



Restoring Public Confidence in Clinical Research

Lessons from the Organ Donation Sector

Strategies and tactics employed by the organ donation sector offer valuable lessons and insights into repairing public trust and confidence in the clinical research enterprise.

The clinical research enterprise faces a crisis. The volume of global clinical trials is rising. At the same time, public confidence and trust in the enterprise have eroded and patient recruitment and retention have become far more difficult. The viability and success of the enterprise depend on its ability to engage the public and stimulate awareness and support for research participation.¹

Strategies and tactics employed by the organ donation sector offer valuable lessons and insights into repairing public trust and confidence in the clinical research enterprise. They highlight the importance of public-private collaboration to build and train infrastructure; independent nonprofit agencies to provide support for that infrastructure; regular public communication and education; and the implementation of regulatory and legislative mechanisms and policies to stimulate participation and to improve infrastructure and safety.

There is no question that the organ donation and clinical research sectors are very different across a variety of dimensions, including the types of professionals involved, infrastructure, and levels of oversight, safety, and risk. A patient and family decision to donate an organ is very different from a decision to participate in a clinical trial. Still, the organ donation sector has successfully navigated challenges that bear a striking resemblance to the ones that the clinical research enterprise now faces.

Two decades ago, the organ donation movement suffered from poor public perception and low awareness and trust. Politicians and activists were upset by a series of donor-related medical errors that resulted in patient injuries and deaths; practicing clinicians were having trouble finding organs and donors; and those organs that were available were being inequitably distributed in hospital emergency rooms.

Beginning in the mid-1980s, government agencies and the private sector worked together to tackle these problems. Local and national outreach and education programs were developed and implemented to inform and engage the public. New infrastructure was established and processes and practices reformed. Professionals were trained on ways to communicate with the public and the media more effectively.

During the past 10 years, organ donation rates have increased substantially. In 1988, 5,909 people donated their organs nationally. An estimated 15,250 people will donate their organs nationwide in 2008, and 28,500 organ transplant procedures will be performed in the U.S. in 2008, up from

12,600 in 1988.² Although this level is still well below the nation's current need, it represents a significant improvement. Let's look at some of the initiatives that contributed to achieving these results.

Public-Private Collaboration and Partnership

In the early 1980s, government, foundations, and industry began to recognize the organ shortage as a national and collective problem. Government agencies, foundations, and the private sector began holding hearings and roundtable discussions to identify barriers to donation, infrastructure needs, and legislative reforms to stimulate public support.

In the mid-1980s, state laws were passed allowing people to designate themselves as willing organ donors on their driver's licenses. The National Organ Transplant Act of 1984 effectively created a registry where clinicians could quickly check organ availability and wait times. It also declared organ donation an altruistic act by outlawing the purchase and sale of human organs. This act was followed in 1991 by legislation that encouraged the use of advance directives and durable powers of attorney for healthcare.³

The 1987 Uniform Anatomical Gifts Act and its many subsequent revisions sought to harmonize the laws that govern organ donation, to stipulate the process for giving and harvesting organs, and to limit the liability of healthcare providers assisting in the process.³

In 1997, government agencies in collaboration with the private sector launched the National Organ and Tissue Donation Initiative, which was aimed at reducing the number of Americans who die each year while waiting for an organ transplant. The initiative encouraged the creation of a broad national partnership between public, private, and volunteer organizations to raise public awareness and support and to ensure that deaths are reported to organ procurement organi-

zations (OPOs) whenever there is potential for donation.³

The Donor Leave Act came in 1999, which gave federal employees paid time off from work to be a living organ donor. More importantly that same year, the Medicare program mandated that hospitals refer all potential donors to an OPO.³

Public Education and Outreach

Throughout the late 1980s and continuing through the 1990s, public service announcements—developed and paid for by both the public and private sectors—were launched. Their primary focus was on building national pride in organ donation and in acknowledging the profound gift that donors provide. OPOs and other nonprofit organizations (e.g., the Partnership for Organ Donation) introduced new training programs designed to teach hospitals how to communicate more effectively with families facing the challenging decision whether to harvest the organs of loved ones on the brink of death.⁴

Public opinion polls in the late 1970s and early 1980s documented public resistance to the idea of organ donation. One Gallup poll found that 90% of Americans believed that organ donation was a good idea, but less than 40% said they would consider giving an organ.⁵ Beginning in the late 1980s, public service announcements attempted to put a face on the people who give the profound gift of an organ to improve another person's life. Stories from organ recipients shared personal experiences, put a face on the problem, and showed how organ donation improved the quality of, and saved, lives.

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Isolated episodes of misconduct continue to challenge public trust and confidence. A recent OPO-funded counteroffensive is a national marketing campaign spearheaded by Donate Life America (DLA), a Richmond, Va.-based nonprofit alliance. The DLA works with the private, nonprofit Ad Council to produce public service announcements and promulgate positive donor/transplant stories that OPOs help distribute to local newspapers and television stations.⁶

The Donate Life float appears regularly at the Rose Bowl Parade on New Year's Day. This float is featured typically for no more than 30–40 seconds on national TV, but the broadcast reaches millions of households. More importantly, inspirational stories about transplant recipients riding the float get told multiple times in the local and national media several weeks before and after the event.⁶

Addressing Disparities, Educating Youth

Organ donation rates began to rise during the 1990s, predominantly among multigenerational English-speaking communities. But in large and ethnically diverse, non-English speaking communities like Southern California, organ donation rates languished.⁷

OPOs and nonprofit and private sector stakeholders moved to train requesters to be ethnically and culturally sensitive. Education programs prepared professionals to speak the same language, and to become familiar with the cultural needs of potential donors and their families. Public service announcements were developed to target minority communities.⁸

These efforts have proved successful. OPOs report that between 2000 and 2006, the consent rate rose from less than 20% to nearly 40% among Asian Americans; from 30% to about 45% among African Americans; and from 35% to more than 60% among Hispanics. In the Anglo community, the consent rate runs upwards of 65%.^{2,8}

The organ donation movement is now gaining steam from the Organ Donation Breakthrough Collaborative, founded in 2003 and sponsored by the Division of Transplantation within the Department of Health and Human Services. Key leaders and practitioners from the nation's transplantation and hospital communities have come together to spread known "best practices" to achieve organ donation rates of 75% or higher at the nation's 200 largest hospitals. The conversion rate of eligible to actual donors has already moved from 45% to 60% nationwide. Funding comes from the federal government for major training sessions, but participation is also funded by individual OPOs and by the private sector.⁹

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In the mid-2000s, OPOs have been making a case for organ donation with an outreach program targeting a younger public—high school students. The program is typically tied to the science curriculum and involves classroom visits to talk about organ donation and share donor/transplant stories.⁶

Building a Movement

In recent years, the clinical research enterprise has primarily focused on ensuring professional compliance with federal clinical research guidelines; on improving the capacity and capabilities of human subject protection programs; on minimizing conflicts of interest; and on creating incentives designed to promote the disclosure of research information. These are important initiatives to build enterprise credibility, and measures of the impact

of these initiatives are being gathered. The government and the private sector are now turning their attention to educating and engaging the public.

During the past several years, the National Institutes of Health (NIH), Food and Drug Administration, and various foundations and associations have hosted meetings designed to facilitate a dialogue between clinical research professionals from the public and private sectors. In addition, the NIH has been encouraging its network of clinical research centers to support public outreach and educational programs.

The Center for Information and Study on Clinical Research Participation (CISCRP), an independent nonprofit organization, has been implementing a variety of outreach and educational activities in an effort to build momentum along the same lines as that created by the organ donation sector. Government agencies, foundations, academic research professionals, institutional review boards, investigative sites, and pharmaceutical, biotechnology, and contract research companies are all supporters of CISCRP's initiatives.¹⁰

Now in its fifth year, CISCRP's core mission is to raise public awareness of clinical research participation and the important role that it plays in advancing public health. To name a few key initiatives, CISCRP has:

- Developed and distributed multi-lingual television and radio public service announcements (PSAs) that have been viewed and heard by more than 50 million people in the U.S.;
- Created and distributed, with the assistance of the Department of Health and Human Services, a print PSA entitled "Behind Every Medicine are Thousands of People Who Participate in Clinical Research" in consumer magazines and through pharmacy chains;
- Encouraged congressional representatives and senators to introduce legislation designed to

promote appreciation for clinical trial volunteers;

- Produced and distributed multi-lingual educational materials in print and electronic formats for investigative sites to use when communicating with study volunteers and the communities that they serve;
- Hosted local clinical research awareness days called "AWARE for All" in major metropolitan areas nationwide (e.g., Boston, Philadelphia, Dallas, Indianapolis) in order to recognize study volunteers and put a face on local clinical research professionals and stakeholders;
- Developed and hosts a search engine to assist the public and patients in compiling active clinical trials and research results gleaned from published online registries;
- Developed, consumer tested, and launched a new "Medical Heroes" campaign on national television, radio, and in print;
- Created a speaker's bureau to talk about the clinical research enterprise with the media and at medical schools and community centers; and
- Initiated the creation of a new clinical research exhibit for local science museums and a new national life sciences museum now under development in Washington, D.C.

CISCRP routinely tracks and publishes information about its various initiatives on its website, including the distribution volume of its educational materials; number of attendees for AWARE programs; and numbers of individuals reached by print, radio, and television PSAs.¹⁰

The results of a recent pilot test conducted by Eli Lilly and Company show that CISCRP's "Medical Heroes" public education program can boost monthly enrollment rates substantially. Lilly found that running CISCRP's rebrand-

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ing initiative concurrently with its patient recruitment advertisements for specific clinical trials generated more than a 30% improvement in monthly subject enrollees. This surprising finding suggests that public outreach and education, in conjunction with trial-specific outreach, may provide short-term benefits to accelerating patient recruitment activity for study sponsors.¹¹

There is much to be done to reverse the erosion of public confidence and trust in clinical research. The organ donation sector offers valuable insights that can be applied to guide the development, coordination, and implementation of a comprehensive portfolio of initiatives to improve public awareness, trust, and engagement in the clinical research enterprise.

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