



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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**Contract HHS-GS-23F-9840H
Delivery Order No. 3**

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***August, 2002
(Second Revision)***

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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.