 2001, more than 6,000 patients who were wait-listed for organ transplantation died waiting.[1] From 1995 to 2000, the number of patients waiting for organ transplantation increased by 80 percent, while the number of cadaveric donors grew by less than 12 percent. In 2001, the number of cadaveric donors totaled 6,081, an increased 1.7 percent from 2000, and resulted in the recovery of 21,920 organs. So severe is the shortage that, today, more than 79,000 people remain on the national transplant waiting list for a kidney, liver, heart, lung, pancreas, or intestine.[2,3]

Despite well-publicized increases in organ donation by living donors, enabled by compassion and advances in technology,[4] cadaveric donation is still the primary, though far from fully realized, source of donor organs. The actual number of cadaveric solid organ donors represents only about 30-40 percent of the potential, i.e., medically suitable, cadaveric solid organ donors each year.[5,6] Barriers contributing to the low donation rate of cadaveric organs include misconceptions and fears about donation, low rates of consent by family members, lack of education regarding donation, ambiguous or improper interpretation of intent to donate, and missed opportunities to identify potential donors.[7]

Since 1997, the Department of Health and Human Services (HHS) has been committed to and engaged in addressing the severe shortage in the supply of donor organs and tissues relative to the demand for them. HHS has engaged in multiple efforts to educate the public and raise awareness to overcome barriers to donation. These have included educating the public via donation curricula in driver education programs, encouraging employers and private organizations to educate their workforce about donation, providing grants to community agencies and academic institutions to develop and evaluate strategies to increase family consent and donation rates, and increasing potential donor identification to decrease missed opportunities. The Health Resources and Services Administration (HRSA) has taken a lead role in these efforts, along with other HHS agencies, including the Centers for Medicare and Medicaid Services (CMS, formerly the Health Care Financing Administration), the Office of the Assistant Secretary for Planning and Evaluation (ASPE), and others.

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1 U.S. Department of Health and Human Services. HHS Fact Sheet: "Gift of Life" Donation Initiative. Newsroom release, April 22, 2002.

2 United Network for Organ Sharing (UNOS). Available at: http://www.unos.org.

3 U.S. Department of Health and Human Services. HHS Fact Sheet: "Gift of Life" Donation Initiative. Newsroom release, April 22, 2002.

4 From 1995 to 2001, the number of living donors increased from 3,458 to 6,445. Aside from the highly individualized circumstances of these donations and their recipient designation, the types of organs available from living donation are necessarily limited; of all living organ donations in 2000, kidney donations accounted for 93.0 percent and liver donations accounted for 6.5 percent. UNOS data; available at: http://www.unos.org.

5 Gortmaker SL, Beasley CL, Brigham LE, et al. Organ donor potential and performance: size and nature of the organ donor shortfall. Crit Care Med 1996;24:432-9.

6 Christiansen CL, Gortmaker SL, Williams JM, et al. A method for estimating solid organ donor potential by organ procurement region. Am J Public Health 1998;88:1645-50.

7 U.S. Department of Health and Human Services. State Strategies for Organ and Tissue Donation: A Resource Guide for Public Officials. p. 15.

Recently, HHS and Congress have been examining the potential of donor registries at the state and national level for increasing organ, tissue, and eye donation. Currently, there are 20 states with operational registries, and at least two states are engaged in developing registries. Several bills pertaining to federal involvement in national registries are pending in Congress.

Registries offer a means of narrowing the gap between the demand and supply of organs, tissues, and eyes. However, as discussed at this conference, registries are still new and emerging, and their impact on donation rates is not established. Even in circumstances where potential donors are registered, other factors may impede donation, such as inadequate hospital referrals to OPOs regarding potential donors, whether registration is understood to constitute legal consent, which in effect diminishes the involvement of donor families in the donation process, and physicians' perceived concerns about liability for proceeding with donation in the absence of consent by the family. A fundamental challenge to establishing registries and gaining public participation in them is a widely held public assumption that donor registries, or the functions of registries, are already in effect where this is not necessarily the case. This derives, ironically, from increased (though still far insufficient) public awareness of donor designations on their driver's licenses and donor cards, as well as the existence of the comprehensive organ allocation system of the national Organ Procurement and Transplantation Network (OPTN).[8]

Certain recent developments in the donation process may enhance the utility of registries. The CMS requirement for hospitals to refer all deaths to OPOs under the conditions of participation (CoPs) in Medicare should contribute to identifying a larger proportion of potential donors, including those on organ, tissue, and eye registries. Other favorable developments include greater public awareness, improvements and lower costs of information management, and increasing commitment on the part of HHS, OPOs, and state health departments to increase donation rates.

Organ, tissue, and eye donation registries operate at the nexus of sometimes complex medical, legal, social, and ethical issues. Given important developments in the organ and tissue donation process and considerable interest on the part of HHS, Congress, and the transplant community in registries, this conference provided a timely opportunity to share available experience and perspectives in establishing and operating such registries.

II. PURPOSE OF THE CONFERENCE

In April 2001, HHS Secretary Tommy Thompson announced the Gift of Life Donation Initiative. One of the main elements of this initiative was to conduct a national forum on donor registries. Accordingly, the HRSA Office of Special Programs (OSP), Division of Transplantation (DoT), sponsored the Guidelines for Donor Registry Development Conference, held November 29th and 30th, 2001, in Bethesda, MD. Conference participants included representatives from organ procurement organizations (OPOs), tissue and eye banks, state government entities, national associations, congressional offices, and other federal agencies.

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[8] HRSA DoT provides federal oversight of the OPTN, the Scientific Registry of Transplant Recipients (SRTR), and the National Marrow Donor Program (NMDP) contracts. HRSA DoT administers a contract with the United Network for Organ Sharing (UNOS) to operate the OPTN, which maintains a national computerized list of patients waiting for organ transplantation. More than 20,000 transplants are performed on patients on this list per year.

The goals of the conference were to:

- Develop guidelines for successful donor registries;
- Recommend options for a federal role in facilitating effective donor registries;
- Identify strategies to promote commitment and involvement among government entities, organ procurement agencies, and tissue and eye banks; and
- Inform ongoing policy making regarding donation.

The conference spanned two days. Day 1 focused primarily on developing guidelines and identifying other key aspects pertaining to successful donor registries. Day 2 focused primarily on the anticipated effectiveness and implications of pending federal legislation pertaining to donor registries. The full conference agenda is shown in Appendix A.

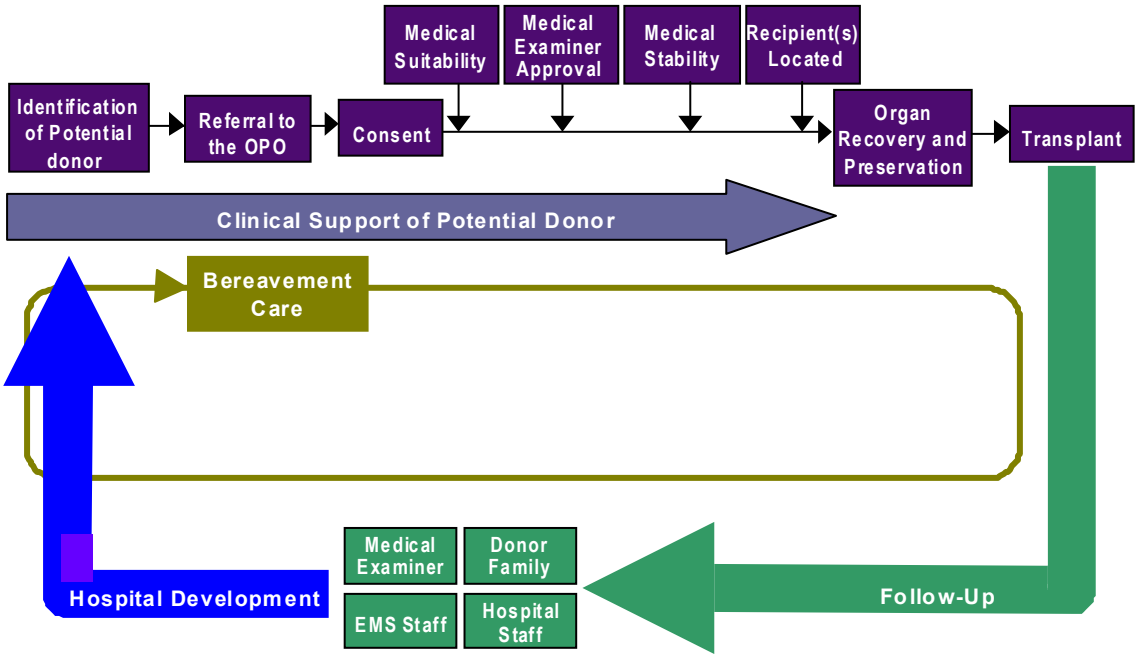
HRSA contracted with The Lewin Group (Falls Church, VA) to conduct several tasks in support of the conference. Among these were to assist in conference planning, to moderate and provide related facilitation for it, and to produce this report of the conference. Further, in preparation for the conference, Lewin updated a report it had produced originally in 1999 for the HHS ASPE, analyzing state actions regarding donor registries and donor rights activities. HRSA contracted with BETAH Associates, Inc. (Bethesda, MD), to provide meeting organizing services and related logistical support.

Rather than strict proceedings of the conference, the rest of the report description summarizes the main points and flow of the deliberations of Day 1 and Day 2.

III. SUMMARY: DAY 1 – DONOR REGISTRY ISSUES AND GUIDELINES

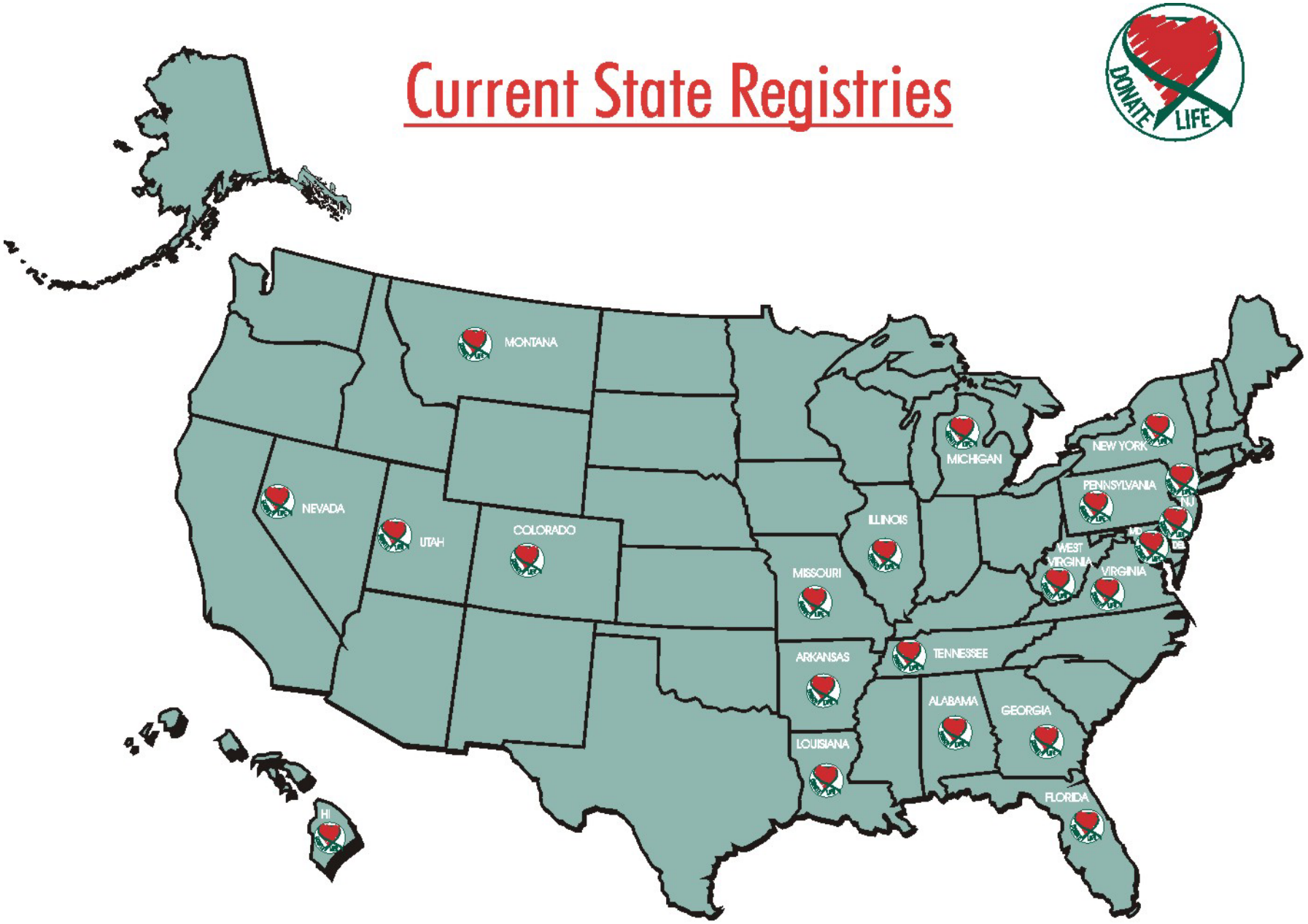
Day 1 focused on developing guidelines and identifying other key aspects pertaining to successful donor registries. Conference moderator, Clifford Goodman, Senior Scientist, The Lewin Group, provided a brief background to the conference and stated the conference goals. He noted that registries can be considered in the broader context of key events in the donation process (Exhibit 1).

Exhibit 1. Events in the Donation and Consent Process



Donor registries may entail such events or functions as: designate donor status, document donor status, collate information into registry, maintain registry, provide timely access to the registry, and utilize registry information at appropriate decision points. In presenting a map of current state-level registry activity (Exhibit 2), Dr. Goodman referred participants to the *Analysis of National and State Actions Regarding Organ Donor Registries* (an updated and expanded version of a similar analysis conducted by Lewin in 1999), prepared by Lewin and distributed to conference participants prior to the conference. (An updated version of the document is included as Appendix B of this report.)

Exhibit 2. Current State Registries as of November 2001 (prepared by HRSA, OSP, DoT)



Dr. Elizabeth James Duke, Acting Administrator of HRSA,[9] welcomed participants and introduced Secretary of Health and Human Services, Tommy Thompson, who provided opening remarks. Secretary Thompson emphasized the importance of organ donation and iterated the conference purpose to develop guidelines for organ donor registries. He noted that conducting this national forum on donor registries is one of the many elements of his Gift of Life Donation Initiative, announced in April 2001, which also include the "Workplace Partnership for Life" (encouraging collaboration with companies and employees on information campaigns), a model donor card, a national gift of life medal, a model education curriculum, and other elements under development. Underscoring and recounting the Department's and his personal commitment to organ donation, Secretary Thompson offered registries as a potential tool to increase donation. He emphasized that a registry can ensure that donor's wishes are carried out, provide an electronic database that is readily accessible within and across states, and may have a positive long-term impact on organ and tissue donation. The Secretary stressed the importance of pursuing the conference agenda, encouraged conference participants to debate topics, and said that he would promote conference findings to Congress and within HHS.

Following the Secretary's remarks, prominent issues and challenges of donor registries were highlighted by Tracy Schmidt, Chairperson of the Association of Organ Procurement Organizations (AOPO) Donor Registry Task Force, and Lori Darr of the Missouri Department of Health, Missouri Organ Donor Program. Russ Hereford, Project Leader of the HHS Office of Inspector General (OIG) Office of Evaluations and Inspections, then provided a brief update on the study that would result in the OIG report on donor registries. Following their individual presentations, these three speakers engaged in a brief panel discussion and question and answer session.

Tracy Schmidt noted that this is an opportune time to pursue registry development. Long envisioned as a key element of effective donation, registries are better positioned now to facilitate donation given recent implementation by the CMS of the hospital CoPs in Medicare requiring hospital referrals of deaths or imminent deaths to OPOs. Improvements in information technology can help to make registries efficient and inexpensive. Still, there are considerable improvements to be made in the referral process and in clarifying the consent process. Mr. Schmidt cited the next steps for the AOPO Donor Registry Task Force, which include increasing coordination among OPOs within and across states and mobilizing support to accelerate the development of a uniform registry network.

Lori Darr's comments drew upon Missouri's experience with its organ donor registry. She emphasized that registry success is a function of its ability to improve the consent process. In order to be successful, registries must always be accurate, accessible in real time to designated users, user-friendly, cost-effective or cost-neutral, and secure. Two main reasons for underuse of registry information are the lack of consensus on the role of registry participation in the consent process, and hesitancy to incorporate registry information in gaining consent. The slides used in Ms. Darr's presentation are shown in Appendix C.

[9] Dr. Duke was named Administrator of HRSA in March 2002.

In providing the update on the current OIG study, Russ Hereford noted that there is little evidence to date for the impact of registries. In addition to a limited number of registries, the people who are likely to enroll in such registries may be risk averse and less likely to be involved in the types of fatal events that yield donor organs. The potential for a national registry to facilitate donation in instances of out-of-state deaths of people who had registered in their home states is limited by the frequency of such events, which number about three per day in the U.S. Also, information exchange among OPOs and bilateral agreements among states with registries might diminish the apparent need for a national registry. In highlighting important points to consider for registry development, Mr. Hereford noted that donor cards, kiosks, and the Internet could be better utilized to facilitate the registration process, automated technology could be used to provide ready and immediate access, and registry information could be more effective if it constituted primary consent. Mr. Hereford cautioned that the DMV's primary purpose is not to support donation, and more consideration should be given to its role in providing access to registry information. Lastly, Mr. Hereford noted the need for more public education and stressed that registries are one of many tools that may increase donation.[10]

Among the generally shared messages delivered by these three presenters were that:

- Consensus is needed on the legal significance of participation in a registry, especially regarding whether it constitutes binding first-person consent or non-binding intent only;
- The donation community must define what "Yes" means in a registry;
- There must be greater public understanding of what it means to participate in a registry;
- The public should have easy voluntary access to registry participation (e.g., via the Internet, mailings, and kiosks) in order to increase the pool of adequately informed donors;
- Registries should contain relatively uniform information that is interpreted in a consistent manner;
- Registry information must be accurate, confidential, and secure;
- OPOs and other designated users should have constant (24 hour/7 days per week), real-time access to electronic, automated registry information;
- Registries need support from and must be coordinated with adjunct agencies, including but not limited to OPOs, eye and tissue banks, hospitals, health departments, and state motor vehicle administrations/departments of motor vehicles (DMVs);
- Registries must demonstrate their effectiveness in terms of their impact on consent and/or rates of successful donation;
- Registries must be cost-effective.

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[10] The OIG report was completed following the conference. Among its findings were that organ donor registries are emerging as useful tools, but the contribution that registries can make to increasing the number of organ donors is limited. The report noted that their use appears to increase consent rates for families, but to date registries contain only a limited number of donors. The report identified a number of practices that could take fuller advantage of registries. See: U.S. Department of Health and Human Services. Office of Inspector General. Organ Donation Registries: A Useful, but Limited, Tool. OEI-01-01-00350. February 2002. Available at: http://oig.hhs.gov/oei/reports/oei-01-01-00350.pdf

Notwithstanding the current shortcomings or concerns that would be cited in the OIG report, Tracy Schmidt and Lori Darr stressed the need to pursue coordination and information exchange among existing registries and between registries and OPOs and eye and tissue banks. Further, they advocated accelerated development of a network among registries, as well as research to inform cost-effective development and use of such systems. Other discussion dealt with whether federal funding for registry development should be designated primarily for DMV-based registries (as advocated by the AOPO) or for registries with non-DMV multiple portals.

A. Working Group Sessions

Prior to the conference, HRSA developed six priority topic areas for working groups at the conference, including recommended sets of discussion points for each session. As part of the conference registration process, participants were asked to rank their interest in joining each working group. HRSA incorporated these preferences, along with other considerations for stakeholder representation and group size, in assigning participants to the respective working groups.

Lynn Rothberg Wegman, Director, HRSA, OSP, DoT, gave the charge to conference participants and reviewed the purpose and process of the working group sessions. Conference participants then proceeded to the six facilitated working groups on:

1. Information registrants should submit when enrolling in a registry;
2. Portals of entry for registry enrollees;
3. Training programs for motor vehicle administration employees and the public;
4. Gaining access to registry information;
5. Funding and legislative support for donor registries/registry improvement;
6. Evaluating the effectiveness/impact of registries.

The working groups and recommended discussion points for each are listed in the conference agenda (Appendix A). Following the working group deliberations, spokespersons for each group reported key points of their sessions in plenary sessions.

1. Working Group 1: Information at Registry Enrollment

Working Group 1 examined the types of information that should be collected for each participant in a registry. Certainly, the effectiveness of a registry depends in large part on the nature of the information collected. Beyond the primary function of identifying people who have expressed their intent to be donors, registry data can enhance the registry's potential for outreach and evaluation. However, increasing the information requirements for a registry can burden the registration process and registry maintenance, and poses concerns about unintended or improper uses of this information.

The discussion points prepared by HRSA for Working Group 1 were as follows.

- What is the basic information required to authorize donation procedures after death?

- What registry information should be made available to procurement organizations at the time of a registrant's death?
- What elements/conditions need to be satisfied to have procurement organizations honor registrations as the primary authorization for donation procedures (e.g., informed consent criteria)?
- What are the pros/cons of registering those wishing to NOT donate? Should non-donors be included in registries? Why?
- What types of donors should be included in registries: living, deceased, marrow, blood, anatomical and/or medical research?
- How can registrants be voluntarily removed from a registry?
- How can registry enrollment remain current? (That is, how can people be removed who have died or moved out of state?)

The working group reviewed the list of questions and discussed them in turn. Participants suggested substituting the word "initiate" for "authorize" in the initial question to reflect more accurately the use of the registry information. The key points raised by this group are as follows.

a) Main Uses of a Registry

Four main uses of data collected at the time of registry enrollment are:

1. Identification of the registrant as choosing to be a donor,
2. Verification of the decedent's identity,
3. Data collection for evaluation, awareness and education outreach, and
4. Registry maintenance.

b) Registry Contents

At minimum, a registry must have the core information necessary to fulfill the verification of the decedent's identity. This core information includes, at minimum: first and last name, date of birth, and Social Security number. Passport numbers or driver's license numbers were suggested as alternate identifiers for those who are reluctant to list their Social Security numbers.

Information collected at the time of registration is necessarily limited by the amount of time and effort required for each additional type of data collected. Given that registering potential donors is not the primary function of the most common portals of entry for donor registries, the state DMVs, the registry development process must weigh the acceptability of additional levels of staff burden, participant time, and related costs.

Core identification information in the registry can be supplemented with additional information to fulfill the other uses of the registry, including:

- Demographic information (gender, race/ethnicity);
- Additional identifiers (height, eye color);
- Contact information (address, names/addresses of contact or witnesses), and information relevant to the donation (e.g., health history information, what the registrant consents/intends to donate and for what purposes).

Although there was not general consensus on this aspect, some participants argued that the registry also should have information that would specify what the registrant intended or consented to donate, and for what purposes. As noted below, this must be considered in light of the information tradeoff and the entailed acquisition time and cost.

c) Validating Informed Consent

The group did not reach a consensus on what data would best ensure informed consent. Participants recognized that the role of registry data in informed consent is subject to ambiguity in legislation, regulations, and their interpretation regarding legally recognized consent. The group recognized that, in the presence of this ambiguity, it is difficult to determine what data elements in a donor registry are needed to satisfy consent requirements. Some participants noted that, aside from any explicit legal requirements, the conditions or circumstances in which donor registration is offered may call into question whether a consent to donate was truly informed, and whether it was affected by factors that may have biased one's inclination to indicate consent. In this discussion, participants cited the sometimes rushed or frustrating settings of acquiring or renewing driver's licenses and the potential effects of bias among DMV personnel who may regard donor registration as a secondary task or express their own opinions about donation. One participant speculated that informed consent is more likely to be presumed when the registration is more cumbersome. The group also discussed whether a legislative mandate or regulatory requirement could specify that one's inclusion in a registry constitutes a statement of consent, as opposed to a statement of intent.

The group concurred that the most effective method of documenting informed consent is by electronically scanning a consent document signed by the donor, particularly because presenting a copy of this would be most persuasive to family members. The advantages of this form of documentation must be weighed against the time and cost of implementing it.

d) Who Should be Included in the Registry

The group concurred that only posthumous donation should be included in a state registry. Living, anatomical, and medical research donation should be considered separately. Marrow and blood donors are already listed in separate registries. Educational materials related to donor registries and the donation process should include and address these various donor types.

Participants were sensitive to the tradeoffs inherent in expanding the scope and data requirements of registries. While anatomical and medical research donation are important, the effort and potential complexity and confusion that may arise in asking registrants to specify alternative types of donation could detract from the already challenging effort of registering as an

organ donor. Currently, the downside of this additional tracking is considered to be too great. Participants did emphasize that OPOs should educate the public on living donation, even though this process is significantly different from posthumous donation and is managed by transplant centers.

The group addressed the pros and cons of registering those wishing not to donate. Participants noted that registering non-donors would diminish perceptions of impropriety on the part of the registration process, and may strengthen the ethical foundation of the registry. The main disadvantage to registering non-donors is that doing so may be interpreted to mean that those who have not been asked about their preference or who need more information have not had the opportunity to decline, and therefore might be counted as "Nos." Participants argued that not being present on a registry should not constitute a presumed "No," and that families should be consulted in such instances. Some participants stated that information about non-donors is of no particular value to OPOs and other procurement organizations. On the other hand, in states where registries of consent apply, it may be regarded as unethical to approach families to gain consent for decedents who are not listed in such registries.

It was quite apparent to the group that greater clarity, preferably at the legislative or regulatory level, is needed regarding the interpretation of consent based on designation in donor registries.

e) Maintaining the Registry

Registries must permit voluntary disenrollment of registrants and removal of those who have died or who have moved out of state. Maintenance mechanisms include free and password-protected Internet or telephone access to change registry information. Social Security numbers and other alternatives were raised for use as identification numbers and passwords. As noted above, other suggestions included maintaining scanned consent documents with registrants' signatures, as well as other electronic updates and data sharing. Some participants expressed the opinion that, while they should have immediate access to registries, OPOs should not maintain registries.

Participants noted some concerns about relying upon DMVs to provide current information about donor registrants. Despite requirements that they provide updates of address changes and other information to DMVs on a timely basis, drivers often delay or neglect doing so. To the extent that registries are based on information derived from DMVs, they may be out of date or otherwise incorrect. Some participants suggested having DMVs maintain registries as a function apart from the driver's licensing function. Participants familiar with DMVs noted that state bureaus of vital statistics arrange with DMVs to provide updates, and that the Social Security system updates its information on a regular basis. As such, states could arrange for provision of updated information for maintaining the currency of donor registries.

f) Unresolved Issues

The group identified the following as issues that must be resolved.

- The information required to maintain an effective registry depends, in part, on prevailing state and national legislation and regulations pertaining to intent and consent, and how

these are interpreted at the time of donation. To the extent that these are ambiguous or conflicting, the effectiveness of registries may be compromised.

- The design of registries, including their data elements, should be informed by the ways in which the effectiveness and the accountability of registries are to be assessed.
- Although DMVs are likely to remain a primary portal for donor registries, this is not their primary function. The setting of DMVs is not ideal for donor registration, and they may be subject to lags in updating data. However, DMVs offer many advantages for acquiring information for donor registries. Therefore, donation stakeholders should work closely with DMVs on an ongoing basis to improve their role in donor registration.

2. Working Group 2: Portals of Entry

Working Group 2 discussed issues related to portals of entry for registry enrollees. The primary portal into a registry remains the DMV, although registration may be available through other venues. An effective registry must draw from and coordinate various portals of entry and exit, if applicable.

The discussion points prepared by HRSA for Working Group 2 were as follows.

- What are the most successful portals for registering new donors?
- What are the pros/cons of each portal?
- If registrations do not occur at the DMV, how are they facilitated and to whom is the registration information provided?
- What technologies have been successful in providing citizens' access (other than the DMV) to registries?
- How should the availability of alternate portals be advertised?
- What are the most reasonable options for linking registries among states? Are these options currently formalized?
- What are the portals of exit if a registrant chooses to rescind his/her donation declaration?

Participants loosely followed the questions on the list, providing views not only on the most successful portals but also discussing the importance of education for a portal, and ultimately the registry, to be successful.

a) Characteristics of a Good Portal

The working group explored various possibilities for portals to a donor registry, and agreed that the ideal portal allows:

- Easy public access to enter the registry;
- Validation of data at enrollment and follow-up; and

- Ease of registry maintenance by its gatekeeper.

Participants pointed out that the "ideal" portal does not exist. Given funding and logistical limitations, there are tradeoffs in the attributes of alternative portals. For example, a kiosk in a busy shopping center may be visible and attract a large number of potential donors, but if improperly equipped and managed, it also may attract underage and uninformed people who may enter invalid or inappropriate data about themselves or others.

The group agreed that the utility of a portal must be evaluated in terms of whether the registry is one of informed consent or only intent. A registry of consent requires portals with higher levels of validation and follow-up.

b) Types of Portals

DMVs are recognized as the most common type of portal. Participants engaged in discussion of the advantages and disadvantages of the DMV and made recommendations on how the DMV can best be utilized as a registry portal. DMVs have the advantage of being familiar and reliable portals. Consistent with DMVs' current relationships with donation efforts, the public increasingly expects the DMV to be a place to designate donor status. A large portion of the public makes periodic visits to DMVs to acquire or renew licenses and update information. Participants recognized that a major disadvantage of the DMV as portal of entry into a donor registry is that securing donation status is not the DMV's primary function. With their limited resources, DMVs do not have the capacity to educate their staff or the public in an optimal fashion about donation. DMV staff are often unable to dispel misconceptions about donation, and may convey misinformation.

Participants also suggested online registration as another promising portal that several states have begun to explore as a method of signing up registrants. Registrants emphasized that access to a "helpdesk" and a stable and appropriately sized server are necessary to make online registration an effective portal.

The group suggested several portals that are less commonly utilized, or not utilized at all, in the U.S. Participants suggested coupling donor registration with employment orientation procedures, such as signing up for health insurance. One disadvantage noted about this suggestion was that some employees might distrust the option if the federal government initiates it. Doctors' offices, pharmacies, and credit card application processes were also suggested as potential portals. Health care encounters, especially hospital admissions, may not be ideal portals, as these settings could have the potential of being interpreted as coercive to patients and implying to some patients that the hospital stay may result in death. An advantage to these alternative portals is that they are accessible to a large portion of the public, are places that people frequently visit, or are processes in which they frequently participate.

Some participants suggested that the portal of entry be national. The OPTN system that links all OPOs and transplant centers was suggested as a prototype. Several other participants suggested that the use of the DMV as a universal portal could be explored as a possibility through collaboration with the American Association of Motor Vehicle Administrators (AAMVA),

members of which participated in the conference, which has suggested the eventual creation of a system of standardized licenses and a single database.

Participants also discussed the relative merits of having multiple portals versus a single portal. One participant suggested that multiple portals are possible as long as there is sufficient interaction to ensure informed consent.

c) Portal versus Gatekeeper

One participant suggested that states might relieve some of the responsibility from the DMV by downloading the information, thus decoupling the portal role from that of gatekeeper or custodial role. In that instance, the DMV might not feed information directly into the registry, but would provide the gatekeeper with the names of individuals potentially interested in entering the donor registry. On the other hand, this would add another hurdle to the registration process and likely diminish the pool of registrants.

d) Importance of Public Awareness and Education

Participants agreed that once states have determined which portals to use, advertising campaigns to make the public aware of those portals is essential to the registry's success. Participants agreed that a public awareness campaign must aim at managing public expectations regarding the meaning of signing up for the registry. One participant cautioned that any campaign must address how being absent from a registry is interpreted. The participant cited anecdotal evidence of families who declined to consent to donation because the decedent's name did not appear in the registry. Another participant emphasized that public awareness and education should include a message to registrants to inform their families of their donor status. Participants also raised the importance of outreach to minority communities as one element of a successful campaign.

Often, the portal is used as a venue or method to deliver public education and awareness messages. For example, one participant described the DMV as an optimal location to provide donor education, given that individuals visiting the DMV must often wait in long lines to be served, during which they could be educated about organ donation. A representative of a state DMV cautioned that people often mistake the DMV for the developers of registries and stressed the importance of informing the public regarding the process and agencies involved in organ, tissue, and eye donation. Several media were suggested, including pamphlets, sign-up sheets, video, and handouts, including guidelines advising registrants about how to discuss their intentions with family members.

Participants identified other examples of successful education sites and strategies, including outreach through the workplace, churches and other religious institutions, rotary clubs, driving schools, donor drives by charitable organizations, health fairs, and collaborating with politicians or other prominent figures to raise awareness. Participants agreed that such efforts are most successful when focused locally. Without proper communication and coordination among different organizations launching campaigns, there is a risk in their delivering conflicting messages to the public.

e) Linkages Within and Across States

The group described current linkages between states and procurement organizations as variable. Sometimes multiple OPOs serve one state, while in other instances an OPO serves more than one state. Participants described current linkages as being largely informal. Participants agreed that it is too early to determine to what degree formal linkage is possible or needed to promote organ, tissue, and eye donation. One participant stated that formal links would be possible if all states had registries and if a sufficient number of out-of-state donations occurred. The group emphasized the importance of forming and maintaining linkages with eye and tissue banks.

f) Maintenance

The group concurred that choice of portal notwithstanding, ongoing maintenance of registry data is necessary. One participant described his state registry's method of linking the registry to death statistics to remove deceased registrants. Others brought up the issue of duplicate names, which may make it difficult to derive accurate estimates of the success of registry outreach. Other participants noted that the cost of eliminating duplicate names can be high. Participants discussed methods by which individuals could log onto the Internet and gain password-controlled access to their information, but others cautioned that online updating could be costly.

g) Unresolved Issues

Participants raised the following unresolved issues.

- The advantages of using registry portals as means of gaining informed consent from large numbers of people may be diminished to the extent that this process is lengthy or cumbersome.
- Although promising, the effectiveness of online registries is unknown. A pilot research project could provide some answers, along with practical insights, to this question. Currently, the State of Utah is evaluating the effectiveness of online registries that may provide valuable information regarding online registry effectiveness. Funding for this project is provided by the HRSA/DoT.
- Although useful in principle, the effectiveness of cross-state linkages in increasing donation is unknown.

3. Working Group 3: Training DMV Employees and the Public

Donor registration is not the primary function of DMVs, which are generally not required by law to have a role in donor registration. However, given the DMV position as primary portal for most registries, special consideration must be given to training of, and related incentives for, DMV staff, who are otherwise unlikely to have organ, tissue, and eye donation expertise or commitment. Although they require DMV resources, donor registries create additional work for DMV staff. For DMVs to be effective portals, it is necessary to ensure that they have adequate resources and clear statements of their responsibilities, and that DMV staff have sufficient preparation to provide basic information to the public.

The discussion points prepared by HRSA for Working Group 3 were as follows.

- How can motor vehicle administration employees contribute to registry success?
- What types of feedback should be provided to motor vehicle administration employees regarding their participation in the donor registry?
- What are the elements of a successful training program for motor vehicle administration employees?
- How can DMV's promote donation—videos, posters, brochures; information in driver's license manuals; license renewal notices; questions on driver's tests?
- What, if any, incentives exist to cultivate the support of MVA offices and/or employees?

Participants drew extensively on their own DMV experiences to address these points. They initially examined the topic's underlying assumption that the DMV is an important enough portal to merit specific training of staff. Although the group recognized that the DMV is an important portal, given its function as a common point of interaction with a large segment of the general public, the group concurred that the public must be educated about organ, tissue, and eye donation and motivated to register prior to visiting the DMV. A participant from Colorado cited a state survey that found 8 out of 10 people had made their decision about organ and tissue donation prior to going to the DMV.

a) Expectations of DMV Staff

Matters related to donation must be incorporated into the DMV without diminishing DMV staff's ability to perform other functions that are mandated by law. Participants suggested several guidelines to help the donation community manage their expectations of what the DMV is willing or able to do with regard to donation. Participants suggested that the DMV staff should not be expected to attain a high level of knowledge in organ and tissue donation issues, but that staff should be made to understand that they do have an important role in the process. DMV staff should be expected to provide answers to commonly asked questions in a neutral manner, but more complicated questions should be referred to a procurement agency, a brochure, or other official source of information. To this end, participants suggested that such additional information should be made available to DMV staff to distribute to the public. States have attempted to relieve the burden on DMV staff by having them ask a minimal number of questions and then recording the driver's response accordingly.

b) Effective Strategies for Preparing DMV Staff

Participants suggested several tactics that states have found effective in training DMV staff. These include:

- Preparing staff with only general information;
- Creating a personal interest in donation among DMV staff;

- Ensuring that DMV staff are capable of answering a few frequently asked questions, such as "Am I too old?" (No); and
- Ensuring that staff know to tell new registrants that their next step is to communicate their donation decisions with their families.

Participants suggested the following as examples of ways to promote a personal stake in the organ donation process.

- Demonstrating to staff the beneficial impact of organ, tissue, and eye donation;
- Monitoring improvements in registration and donation rates;
- Courting the support of the DMV administration; and
- Giving positive personal feedback and encouragement to the DMV staff.

c) National Possibilities

Participants suggested that the organ, tissue, and eye donation community's future collaboration with the DMV should consider the role of AAMVA. Several participants reported that AAMVA is contemplating a national driver's license database from which the donation process could eventually benefit.

d) Unresolved Issues

- The potential for national collaboration with AAMVA should be explored.

4. Working Group 4: Registry Access

Defining access to a registry must include who may obtain information from the registry, and when and how information may be obtained. Because the registry includes both confidential and time-sensitive information, registry access policies and procedures must be specified.

The discussion points prepared by HRSA for Working Group 4 were as follows.

- How should the privacy of registrants be protected?
- How should procurement organizations and registry staff cooperate to facilitate timely release of information about decedents?
- How can hard copies of donor registry enrollments be made available in a timely manner (if requested by surviving next-of-kin at the time of a registrant's death)?
- How can procurement organizations communicate across state lines to access registries for out-of-state deaths?

The participants used the questions provided by HRSA as points of departure for their discussion. The group decided to address them in the context of a broader discussion of who has access to the registry, what information can they access, and when.

a) Uses of Data

Participants established two uses of data in a donor registry. The primary use is to facilitate the process of organ, tissue, and eye donation. A secondary use is to improve organ, tissue, and eye donation education and outreach.

b) Who Has Access

This discussion centered on the question of access to donor registry information. Participants agreed that access and use of data should be restricted in order to establish the public's trust that privacy will be protected. Allowing broad access would compromise registry security and undermine the public's trust and participation in registries.

The gatekeeper receiving a referral needs to have direct access to the registry, preferably in real time and online. This would include OPOs, eye banks, and tissue banks or their designees. Even for authorized procurement organizations, participants recommended limited indirect access to registry data for only those on the staff who are responsible for taking referrals or verifying donation consent. For procurement organizations with online access, each individual who has authorized access to the registry should be given a password-protected log-in name for security and tracking purposes. Participants discussed the pros and cons of direct access for hospital personnel. For example, one type of misuse could arise if hospital staff discovered that a decedent was not listed in a registry, and then was less inclined to make a referral to an OPO, although failing to make the referral would appear to be contrary to the Medicare CoPs for hospitals. The group agreed that limiting direct online access should not preclude the possibility that other organizations, such as out-of-state OPOs who have not been granted log-in capability, might also need access to the registry. These organizations should be permitted indirect access through the gatekeeper.

c) What Can Be Accessed

Participants agreed that accessible information should be limited to those data elements that are necessary to verify the identity of the donor, i.e., name, address, donor status, birth date, identifying features such as height and weight, and potentially the Social Security number. The group recognized that the management of registry information (collection, maintenance, access, etc.) must comply with applicable state and federal regulations, including the Medicare CoPs and Health Insurance Portability and Accountability Act (HIPAA). Data collection should be as consistent as possible across states. Consistency and accessibility of data elements would be facilitated by creating a national identification card and a data bank system, currently in discussion at the federal level.

d) How and When Information Can Be Accessed

Information must be accessible at all times in order for a registry to be reliable and useful. Furthermore, the currency of data must be maintained and documentation (e.g., of intent and consent) must be validated.

Two methods of achieving real-time access were discussed: 1) online access and 2) maintaining adequate staff to support a 24-hour/7 days per week system. The method employed for any registry will depend in part on the costs of developing and maintaining an automated versus a staffed system, or combination of these. Participants agreed that an online system is the preferred means of access. They also noted that any online system must be consistently reliable and have a secure log-in procedure in order to ensure its utility and public confidence in it.

Participants agreed that the need for hard copy documentation becomes greater for registries of consent. The group noted that, for registries of consent, state laws or regulations must afford immunity or other protection for hospitals and OPOs that rely on this information to act in accordance with the decedents' consent to donate. There was a lack of concurrence about whether current information technology can provide true real-time access to registry data, particularly for presenting images of donor consent statements to family members. Some participants reported that the necessary technology was unavailable, while others stated that advanced optical scanning technology makes hard-copy documentation feasible (e.g., by faxing a copy of the scanned document to the hospital).

One participant introduced the idea that, if at the initial referral the family is clearly not willing to donate, then the registry should not be accessed. However, this may be contrary to regulations regarding the interpretation and use of donor registry information on intent and consent.

e) Communication Across State Lines

Participants discussed the importance of communication across state lines. In some regions, an OPO operating in the state in which a decedent is located can contact the appropriate OPO in the decedent's home state. Such arrangements do not imply that OPOs should have direct access to other states' registries. Participants discussed the potential advantages of a national database of linked registries that could be searched by multiple OPOs.

f) Outstanding Issues

The group identified the following areas requiring further study:

- Private registries exist, but whether they complement or detract from existing state registries is unknown.
- The potential for donor registries to improve organ and tissue donation will be limited by certain factors that may have to be resolved or clarified via legislation, regulation, or other authoritative guidance. These factors include immunity or other protection for hospitals and OPOs that rely on registry information to act in accordance with decedents'

wishes, compliance with HIPAA and other matters of privacy protection, and limitations on access to registry information.

5. Working Group 5: Funding and Legislative Support for Registries

Without the proper financial and legislative support, efforts related to donor registries, including education, maintenance, and evaluation, cannot progress. The start-up cost of implementing a registry may pose a barrier in many states. Existing registries have been funded with both public and private dollars. Legislation is necessary to resolve or clarify issues related to limiting registry access or use, issues that arise if hospitals or OPOs rely on registry information as first-person consent, and/or privacy issues.

The discussion points prepared by HRSA for Working Group 5 were as follows.

- What options exist to secure start-up funds for registries?
- What are the funding options to facilitate maintenance and/or improvement of registries?
- How are registry annual operating costs determined? What operating costs can states anticipate?
- What is the feasibility of using public/private partnerships to promote registry development?
- What types of legislative initiatives may be helpful in developing/funding a donor registry?
- How should HHS work with federal, state, and local groups to further this legislative agenda?

Upon reviewing these points, the group added the following ones for its consideration.

- What mix of funds is spent on activities such as marketing?
- What will happen to money spent on state registries if there is a national registry?
- What is the penetration rate of states that have registries?
- What mechanisms exist to generate state legislation?
- What funding exists for technology improvement?
- What can HHS do?
- What type of data could be collected to communicate registry value or effectiveness?

The group acknowledged that donor registries are a new type of resource, and little is known about their cost and the practical implications of legislation pertaining to them. Instead of being able to resolve all of these questions in the allotted time, the group recognized that some of them should be the subject of research or other evaluation in support of formulating donation policies and procedures. Discussion continued with participants sharing their ideas and experiences

about such related matters as start-up costs, sources of funding, legislation, and the role of HHS in funding and clarifying the nature of needed legislative action pertaining to donor registries.

a) Start-up and Operating Costs

The group agreed that little is known about the costs of starting up and maintaining a registry, and that costs will vary depending upon the type of registry and its features. As such, more research is needed to adequately determine the costs involved in registry development. Broad decisions to develop future registry activity around one national registry, or among multiple independent state registries, or among multiple cross-linked state registries will affect the magnitude and distribution of costs.

The knowledge that does exist about registry costs is often not shared. The group recommended conducting a formal survey of states with registries to determine their start-up, human capital, and operating costs as an ideal next step to filling this knowledge gap. The survey also could provide more detailed information about types and structure of registries and their respective costs. (This survey could build upon the information about registries that was compiled and updated by The Lewin Group in conjunction with this conference.) The group noted that further research about registry costs must include a description of registry operations and the legislative context in which the registry operates to adequately define registry types or models.

The following were suggested as variables that may be included in a cost-benefit (or cost-effectiveness) study of donor registries: respective differences between estimated and actual registry costs; penetration rate of donor designation among driver's license populations and other populations; DMV staff training; costs of registry maintenance, education and outreach; use of technological advances such as scanned cards with signatures; and the extent to which OPOs and hospital requesters approaching potential donor families use existing registry information.

The group suggested that other types of databases operated by states (e.g., databases for tracking child support payments) have some processes and technical requirements that are similar to those of donor registries, and may provide useful insights and experience for estimating the development and maintenance costs of donor registries.

b) Sources of Funding

The group agreed that the organ and tissue donation effort needs financial support from the federal government, but devoted greater discussion to state-level funding. Participants discussed existing state strategies to secure funds such as the following.

- Some states, such as Montana and Pennsylvania, collect mandatory contributions or request voluntary contributions through tax return forms or DMV vehicle registration.
- One state, Florida, acquires funding through an OPO business tax. Participants acknowledged that such taxes are not favored by OPOs.

Other suggestions include the following.

- Additional financial support could be raised through working partnerships with corporations, including but not limited to those that are included in the Secretary's Gift of Life Donation Initiative. One participant noted that collaboration is especially promising if someone from a corporation or its board has had a transplant or some other connection to the transplant community.
- One participant suggested that a surcharge on drunken driving and speeding tickets could be another source of revenue; however, others argued that such a policy could increase fines and have the potential of creating negative publicity for organ donation.

c) Legislation

The group concurred that interstate communication will be a key element of effective organ donor legislation. The group recommended that state representatives of registries meet on a regular basis to determine what is working and what is not. The National Governors Association meeting was cited as a potential opportunity for such communication. The group also cited the need for OPOs to similarly communicate across and within states.

The group recommended that states strive for nationwide uniformity of donation laws, enforce first-person consent, and provide for education for the public and health care professionals. Legislation needs to state clearly that enrollment in a registry is a clear statement that the individual wishes to be a donor, and that absence from a registry is not necessarily a refusal to donate.

The group also addressed the need to align statutory authority for registries with legislation that provides funding. Participants noted that obtaining legislative authority to establish a registry is virtually useless without adequate funding.

d) HHS Responsibilities

The group recommended that HHS Secretary Thompson should continue to promote effective and consistent donor legislation among the governors. Health organizations or representative committees could also serve as advisors.

The group acknowledged that states, OPOs, and the federal government have the responsibility of motivating leaders and citizens to take action, generating the momentum necessary to make organ donation a prominent issue.

e) Unresolved Issues

Besides seeking answers to the HRSA and additional discussion questions outlined above, the group identified the following unresolved issues.

- Studies or evaluations must be performed to determine the true cost and cost-effectiveness of running donor registries.

- Legislative authority to establish and maintain registries must be accompanied by timely and adequate funding.

6. Working Group 6: Evaluating Registries

The goals of evaluating the effectiveness and impact of donor registries are to understand how well public education initiatives, donor awareness campaigns, and donor registration processes are being implemented, and to determine the extent to which these efforts affect desired outcomes, such as donation rates. The ability to demonstrate registry effectiveness and impact could strengthen existing registries and increase support for donor registries in states where they do not exist.

The discussion points prepared by HRSA for Working Group 6 were as follows.

- How can registry data be made available to procurement organizations, researchers, and/or government entities to track the effectiveness of public education programs, donor awareness campaigns, donor registration processes, etc.?
- What type of registry data would be useful to track the effectiveness of public education programs, donor awareness campaigns, donor registration processes (such as number of people registering by each portal of entry)?
- How can registry databases remain current? (For example, how can databases be free of duplications or the names of people who have died?)
- What type of entity is necessary to monitor registry activities and provide guidance on future registry initiatives/developments?
- How are donations resulting from participation in a registry tracked and reported?
- Should procurement organizations re-evaluate their marketing strategies to focus on registry enrollment?
- Should we consider developing a multi-state or national marketing effort to promote registries (regardless of whether registries are state or national)?

Although participants addressed several of these questions, they also chose to discuss topics assigned to other working groups, given that decisions about evaluation overlap with decisions about registry operations.

a) Tailor Evaluation to Registry Type

In general, the group agreed that registries are beneficial, that every individual should have access to enrolling in a registry, and that, ideally, every state should have a registry. Before discussing the type of data that would be useful to track registry effectiveness, the group concurred that variability among registries makes them difficult to evaluate in a uniform manner. Therefore, the design of an evaluation should reflect the registry purpose (pertaining, e.g., to consent, intent, or education) and other structural characteristics (e.g., voluntary, inclusive,

"Yes" only, or processes at the portals of entry and exit). The group also agreed that common definitions are necessary for an effective evaluation process.

Experienced evaluators and database analysts should be included in the process of registry design and development (for new registries) and maintenance (for existing registries) in order to ensure properly focused evaluation and that evaluation results will be of practical use in improving registries.

b) Types of Evaluation Measures and Areas of Study

The group identified three types of evaluation measures as being important to the study of registry effectiveness: structural, process, and outcome. Structural measures assess the attributes of the registry type (i.e., whether a registry has characteristics considered to be correlated with success). Process measures determine how well the registry is operating, such as access to the registry, registry enrollment (including by portal, demographic characteristics, etc.), registry maintenance, registry marketing (e.g., numbers reached via marketing or education campaigns), and costs. Outcome measures track what has changed as a result of the registry, e.g., consent rates and donation rates. The group agreed that the most important outcome measure is whether or not a registry is successful at increasing the number of donations, and that the registry's impact on consent is an important secondary outcome.

It is important to track registry performance in the short, intermediate, and long terms. For example, while evaluation is ultimately intended to determine whether registries increase rates of consent and donation, these impacts can only be assessed over the long term. Tracking short and intermediate measures, e.g., the numbers enrolled in a registry after an education campaign, ensures that evaluations produce useful results that can enlist support from government entities for organ donor registries, and may encourage states without registries to develop them.

In addition, evaluations could be conducted from the perspective of an individual state registry or that of the nation. For example, intermediate process evaluation measures proposed by participants from a state's perspective include the number of people that are registering and their demographic characteristics. Process measures from a national perspective might include: the number of states with registries, and what works to increase the number of states with registries. If the transplant community chooses to promote organ and tissue donation at the national level, the group suggested that an important indicator to track would be registry enrollment across the nation, calculated by adding individual state enrollment numbers. These findings could be useful in influencing national, state, and local governments and legislators.

The possible areas of investigation discussed by the group include the following.

- Do registries increase organ/tissue availability? What are the characteristics of individuals choosing to register?
- Do registries ultimately help transplant patients?

- How effective are DMVs as portals of entry? This could involve tracking the number of individuals who seek traditional services at the DMV against the number that register as donors over time.
- How aware are registrants about the meaning of their enrollment status, e.g., donor intent or consent? What is the relationship between this status and decisions to authorize donation procedures at the time of death?
- Among registries of intent, what are the numbers and sources of consents, and how do these change over time?
- What is the difference in effectiveness when OPOs seek consent by sharing potential donors' intent to donate (as documented in a registry) with surviving family members versus approaching the family without being aware of the decedents' intentions regarding donations?
- Does each OPO use donor registry information? How do OPOs use this information?
- Do registrants notify family members of their enrollment in the donor registry?
- Regarding registries of consent:
  - Are registrants more likely to opt in or out of registries at certain stages of their lives?
  - How are potential donors asked to join a registry? (For example, the question may be "Do you want to be a donor?" or "Do you want the donor designation on your license?") How are the subsequent answers ("No" vs. "I don't know" vs. "I don't want the designation on my license, but I do want to be a donor") interpreted or recorded in the registry?
  - Are registrations confirmed with follow-up correspondence? How often do people rescind their decisions at the time of such confirmations?
  - Is documentation of donation consent (e.g., with a facsimile copy of a signed donor document) effective at enlisting the family's support for donation?
  - Do registries of consent affect the emotional burden on donor families? Do registrants consider their enrollment as binding on their families?
- Does knowledge of a donor registration make a family's deliberations (at the time of registration or at the time of death) easier? How can this be assessed?
- How secure are registry data?

Baseline data are important to collect in any evaluation of registries, particularly when evaluating the impact of a donor awareness or registry education campaign. The group suggested that baseline be defined as registry enrollment after the initial registration cycle. An alternate definition for baseline is measurement in the year prior to establishing the registry.

c) Evaluation Supports Education, Outreach, and Marketing to Increase Registry Enrollment

Demographic information stored in registries would be useful to support development of education efforts, particularly in geographic areas or communities where registry enrollment is low. Participants agreed that the current level of data collection, which in many states is limited to minimal demographic information, such as age and sex, is insufficient for targeted marketing and promotion efforts. The group suggested that states work to establish uniform guidelines for demographic information collected at the time of registration.

Participants suggested other sources of information that could inform marketing efforts. The group agreed that focus groups and professional polling could help states establish realistic goals for registration enrollment. Participants discussed the need to understand which types of events and locales prove most or least effective in enrolling registrants. To this end, participants suggested that states with high registry enrollment could share their education, outreach, and marketing strategies with other states to assist them in developing effective marketing plans.

Participants suggested that procurement organizations, states, and other stakeholders that perform outreach to the public might benefit from a standard national registry-oriented campaign, such as the Coalition on Donation's approach of creating uniform local donation campaigns, to minimize public confusion caused by the absence of educational messages or multiple or inconsistent ones.

d) Maintaining the Registry and Tracking Events Over Time

To maintain the currency of registries, participants proposed that various state organizations share data with them (e.g., death notification to the state registrar can be cross-referenced with the donor registry to remove registrants who have died; address changes notified to the DMV can be cross-referenced with the donor registry entrants). The desired medium for registries was electronic, such that databases are easily accessible and can be linked with other data sources to facilitate maintenance.

Participants discussed ways in which events in the donation process can be tracked in a donor registry database and who should be tracking that data. For example, LifeNet of Virginia is tracking its donation authorization rate, i.e., the rate at which indications in the donor registry provide authorization for LifeNet to proceed with donation. It also tracks donation consents that are obtained from next-of-kin in cases where the donor is not included in the registry. Participants wanted to know whether states currently link electronically existing registry data to organ procurement data (as in New York) and if procurement organizations are tracking whether referred potential donors are on a registry, and whether they actually become donors. Participants wondered if it would be possible to track information about those who die and do not get referred, and asked if these people were on the registry.

The group also considered who should be tracking registry information. It seems likely that the procurement organization will possess the greatest motivation to track enrollments and evaluate the impacts of registries. However, in order to promote a stronger working relationship between

the procurement organization and the state, participants recommended sharing outcomes data with the state entity responsible for maintaining the registry.

As is the case for any database, accountability mechanisms need to be in place regarding how and when registries are used. The group cautioned that users or analysts understand the meaning of each data point in a registry. Specifically, it is important to have clear definitions and policies regarding the meaning of "Nos" in a registry. It is possible that a "No" means any of the following: "I don't want to think about this," "I don't know if I want to be a donor," "I don't want my donation intent put on my driver's license," "I don't have enough information to make this decision," or "No, I don't want to be a donor." Many procurement organizations favor "Yes-only" registries to avoid these potential misinterpretations.

e) Outstanding Issues

- Evaluations of registries are needed to fill gaps in knowledge about their impact or effectiveness.
- Consistency in definitions of registry and accountability mechanisms for how and when registries are used are essential for meaningful evaluation.
- Clear policies and public awareness are needed regarding the difference between consent and intent as recorded in donor registries.
- In particular, further research and analysis is needed to clarify the process of securing consent for donor registries and the clinical and legal implications of registries of consent.

IV. SUMMARY: DAY 2 – OPTIONS FOR A FEDERAL ROLE

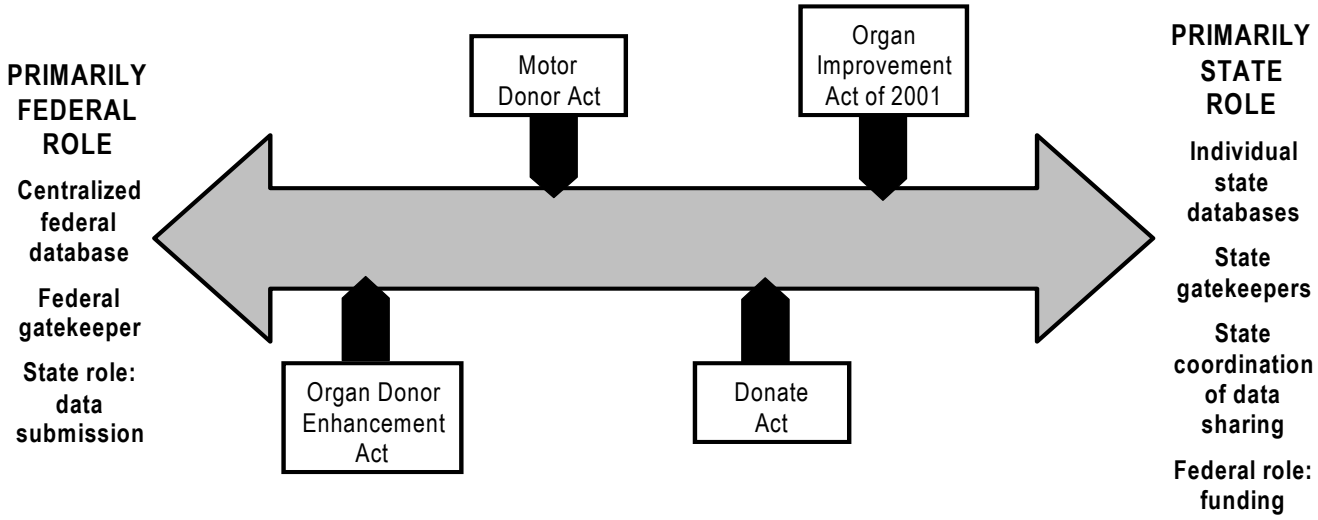
A. Overview of Pending Federal Legislation

Day 2 focused primarily on the main attributes and implications of pending federal legislation pertaining to donor registries. The day began with a plenary session comprising an overview presentation of four relevant bills followed by a panel discussion on certain of their relative merits. Following the panel, conference participants split into three facilitated breakout sessions to further discuss the legislation and potential federal role in donor registries. As in Day 1, participants were pre-assigned to the sessions, although the purpose of discussion in all three sessions was the same. Following the breakout sessions, all participants reconvened in plenary, where each group provided a spokesperson to present its main findings. Day 2 concluded with a plenary discussion intended to identify the themes of the conference and recommendations for strategies to promote donor registries.

Drawing from The Lewin Group's *Analysis of National and State Actions Regarding Organ Donor Registries* prepared for the conference (Appendix B), Clifford Goodman presented and contrasted basic information about each bill, including the nature of the proposed registry or coordination activity and the respective federal and state roles for each. The interest in a federal role in donor registries has become more prominent in recent years, and particularly since the

Secretary's Gift of Life Donation Initiative. HHS has increased its involvement as well as funding for donation activities and studies. On the part of Congress, four donor registry bills had been introduced at the time of this conference, including: The Motor Donor Act, The Donate Act, The Organ Donation Improvement Act of 2001, and The Organ Donor Enhancement Act.[11] Exhibit 3 illustrates the spectrum of relative federal and state roles in each bill. Exhibit 4 shows summary information for each bill.

Exhibit 3. Federal and State Roles



- ***The Organ Donor Enhancement Act*** (H.R. 955) is sponsored by Rep. Jay Inslee (D-WA). The bill would establish a centralized national living donor registry to be maintained under the Secretary and a board of directors assigned by the Secretary. The bill also provides for a program of educational activities to recruit living organ donors.

- ***The Motor Donor Act*** (S. 788 and H.R. 2645) is cosponsored by Senator Charles E. Schumer (D-NY) and Representative Leonard Boswell (D-IA). The bill would create a national organ and tissue donor registry of intent, specifically linked to the motor vehicle license application process. The bill would create a national database administered and maintained by HHS. The bill also calls for the creation of a website that would allow residents in states without donor registries to sign up and participate as organ donors. Other provisions include 24-hour access for procurement organizations, specified contents for the registry, grants provided to states to plan and implement registries through the DMV as well as for public awareness and education activities, and the creation of an advisory task force from various stakeholder groups.

- ***The Donate Act*** (S. 1062) is sponsored by Senator Richard Durbin (D-IL). The bill aims to facilitate best practices and interstate linkages among donor registries. The focal point

[11] A fifth bill was introduced following the conference, The Organ Donation and Recovery Improvement Act (S. 1949), sponsored by Senators William Frist (R-TN), Christopher Dodd (D-CT), Tim Hutchinson (R-AR), James Jeffords (I-VT), and Mike Enzi (R-WY).

of the bill is the establishment of a National Organ and Tissue Donor Registry Resource Center. The center would serve as a clearinghouse for technical assistance, provide linkage and access to other states' donor registries, and establish consensus guidelines for a standard registry model. Consensus guidelines would address a registry's core function, set minimum or standard levels of legal and ethical guidelines, and establish privacy safeguards and cross-state data protocols. The bill would provide grants to states to develop or expand registries as well as allow funds for public awareness activities. It also would establish a grant program for hospital organ donation coordination and an advisory task force comprising various organ donation stakeholder groups.

- ***The Organ Donation Improvement Act of 2001*** (H.R. 624) is sponsored by Rep. Michael Bilirakis (R-FL). The bill would promote organ donation in two ways. First, it would allow the Secretary to make grants and contracts (subject to eligibility criteria) to states, transplant centers, OPOs, and other private or public entities to pay for expenses incurred in the course of living donations. Second, the bill would allow the Secretary to fund public and private entities to conduct studies and demonstration projects related to public awareness and education programs designed to increase organ donation. In order to help them carry out their public awareness activities, the Secretary may provide grants to eligible states to establish yearly benchmarks as well as develop, enhance, or expand their donor registries.

The relative merits of the pending legislation were addressed by three panelists, including John Eiche of The Living Bank, Louise Jacobbi of Saturn Management Systems (formerly of the Louisiana OPO), and Antigone Klima of the Transplantation Society of Michigan, representing perspectives of private registries, OPOs, and states, respectively. In his comments, John Eiche focused on the relative weaknesses of the bills including: not addressing the states that do not have registries, inadequate levels of funding, and lack of specification of the federal government's role. Mr. Eiche noted that registry information should be made available to all organ procurement organizations, including eye and tissue banks. In closing, he stated that registries are useful tools to raise awareness, the linkage of registries is desirable, and the Living Bank serves as a model for a national registry. Louise Jacobbi noted some of the more favorable aspects of the bills to be their promotion and education provisions, use of IRS mailing lists to disseminate information and promote organ and tissue donation, and the development of a congressional medal to honor donors. Ms. Jacobbi pointed to the Durbin Bill as the most comprehensive of the four bills. However, she cited some drawbacks of it, including lack of definition of the Resource Center's role, lack of mention of how registries would be maintained after the grant period, and lack of inclusion of people outside the transplant community for the Advisory Task Force Committee. Lastly, Ms. Jacobbi stressed that registries are a powerful tool for raising awareness, and consideration must be given to providing a consistent message to the public. Antigone Klima raised the issues of improved database maintenance and education for the public and health care professionals as key aspects that would help in setting up a registry. She noted that state legislation establishing a registry and adequate levels of funding are significant facilitating factors in registry development. Moreover, other aiding factors include being linked to a routine referral database and using first person consent. For the Motor Donor Act, Ms. Klima noted the lack of funding for hospitals and the lack of first person consent as

drawbacks. Regarding the Donate Act, Ms. Klima remarked that, while the decision to make the registry a "Yes" only registry was a benefit, it is a drawback to have an intent-only registry.

As a group, the panelists identified several types of strengths among the bills, including: focus on registry development and enhancement, linkage of registries, inclusion and recognition of the importance of public education and awareness (including recognition of registries as means of education), providing for immediate access to registries, ensuring security and confidentiality, and formation of advisory panels. The panelists identified multiple aspects of the bills that need further development and refinement. Among these are the involvement of states that do not establish registries, more details on how states would be linked, insufficient definition regarding HHS' role, inadequate funding to implement the bills' provisions, insufficient mention of other procurement organizations such as eye banks, lack of specification on data maintenance and registry setup, lack of provisions for funding after the termination of initial grant periods, and lack of first-person consent (i.e., where registry participation constitutes binding consent).

B. Breakout Sessions on the Federal Role

The main discussion points, including favorable and insufficient/unfavorable attributes of each bill, derived from the three parallel breakout sessions on federal involvement in registries are summarized below. Exhibit 4 presents a summary of these points.

The Motor Donor Act. Among the main favorable attributes that participants cited in the bill are that it provides for a federal framework for registry development and builds on existing infrastructure. Other favorable attributes identified are that the bill: allows for voluntary exit and notification regarding registry participation status, calls for and designates a minimum data set, provides for people who reside in states without registries to sign up as donors via a website, provides funding for public awareness and educational activities tied to demonstrated collaborations, and provides for using IRS mailing lists to disseminate registry and donation information. Further, the bill has support in both the House and Senate.

Registering donors through state agencies was deemed favorable. However, participants expressed some concerns about designating the DMVs as the state agencies for this role, given the bill's lack of specification of the responsibilities and resources regarding DMV involvement. Participants acknowledged the possible beneficial aspects that come with private-government partnerships (i.e., between state agencies and private OPOs, eye, and tissue banks). Of benefit would be bypassing competition among OPOs for registering donors and communicating a clear and consistent message to the public, and displaying government involvement and support of organ, tissue, and eye donation. In forming private-government partnerships, participants thought it was important for the public to distinguish between a registry that is state-run (i.e., state is the gatekeeper) and a registry that has state agency involvement.

Attributes of the bill that were viewed as insufficient or unfavorable included lack of provisions for hospitals to develop organ procurement coordination, not having family members of donors on the advisory board, lack of clarity regarding the registration question asked of the public when enrolling, and lack of definition and resources for the DMV. While participants acknowledged that having a single portal of entry provided a straightforward means of public access, the bill does not address other portals that may broaden access.

The outstanding areas needing further development include better defining the role of the DMV as the designated state agency, providing a means for implementing the bill (such as through a federal mandate similar to the National Voter Registration implementation process), and having ongoing data updates.

The Donate Act. Participants expressed with apparent unanimity that The Donate Act is the most comprehensive of the four bills under consideration. Participants favored the bill's emphasis on the primary role of states in registries along with federal support in important selected functions. Also highly favored was the provision for evaluation of state registries.

Other favorable attributes include: provision of uniform consensus guidelines regarding consent, privacy, data exchange protocols, adequate level of funding, provisions to assess the effectiveness of state donor registries, support for demonstration projects to evaluate and incorporate effective interventions, allowance for support of living donor expenses, and creation of a congressional medal to commemorate organ donors and their families. Participants also favored the provision for an information clearinghouse to provide technical and legal assistance along with oversight.

Insufficient or unfavorable attributes of the bill included: ambiguity concerning the role of the Resource Center as an oversight, epicenter, or coordinating entity; and the apparent absence of epidemiologists, data experts, ethicists, and other technical experts in the design group who are not necessarily present in the transplant community but who would contribute to the viability of the registry.

Three areas identified as needing further consideration and development are specifying the linkages among states to the Resource Center, revising the timeline and contents of the Institute of Medicine (IOM) reports on assessment of registries, and whether to include living donors. Further clarification is needed as well regarding the means and conditions for linkages among state registries and between state registries and the Resource Center, as well as procedures for data access by the relevant parties.

As stated in the bill, the IOM evaluation would be implemented upon enactment of the bill, and would be issued no later that 18 months thereafter. Participants indicated that it would be preferable for the assessment component to be completed prior to any major state actions toward registry development or enhancement. Participants suggested having the IOM report address additional aspects, including: determinants and best practices of an effective registry, assessment of public preferences regarding having registries of consent or intent, and feasibility of including various donation designations (recognizing the tradeoffs of simplicity and specificity in designating donor preferences).

The Organ Donor Enhancement Act and The Organ Donation Improvement Act of 2001. Although these two bills are not as detailed as the aforementioned bills, participants lauded both bills for their efforts to address this important issue. Participants cited The Organ Donor Enhancement Act's focus on public awareness and providing financial incentives to develop donor registries. While the primary focus of The Organ Donation Improvement Act of 2001 is on living donors**,** conference participants acknowledged that it would improve public awareness

of an increasingly valuable way to provide much needed organs as well as the importance of organ donation in general.

Participants raised significant considerations and concerns regarding the relationships between administering living donations and cadaveric donor registries. In particular, many participants expressed the need for separate management of these, given that the target populations and their motivations may be quite different, and that combining these in a common registry may give rise to public confusion on organ and tissue donation.

Although no formal vote was taken at the conference, when asked by the conference moderator for an indication of the level of support for each of the four bills, participants expressed apparently unanimous agreement that The Donate Act presented the most favorable set of provisions in support of donor registries. This was based largely on such overarching considerations as funding, awareness and education components, provisions for registry development and assessment, and emphasis on state-level autonomy.

Exhibit 4. Conference Participants' Views of Favorable and Unfavorable Attributes of Four Organ Donor Registration Bills

	Favorable Attributes	***Insufficient/Unfavorable Attributes***
The Motor Donor Act (S. 788 and H.R. 2645)	• House and Senate support • Provides for federal framework and builds on existing infrastructure • Linkage via the motor license and application process; • Includes funding for public awareness and educational activities • Voluntary exit, update, notification regarding registry participation status • Funding to states being tied to demonstrated collaborations • Specifies a minimum data set to be collected and entered into the registry • Website is good and addresses registration for people residing in states without donor registries • Use of IRS mailing list to disseminate registry information • Designates a "government entity" to oversee registry	• No funding provided for hospitals to develop organ procurement coordination • Single portal of entry • Advisory board does not include families of organ donors • Unclear registration question • DMV role must be further defined and must address resource issues • Implementation strategy & process • Designates too long a period (4 months) to input and update data; data needs to reflect real-time as much as possible
The Donate Act (S. 1062)	• Comprehensive • Provides uniform consensus guidelines regarding consent, privacy, data exchange protocols • Adequate funding levels • Evaluates state donor registries and	• Needs to better define role of the Resource Center—oversight, epicenter, or coordinator • Design group should include other groups like epidemiologists, data experts, ethicists, technical experts to

	Favorable Attributes	***Insufficient/Unfavorable Attributes***
	their effectiveness • Demonstration projects stress evaluation of effectiveness • Provides for an information clearinghouse providing technical and legal assistance • Recognizes states' rights/ efforts, while allowing for a minimum federal role • Supports living donor expenses • Creates congressional medal	compensate for transplant community's lack of knowledge on certain issues • Including living and cadaveric donor registries may confuse public
The Organ Donor Enhancement Act (H.R. 955)	• Addresses living donation, raising awareness for other donation efforts • Addresses and funds public awareness and educational activities	• Living donor registry may confuse public • Lack of information on registry set-up, development, and maintenance
The Organ Donation Improvement Act of 2001 (H.R. 624)	• Raises public awareness of the need for organ donation • Recognizes generous contribution of living donors and provides payment of travel and subsistence expenses • Provides financial incentives to states to promote organ donation	• Lack of specificity • Funding is not tied directly to registry development

C. Selected Cross-cutting Issues

In the course of discussing the relative merits of different models for donor registries and pending legislation, certain cross-cutting issues arose repeatedly. Included among these were: the importance of distinguishing between registries of consent and intent; the crucial role of education and public awareness activities; the need for greater coordination in the organ, tissue, and eye donation community; and the need for more research and evaluation.

Registry of Consent or Intent

Whether registries should be of consent or intent to donate persisted as a major issue throughout the conference. This issue has implications for registry development because it directly affects the purpose and role of the registry. Aside from its practical function of being a centralized database of names and other relevant identifying information, inclusion in the registry also could constitute documentation of an advance directive, thereby superseding preferences of the decedent's family. Although participants noted further research on this matter is warranted, many participants indicated that consent registries have the potential to facilitate the donation process and increase donation rates by fulfilling the wishes of the registered donor. Most current registries record intent. However, several states, such as Colorado, Pennsylvania, Virginia, and Indiana, have enacted legislation designating registries of consent. Given the lack of consensus on this issue, participants agreed to the need for further examination of the matter of registries of

consent vs. intent. Some of the implications raised by participants about registries of consent are the following.

- A "Yes" submitted by a registrant is to be interpreted and implemented as binding consent to donate.
- The disclosure process in registering must ensure that the potential donor is adequately informed of the ramifications of this decision.
- Where DMVs are the portals of registration, policies and procedures must address the role and adequacy of the DMV and its staff in facilitating disclosure, the ability of the DMV to address this function as well as the primary functions of the DMV, and any other DMV obligations to other programs and campaigns.
- Legislation may be needed to address any uniform standards of informed consent for inter-state reciprocity, ensuring adherence to donor consent, providing liability protection for providers adhering to donor consent, and other ethical guidelines.
- Sufficiently funded education and public awareness initiatives should be established to inform the public and the health care community about donor consent.
- Evaluations should be conducted to determine and track the effectiveness of consent registries.

Importance of Education, Outreach, and Public Awareness

Education, outreach, and public awareness will continue to be essential for continued progress of the donation initiative, including development and maintenance of registries. Participants stressed the importance of acknowledging that a registry is not limited to being an information resource at the time of donation, but also can serve as a functional, effective, and cost-effective resource for education and outreach. As such, conference participants highlighted the importance of ensuring adequate funding for educational and public awareness efforts in conjunction with funds designated for registry development or enhancement. Implications include the following.

- Federal and state organ, tissue, and eye donation legislation should include provisions for funding designated public awareness and education.
- Evaluation and assessment reports should include evaluation of effective demonstration projects, including those for staff training programs at registration portals.
- Education and public awareness efforts need to be coordinated in order to provide a consistent message to the public pertaining to registries.

Communication within the Organ Community

In order to develop and ensure coordination of efforts, participants noted the need for improved communication within the organ, tissue, and eye donation community. Recent efforts such as this conference and the resource guide from HRSA, *State Strategies for Organ and Tissue Donation: A Resource Guide for Public Officials,* facilitate such communication. Participants,

especially from those states developing or enhancing registries, called for additional efforts for coordination and exchanging information and experiences regarding successful donor registries.

Need for More Research and Evaluation

Participants stressed the importance of and the need for more research and evaluation related to registry development, registry effectiveness, and current donation practices. In the course of discussing key aspects pertaining to successful registries in the six working groups, many participants pointed out significant gaps in knowledge that have hindered the development of successful registry guidelines. Further, participants noted the need to evaluate existing donation practices and registry operating protocols so that such practices and protocols will be adopted and sustained based on actual data rather than their assumed effectiveness or familiarity.

D. Themes and Strategies

Day 2 of the conference concluded with a plenary session devoted to strategies toward successful donor registries. These strategies were developed around the following eight overarching themes, drawn from the working group sessions and other discussions leading into this closing session. Participants reviewed key aspects of each theme and strategy, and then identified relevant stakeholders who might be responsible for implementing or promoting them.

1. Make Organ Donation a Public Health Imperative

Participants agreed on the principle that donation must be elevated to the level of a public health imperative. This applies to the full process of donation, including donor registries as key elements for promoting and implementing donation. Participants emphasized that, in order to close the unacceptable gap between the need for life-saving organs and their availability, donation should be considered not only a humanitarian gesture, but also a public health responsibility. This does not mean that all U.S. residents should be obliged to become organ donors. It does mean that every reasonable effort should be made to provide well-informed, readily accessible opportunities for people who choose to be donors to register as such, for families who choose to provide consent to do so when their consent is required to proceed with donation, and for the donation community to fulfill these designations. Key stakeholders responsible for communicating this message include the following.

- The Secretary of HHS should continue to promote donation as a public health issue.
- Congress can enact legislation to develop and support donation.
- The Secretary of HHS can help to clarify or explain existing federal laws and regulations pertaining to organ procurement (including donation) and transplantation, and the intent or implications of relevant proposed laws and regulations.
- State governments can promote donation in their state and linkages with other states.

2. Clarify Consent versus Intent

The concept of consent vs. intent to donate must be clarified not only to the public, but also to providers and other stakeholders in the donation process. State and federal laws pertaining to consent vs. intent should be examined, and inconsistencies and ambiguities on this matter should be addressed. Key stakeholders responsible for clarifying this matter include the following.

- The Secretary of HHS can request an IOM study to examine the ethical, legal, and practical issues surrounding registries of consent and intent, and the policy implications of these. Such a study has the potential to validate the work of the donation community and to influence Congress. Individuals to be recommended as committee members for such a study should represent experts and other stakeholders in organ, tissue, and eye donation as well as experts in health policy more broadly.
- Various stakeholder groups in the donation and recovery communities can provide input to the IOM for such a study of the issue of consent vs. intent to donate.
- Organ, tissue, and eye recovery agencies, registries, and other groups should increase public awareness of the importance of consent vs. intent to donate.

3. Retain and Respect State Autonomy

While appreciating the potential of federal involvement in donor registries, conference participants emphasized the need to maintain state autonomy, i.e., their principal or leading roles in donation, by respecting state donation activity and promoting donor registries at the state level. As noted below, this does not preclude federal involvement in facilitating or encouraging registry efforts within or among states, or even mandating that states establish registries meeting certain minimum requirements. Stakeholders responsible for delivering this message include the following.

- The Secretary of HHS can emphasize the need to respect and build upon, rather than supersede, the principal role of states.
- Congress can recognize the principal role of states in the context of future legislation and related funding regarding donation.
- State and local procurement organizations (both OPOs, eye and tissue banks, and other transplant consortia) and other state level entities have the responsibility of educating the public on the importance of donation and these organizations' respective roles in donation.
- Other entities that should promote this message include: the National Governors Association, state governors, state legislatures, state legislative organizations, voluntary health associations, and transplant centers.

4. Do Not Establish a National Registry at This Time

The group agreed that since donation laws are state-based, and given the current status of knowledge and the importance of retaining state autonomy, a national registry, particularly one that would supersede or interfere with state registry efforts, is not necessary at this time. This does not preclude national efforts and certain desirable and adequately funded federal involvement in facilitating state-level efforts, interaction among states, research and demonstrations, and evaluation efforts.

Participants emphasized the need to build on existing state structures, registries and legislation, such as the Uniform Anatomical Gift Act (UAGA). Donor registries are still emerging entities in much of the country. Participants did not discount the possibility of a national database in the future, but agreed with apparent unanimity that the current emphasis should be on building state-level activity. If it becomes apparent that a large portion of states are not establishing and maintaining effective donor registries, thereby limiting readily accessible and informed opportunities for the public to register as donors, then a national registry should be considered.

Stakeholders that could deliver this message include:

- The Secretary of HHS can clarify that the role of registries in strengthening donation does not require a national registry.
- Congress can enact legislation that provides selective federal involvement in facilitating state registries, their interaction, and other aspects, but not a national registry.
- State governments can promote their own state registries and facilitate relationships with states that have yet to develop registries.

5. Define the Federal Role

The group agreed that there exists a need to define the national role in terms of such key aspects as public awareness and education, linkages among states, research and demonstrations, and evaluation of registries. Responsible stakeholders include the following.

- Congress can enact legislation and funding in concert with its federal role.
- The Secretary's Advisory Committee on Organ Transplantation (ACOT) can collect and consider relevant information and advise the Secretary concerning the most effective federal role.
- AOPO, American Association of Tissue Banks (AATB), Eye Bank Association of America (EBAA), and other organizations in the donation recovery community can help to delineate aspects of donation most suited to federal involvement.
- State governments can contribute to an appropriate federal role by providing input, communicating with relevant stakeholders, and committing to partnerships across agencies and with the federal government.

6. Minimize Public Confusion

Conference participants emphasized that educating the public, including clarifying consent vs. intent to donate, explaining the donation process and registry participation, and dispelling myths about donation, are of utmost importance in increasing donation. All stakeholders have a role in public education and awareness.

7. Provide Opportunities for the Public to Register

The public must have readily accessible, informed opportunities to register as donors. The ability to do so varies widely among states, as well as within regions or communities within states. Among the means for opening opportunities to register throughout the country, policy makers should consider, as appropriate, federally funded mandates and other sufficient federal funding as incentives to establish and operate effective state registries. To the extent that the federal government becomes involved in any such mandate or other incentives, more work is needed to define the minimum characteristics of effective donor registries. One potential means of enhancing opportunities to register would be a national portal to provide entry to existing registries. Registration opportunities may be expanded via creation of linkages between states that do not have registries to those that do. Responsible parties to implement greater opportunities for the public to register include the following.

- The Secretary of HHS can call for readily accessible, informed opportunities for registering as a donor.
- Congress can provide incentives and related means to encourage states to establish new registries and enhance access to existing ones.
- States can periodically evaluate and upgrade accessibility to their registries.
- State agencies (including DMVs and departments of health and education), voluntary health agencies, consumer organizations, and professional associations can support public awareness campaigns on how to register as a donor.

8. Ongoing Evaluation and Accountability of Registries

At the national, state, or regional levels, ongoing evaluation is necessary for understanding what works and what does not for improving the effectiveness of registries. This is particularly needed given that most registries are new and emerging, and the knowledge base for successful registries is small, but growing. Furthermore, advances in information management and communications, along with shifts in the demographic characteristics in populations and public interest and awareness in organ and tissue donation, are changing the societal context in which donor registries operate. As such, any currently effective registry will have to adapt to remain effective. Data must also be collected on an ongoing basis to ensure that registries are accountable to their purposes and to their stakeholders, including registrants, families, procurement organizations, health care providers, and the public. Responsible parties to implement this strategy include the following.

- The Secretary of HHS can insist that donation-enhancing efforts, including registries, be subject to ongoing, objective evaluation and accountability. This may include funding a national study pertaining to proper approaches to such evaluations.
- Congressional support for organ donation efforts, including registries, can be tied to requirements for evaluation and accountability.
- Other agencies and organizations that should incorporate evaluation and accountability in their donation efforts include: state governments, the registries themselves, and the DMVs.

V. CONCLUSIONS

Participants addressed the following four main goals during the two-day conference.

- Develop guidelines for successful donor registries;
- Recommend options for a federal role in facilitating effective donor registries;
- Identify strategies to promote commitment and involvement among government entities, organ procurement agencies, and tissue and eye banks; and
- Inform ongoing policy making regarding donation.

Pursuant to these goals, the main conclusions of the conference participants are described below.

A. Guidelines for Successful Donor Registries

Donor registries are still new and emerging, with considerable variation in their mandates, funding, administration, means and ease of access, data requirements, and other attributes. Registry staff, OPOs, and others in the donation community have numerous and oftentimes concurrent suggestions regarding what makes for successful registries. Suggested guidelines upon which conference participants agreed include:

- A core data set for registries;
- Easy and timely access to registry information by recovery agencies;
- Provisions that incorporate education and public awareness components into the registration process;
- Provisions assuring confidentiality and ethical use of registry information; and
- Provisions that ensure currency of registry information.

Even so, there has been insufficient experience among registries upon which to base best practices or guidelines in other areas. Such areas requiring further information include:

- Start-up and operating costs;
- Cost-effectiveness of registries;

- Use of multiple portals in gaining informed consent;
- Use and effectiveness of online registries; and
- Validated and accepted measures to evaluate the effectiveness of registries.

As demonstrated by this conference, there is a steadily growing base of experience in the development of donor registries and a high degree of interest in information sharing among registry personnel, OPOs, tissue and eye banks, DMVs, national associations, and the federal government. The participants in the transplant community recognize that the purposes, roles, and interaction among registries depend upon such upstream factors as whether enrollment in registries is for consent or intent to be a donor, placement of registries in DMVs or other agencies or institutions, portals of registration, data requirements, liability protection for organ and tissue procurement decisions based on registry information, and restrictions on access to registry data. Further, participants recognize that improvement in the development and maintenance of registries will rely upon ongoing research and evaluation.

B. Options for Federal Role

At this time, the donation community is decidedly in favor of strengthening and preserving state registries rather than establishing a national registry, especially to the extent that such a national registry might supersede, interfere with, or diminish the incentives for state registries. However, this does not preclude certain desirable and adequately funded federal involvement in facilitating state-level efforts. Important among these are providing incentives, via adequately funded mandates or other funding as appropriate, to establish and operate effective registries, and facilitating opportunities for interaction among states, research and demonstrations, and evaluation efforts. The federal government should continue to expand its laudable recent initiatives to promote education and public awareness about donation. Further, the federal government should provide incentives, through funded mandates and other funding as appropriate, to establish and operate effective registries. To enhance opportunities for potential donors to participate in registries, the federal government should support establishment of linkages between states that do not have registries and those that do, and should consider providing a national portal for enrollment in existing registries of potential donors in states without registries. If it becomes apparent that, despite these efforts, a large number of states are not establishing and maintaining effective donor registries or linkages to such registries in other states, thereby limiting readily accessible and informed opportunities for the public to register as donors, then a national registry should be considered.

C. Strategies to Promote Commitment and Involvement in Registries

Conference participants derived the following eight themes and strategies for promoting successful donor registries.

- ***Make organ donation a public health imperative.*** Given the unacceptable gap between the availability of and the need for organs, organ donation must be elevated to the level of a public health imperative. This does not mean that all U.S. residents should be obliged to become organ donors. It does mean that every reasonable effort should be made to

provide well-informed, readily accessible opportunities for people who choose to be donors to register as such, for families who choose to provide consent to do so when their consent is required to proceed with donation, and for the donation community to fulfill these designations.

- ***Clarify consent versus intent.*** The concept of donor consent vs. intent must be clarified, not only for the public, but so that hospitals, OPOs, families, and others involved in the donation process can comply with the designation made by the donor. The absence of such clarification may limit significant improvement in public confidence in the organ donation process and in donation rates.
- ***Retain and respect state autonomy.*** Continued development and successful operation of donor registries will depend upon maintaining and promoting state-level donor registries. States will continue to build practical, diverse experience with registries, contributing to the knowledge base of what works in donor registries and enhancing information exchange and other productive linkages with other states.
- ***Do not establish a national registry at this time.*** A national registry, particularly one that supersedes or interferes with state registry efforts, is not necessary at this time. However, this does not preclude national efforts or selective federal involvement in facilitating state registries, their interaction, and other aspects.
- ***Define the federal role.*** There exists a need to define the national role in terms of such key aspects as public awareness and education, readily accessible portals of entry, linkages among states, research and demonstrations, and evaluation of registries.
- ***Minimize public confusion***. More coordination and education is needed to clarify consent vs. intent to donate, explain the donation process and registry participation, and dispel myths about donation. These and other aspects of public confusion act as significant barriers to donation.
- ***Provide opportunities for the public to register.*** The public must have readily accessible, informed opportunities to register as donors. The diverse means of registering among states should provide a basis for identifying effective means of access. Registration opportunities may be expanded via creation of linkages between states with and without registries, and by a national portal for accessing existing registries, as appropriate.
- ***Ongoing evaluation and accountability of registries.*** Ongoing evaluation is necessary for understanding what works and what does not for improving the effectiveness of registries. Further, evaluation is needed to ensure that registries are accountable to their purposes and to their stakeholders, including registrants, families, procurement organizations, health care providers, and the public.

D. Pending Legislation in Congress

In comparing the attributes of four organ donation bills pending in Congress at the time of the conference, participants found with apparent unanimity The Donate Act (S. 1062) to be the most comprehensive. Participants favored the bill's emphasis on the primary role of states in registries, federal support in important selected functions, the provision for evaluation of state

registries, and other qualities. Favorable attributes of The Motor Donor Act (S. 788 and H.R. 2645) include that it provides for a federal framework for registry development, builds on existing infrastructure, calls for and designates a minimum data set, and provides for people in states without registries to register as donors via a website. Participants cited the focus of The Organ Donor Enhancement Act (H.R. 955) on public awareness and providing financial incentives to develop donor registries. While the primary focus of The Organ Donation Improvement Act of 2001 (H.R. 624) is on living donors, participants acknowledged that it would improve public awareness of an highly valuable means of providing much needed organs as well as the importance of organ donation in general.

E. Roles and Responsibilities

Policy makers and other stakeholders can assume certain roles and responsibilities toward successful implementation of these strategies. These include, but are not limited to, the following.

The Secretary of HHS can:

- Continue to promote donation as a public health issue;
- Help to clarify or explain existing federal laws and regulations pertaining to organ procurement (including donation) and transplantation, and the intent or implications of relevant proposed laws and regulations;
- Request an IOM study to explore the ethical, legal and practical issues surrounding registries of consent and intent;
- Emphasize the need to respect and build upon, rather than supersede, the principal role of states;
- Clarify that the role of registries in strengthening donation does not require a national registry;
- With the advice of the Advisory Committee on Organ Transplantation (ACOT) and other expert sources, determine the most effective federal role in donor registries;
- Call for readily accessible, informed opportunities for registering as a donor; and
- Insist that donation-enhancing efforts, including registries, be subject to ongoing, objective evaluation and accountability.

The Congress can:

- Enact legislation and provide adequate funding to develop and support the donation initiative;
- Recognize the principal role of states in the context of future legislation and related funding regarding donation;
- Provide incentives for states to establish new registries and enhance access to existing ones;

- Enact legislation and provide adequate funding for selective federal involvement, but not a national registry; and
- Tie support for organ donation efforts, including registries, to requirements for evaluation and accountability.

State governments, including governors, legislatures, and legislative organizations, can:

- Promote donation in their state and linkages with other states;
- Promote their own state registries and facilitate relationships with states that have yet to develop registries;
- Periodically evaluate and upgrade accessibility to their registries; and
- Contribute to an appropriate federal role by providing input, communicating with relevant stakeholders, and committing to partnerships across agencies and with the federal government.

Donation and recovery organizations, including organ, tissue, and eye agencies, registries, AOPO, AATB, EBAA, and others can:

- Educate the public on the importance of donation and these organizations' respective roles in donation;
- Increase public awareness of the importance of consent vs. intent to donate;
- Provide input to the IOM for a study of the issue of consent vs. intent to donate; and
- Help to delineate aspects of donation most suited to federal involvement.

Other stakeholders:

- The National Governors Association, transplant centers, and others can promote the message to retain and respect the principal role of states.
- State agencies (including DMVs and departments of health and education), voluntary health agencies, consumer organizations, and professional associations can support public awareness about how to register as a donor.